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Federal Register

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## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 25

[Docket No. FAA-2015-2567; Special Conditions No. 25-588-SC]

#### Special Conditions: Bombardier Inc., Models BD-700-2A12 and BD-700-2A13 Series Airplanes; Side Stick Controllers: Pilot Strength, Pilot Control Authority, and Pilot Control

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final special conditions; request for comments.

**SUMMARY:** These special conditions are issued for the Bombardier Inc. Models BD-700-2A12 and BD-700-2A13 series airplanes. These airplanes will have a novel or unusual design feature when compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. This design feature is side stick controllers for pitch and roll control instead of conventional wheels and columns. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards. **DATES:** This action is effective on Bombardier Inc. on August 7, 2015. We must receive your comments by September 21, 2015.

**ADDRESSES:** Send comments identified by docket number FAA-2015-2567 using any of the following methods:

- *Federal eRegulations 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.

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*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:** Joe Jacobsen, FAA, Airplane and Flightcrew Interface Branch, ANM-111, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98057-3356; telephone 425-227-2011; facsimile 425-227-1149.

**SUPPLEMENTARY INFORMATION:** The substance of these special conditions has been subject to the public comment process in several prior instances with no substantive comments received. The FAA therefore finds that good cause exists for making these special conditions effective upon publication in the **Federal Register**.

### Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

We will consider all comments we receive on or before the closing date for comments. We may change these special conditions based on the comments we receive.

### Background

Bombardier Inc. located in Montreal, Canada, applied to Transport Canada Civil Aviation (TCCA) on January 7, 2012, and May 30, 2012, for two amended type certificates in the transport airplane category for two new airplane models designated as the BD-700-2A12 and BD-700-2A13. The BD-700-2A12 and BD-700-2A13 airplanes are 19-passenger, twin-engine, ultra long-range large airplanes targeting the executive interior business jet market. These airplanes share an identical supplier base and significant common design elements.

The BD-700-2A12 and BD-700-2A13 airplanes will use side stick controllers for pitch and roll control. Regulatory requirements pertaining to conventional wheel and column, such as pilot strength and controllability, are not directly applicable for the side stick. In addition, pilot control authority may be uncertain because the side sticks are not mechanically interconnected as with conventional wheel and column controls.

### Type Certification Basis

Under the provisions of Title 14, Code of Federal Regulations (14 CFR) 21.17, Bombardier Inc. must show that the BD-700-2A12 and BD-700-2A13 airplanes meet the applicable provisions of 14 CFR part 25 as amended by Amendments 25-1 through 25-138 except for Amendment 25-137.

If the Administrator finds that the applicable airworthiness regulations (*i.e.*, 14 CFR part 25) do not contain adequate or appropriate safety standards for the BD-700-2A12 and BD-700-2A13 airplanes because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.



Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same or similar novel or unusual design feature, the special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the BD-700-2A12 and BD-700-2A13 airplanes must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36, and the FAA must issue a finding of regulatory adequacy under § 611 of Public Law 92-574, the "Noise Control Act of 1972."

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type-certification basis under § 21.17(a)(2).

#### Novel or Unusual Design Feature

The BD-700-2A12 and BD-700-2A13 airplanes will incorporate the following novel or unusual design feature: Side stick controllers for pitch and roll control, which are not mechanically interconnected as with conventional wheel and column controls. These airplanes also have a fly-by-wire electronic flight control system. This system provides an electronic interface between the pilot's flight controls and the flight control surfaces for both normal and failure states, and it generates the actual surface commands that provide for stability augmentation and control about all three airplane axes. In addition, pilot control authority may be uncertain, because the side sticks are not mechanically interconnected as with conventional wheel and column controls.

#### Discussion

Current FAA regulations do not specifically address the use of side stick controllers for pitch and roll control. The unique features of the side stick must therefore be demonstrated through flight and simulator tests to have suitable handling and control characteristics when considering the following:

1. The handling qualities tasks/requirements of the BD-700-2A12 and BD-700-2A13 airplanes special conditions and other part 25 stability, control, and maneuverability requirements, including the effects of turbulence.
2. General ergonomics: Arm rest comfort and support, local freedom of

movement, displacement angle suitability, and axis harmony.

3. Inadvertent input in turbulence.
4. Inadvertent pitch-roll cross talk.

These special conditions elaborate on these requirements and contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

The FAA Handling Qualities Rating Method (HQRN) in appendix 5 of Advisory Circular 25-7C, "Flight Test Guide for Certification of Transport Category Airplanes," may be used to show compliance.

#### Applicability

As discussed above, these special conditions are applicable to the Bombardier Inc. Models BD-700-2A12 and BD-700-2A13 series airplanes. Should Bombardier Inc. apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, these special conditions would apply to that model as well.

#### Conclusion

This action affects only certain novel or unusual design features on two model series of airplanes. It is not a rule of general applicability.

The substance of these special conditions has been subjected to the notice and comment period in several prior instances and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. Therefore, the FAA has determined that prior public notice and comment are unnecessary, and good cause exists for adopting these special conditions upon publication in the **Federal Register**. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

#### List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

- The authority citation for these special conditions is as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

#### The Special Conditions

- Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification

basis for the Bombardier Inc. Models BD-700-2A12 and BD-700-2A13 series airplanes.

- In the absence of specific requirements for side stick controllers, the following apply:

1. *Pilot strength:* In lieu of the "strength of pilots" limits shown in § 25.143(d) for pitch and roll, and in lieu of specific pitch force requirement of §§ 25.143(i)(2), 25.145(b), and 25.175(d), Bombardier must show that the temporary and maximum prolonged force levels for the side stick controllers are suitable for all expected operating conditions and configurations, whether normal or non-normal.

2. *Pilot control authority:* The electronic side stick controller coupling design must provide for corrective and/or overriding control inputs by either pilot with no unsafe characteristics. Annunciation of the controller status must be provided and must not be confusing to the flightcrew.

3. *Pilot control:* Bombardier must show by flight tests that the use of side stick controllers does not produce unsuitable pilot-in-the-loop control characteristics when considering precision path control/tasks and turbulence. In addition, pitch and roll control force and displacement sensitivity must be compatible, so that normal inputs on one control axis will not cause significant unintentional inputs on the other.

Issued in Renton, Washington, on June 17, 2015.

**Jeffrey E. Duven,**

*Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 2015-19459 Filed 8-6-15; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 25

[Docket No. FAA-2015-2566; Special Conditions No. 25-587-SC]

#### Special Conditions: Bombardier Inc., Models BD-700-2A12 and BD-700-2A13 Series Airplanes; Electronic Flight Control System: Control Surface Awareness and Mode Annunciation

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Final special conditions; request for comments.

**SUMMARY:** These special conditions are issued for the Bombardier Inc. Models BD-700-2A12 and BD-700-2A13 series airplanes. These airplanes will have

novel or unusual design features when compared to the state of technology envisioned in the airworthiness standards for transport category airplanes. These design features are a fly-by-wire electronic flight control system (EFCS) and no direct coupling from the flight deck controller to the control surface. As a result, the pilot is not aware of the actual control surface position. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for these design features. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

**DATES:** This action is effective on Bombardier Inc. on August 7, 2015. We must receive your comments by September 21, 2015.

**ADDRESSES:** Send comments identified by docket number FAA-2015-2566 using any of the following methods:

- *Federal eRegulations 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:* The FAA will post all comments it receives, without change, to <http://www.regulations.gov/>, including any personal information the commenter provides. Using the search function of the docket Web site, anyone can find and read the electronic form of all comments received into any FAA docket, including the name of the individual sending the comment (or signing the comment for an association, business, labor union, etc.). DOT's complete Privacy Act Statement can be found in the **Federal Register** published on April 11, 2000 (65 FR 19477-19478), as well as at <http://DocketsInfo.dot.gov/>.

*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:** Joe Jacobsen, FAA, Airplane and Flightcrew Interface Branch, ANM-111, Transport Airplane Directorate, Aircraft Certification Service, 1601 Lind Avenue SW., Renton, Washington 98057-3356; telephone 425-227-2011; facsimile 425-227-1149.

**SUPPLEMENTARY INFORMATION:** The substance of these special conditions has been subject to the public comment process in several prior instances with no substantive comments received. The FAA therefore finds that good cause exists for making these special conditions effective upon publication in the **Federal Register**.

#### Comments Invited

We invite interested people to take part in this rulemaking by sending written comments, data, or views. The most helpful comments reference a specific portion of the special conditions, explain the reason for any recommended change, and include supporting data.

We will consider all comments we receive on or before the closing date for comments. We may change these special conditions based on the comments we receive.

#### Background

Bombardier Inc. located in Montreal, Canada, applied to Transport Canada Civil Aviation (TCCA) on January 7, 2012, and May 30, 2012, for two amended type certificates in the transport airplane category for two new airplane models designated as the BD-700-2A12 and BD-700-2A13. These airplanes are 19-passenger, twin-engine, ultra long-range large airplanes targeting the executive interior business jet market. They share an identical supplier base and significant common design elements including a fly-by-wire electronic flight control system (EFCS).

#### Type Certification Basis

Under the provisions of Title 14, Code of Federal Regulations (14 CFR) 21.17, Bombardier Inc. must show that the BD-700-2A12 and BD-700-2A13 airplanes meet the applicable provisions of 14 CFR part 25 as amended by Amendments 25-1 through 25-138 except for Amendment 25-137.

If the Administrator finds that the applicable airworthiness regulations (*i.e.*, 14 CFR part 25) do not contain adequate or appropriate safety standards for the BD-700-2A12 and BD-700-2A13 airplanes because of a novel or

unusual design feature, special conditions are prescribed under the provisions of § 21.16.

Special conditions are initially applicable to the model for which they are issued. Should the type certificate for that model be amended later to include any other model that incorporates the same or similar novel or unusual design features, these special conditions would also apply to the other model under § 21.101.

In addition to the applicable airworthiness regulations and special conditions, the BD-700-2A12 and BD-700-2A13 airplanes must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36, and the FAA must issue a finding of regulatory adequacy under § 611 of Public Law 92-574, the "Noise Control Act of 1972."

The FAA issues special conditions, as defined in 14 CFR 11.19, in accordance with § 11.38, and they become part of the type-certification basis under § 21.17(a)(2).

#### Novel or Unusual Design Features

The BD-700-2A12 and BD-700-2A13 airplanes will incorporate the following novel or unusual design features: A fly-by-wire EFCS and no direct coupling from the flight deck controller to the control surface. As a result, the pilot is not aware of the actual control surface position as envisioned under current airworthiness standards.

#### Discussion

These special conditions require that the flightcrew receive a suitable flight control position annunciation when a flight condition exists in which nearly full surface authority (not crew-commanded) is being used. Suitability of such a display must take into account that some pilot-demanded maneuvers (*e.g.*, rapid roll) are necessarily associated with intended full performance, which may saturate the surface. Therefore, simple alerting systems function in both intended and unexpected control-limiting situations. As a result, they must be properly balanced between providing necessary crew awareness and being a potential nuisance to the flightcrew. A monitoring system that compares airplane motion and surface deflection with the demand of the pilot side-stick controller could help reduce nuisance alerting.

These special conditions also address flight control system mode annunciation. Suitable mode annunciation must be provided to the flightcrew for events that significantly change the operating mode of the

system but do not merit the classic “failure warning.”

These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

### Applicability

As discussed above, these special conditions are applicable to the Bombardier Models BD-700-2A12 and BD-700-2A13 series airplanes. Should Bombardier Inc. apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design features, these special conditions would apply to that model as well.

### Conclusion

This action affects only certain novel or unusual design features on two model series of airplanes. It is not a rule of general applicability.

The substance of these special conditions has been subjected to the notice and comment period in several prior instances and has been derived without substantive change from those previously issued. It is unlikely that prior public comment would result in a significant change from the substance contained herein. Therefore, the FAA has determined that prior public notice and comment are unnecessary, and good cause exists for adopting these special conditions upon publication in the **Federal Register**. The FAA is requesting comments to allow interested persons to submit views that may not have been submitted in response to the prior opportunities for comment described above.

### List of Subjects in 14 CFR Part 25

Aircraft, Aviation safety, Reporting and recordkeeping requirements.

■ The authority citation for these special conditions is as follows:

**Authority:** 49 U.S.C. 106(g), 40113, 44701, 44702, 44704.

### The Special Conditions

■ Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for the Bombardier Inc. Models BD-700-2A12 and BD-700-2A13 series airplanes.

1. In addition to the requirements of §§ 25.143, 25.671, and 25.672, the following requirements apply:

a. The system design must ensure that the flightcrew is made suitably aware whenever the primary control means nears the limit of control authority.

Note: The term “suitably aware” indicates annunciations provided to the flightcrew are appropriately balanced between nuisance and that necessary for crew awareness.

b. If the design of the flight control system has multiple modes of operation, a means must be provided to indicate to the flightcrew any mode that significantly changes or degrades the normal handling or operational characteristics of the airplane.

Issued in Renton, Washington, on June 17, 2015.

**Jeffrey E. Duven,**

*Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 2015-19458 Filed 8-6-15; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF COMMERCE

### Bureau of Industry and Security

#### 15 CFR Parts 744 and 746

[Docket No. 150610514-5514-01]

RIN 0694-AG66

#### Russian Sanctions: Addition to the Entity List To Prevent Violations of Russian Industry Sector Sanctions

**AGENCY:** Bureau of Industry and Security, Commerce.

**ACTION:** Final rule.

**SUMMARY:** This final rule amends the Export Administration Regulations (EAR) to further implement U.S. sanctions on certain Russian energy projects. Specifically, in this rule, the Bureau of Industry and Security (BIS) amends the EAR by adding a Russian oil and gas field, the Yuzhno-Kirinskoye Field located in the Sea of Okhotsk, to the Entity List. This Russian field is reported to contain substantial reserves of oil in addition to reserves of gas. The U.S. Government has determined, therefore, that exports, reexports, and transfers (in-country) of all items subject to the EAR to this Russian field by any person without first obtaining a BIS license present an unacceptable risk of use in, or diversion to, the activities specified in the Russian industry sector sanctions. Thus, as part of the BIS “is informed” process, this final rule adds this Russian field to the Entity List to further implement the Russian industry sector sanctions. This Russian field will be listed on the Entity List under the destination of Russia. This final rule clarifies the introductory text of the Entity List to specify that the embargoes and other special controls part of the EAR is also used to add entities to the

Entity List. Lastly, this final rule makes a change to the Russian industry sector sanctions by clarifying the additional prohibition on those informed by BIS also includes end-uses that are within the scope of the Russian Industry sector sanctions.

**DATES:** This rule is effective August 7, 2015.

**FOR FURTHER INFORMATION CONTACT:** For this Entity List-related change, contact the Chair, End-User Review Committee, Office of the Assistant Secretary, Export Administration, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482-5991, Fax: (202) 482-3911, Email: [ERC@bis.doc.gov](mailto:ERC@bis.doc.gov). For the Russian industry sector sanctions referred to in this rule, contact Eileen Albanese, Director, Office of National Security and Technology Transfer Controls, Bureau of Industry and Security, Department of Commerce, Phone: (202) 482-0092, Fax: (202) 482-482-3355, Email: [rp2@bis.doc.gov](mailto:rp2@bis.doc.gov). For emails, include “Russia” in the subject line.

### SUPPLEMENTARY INFORMATION:

#### Background

This final rule amends the Export Administration Regulations (EAR) to further implement U.S. sanctions on certain Russian energy projects. Specifically, in this rule, the Bureau of Industry and Security (BIS) amends the EAR by adding a Russian oil and gas field, the Yuzhno-Kirinskoye Field located in the Sea of Okhotsk, to the Entity List.

This Russian field is reported to contain substantial reserves of oil in addition to reserves of gas. The U.S. Government has determined, therefore, that exports, reexports, and transfers (in-country) of all items subject to the EAR to this Russian field by any person without first obtaining a BIS license present an unacceptable risk of use in, or diversion to, the activities specified in the Russian industry sector sanctions. Thus, as part of the BIS “is informed” process, this final rule adds this Russian field to the Entity List to further implement the Russian industry sector sanctions. This Russian field will be listed on the Entity List under the destination of Russia.

#### Entity List

The Entity List (Supplement No. 4 to Part 744) identifies entities and other persons reasonably believed to be involved, or to pose a significant risk of being or becoming involved, in activities contrary to the national security or foreign policy interests of the United States. The EAR imposes

additional licensing requirements on, and limits the availability of most license exceptions for, exports, reexports, and transfers (in-country) to those listed. The “license review policy” for each listed entity or other person is identified in the License Review Policy column on the Entity List and the impact on the availability of license exceptions is described in the **Federal Register** notice adding entities or other persons to the Entity List. BIS places entities and other persons on the Entity List pursuant to sections of part 744 (Control Policy: End-User and End-Use Based) and part 746 (Embargoes and Other Special Controls) of the EAR.

The ERC, composed of representatives of the Departments of Commerce (Chair), State, Defense, Energy, and, where appropriate, the Treasury, rules on additions to, removals from, and other modifications to the Entity List. The ERC makes decisions to add an entry to the Entity List by majority vote and decisions to remove or modify an entry by unanimous vote.

#### *Addition to the Entity List Consistent With Executive Order 13662*

Under § 746.5(a)(2), BIS in this final rule is adding a Russian oil and gas field to the Entity List and informing the public of a license requirement for exports, reexports, or transfers (in-country) of any item subject to the EAR to that location. This Russian field is added based on being the site of activities that are described in Executive Order 13662 (79 FR 16169), *Blocking Property of Additional Persons Contributing to the Situation in Ukraine*, issued by the President on March 20, 2014. This Order expanded the scope of the national emergency declared in Executive Order 13660 of March 6, 2014 and Executive Order 13661 of March 16, 2014. Specifically, Executive Order 13662 expanded the scope to include sectors of the Russian Federation’s economy as may be determined by the Secretary of the Treasury, in consultation with the Secretary of State, such as financial services, energy, metals and mining, engineering, and defense and related materiel. The Department of the Treasury’s Office of Foreign Assets Control (OFAC), pursuant to Executive Order 13662 and on behalf of the Secretary of the Treasury, has designated certain entities operating in these sectors.

The Yuzhno-Kirinskoye Field is being added to the Entity List because it is reported to contain substantial reserves of oil. Consequently, exports, reexports, and transfers (in-country) of all items subject to the EAR to this Russian oil and gas field by any person without first

obtaining a BIS license has been determined by the U.S. Government to present an unacceptable risk of use in, or diversion to, the activities specified in paragraph (a)(1) of § 746.5, namely exploration for, or production of, oil or gas in Russian deepwater (greater than 500 feet) locations. Therefore, a license requirement for all items subject to the EAR is warranted.

License applications for such transactions will be reviewed with a presumption of denial because such exports, reexports, and transfers (in-country) are for use directly or indirectly in exploration or production from a deepwater (greater than 500 feet) project in Russia that has the potential to produce oil. In addition, no license exceptions are available for exports, reexports, or transfers (in-country) to the field being added to the Entity List in this rule.

This final rule adds the following one Russian gas and oil field to the Entity List to expand the EAR license requirements in § 746.5:

#### **Russia**

(1) *Yuzhno-Kirinskoye Field*, in the Sea of Okhotsk.

#### *Clarification to the Introductory Text of the Entity List*

As noted above, BIS places entities on the Entity List based on certain sections of part 744 (Control Policy: End-User and End-Use Based) and part 746 (Embargoes and Other Special Controls) of the EAR. This final rule, as a clarification for this existing BIS policy for adding persons to the Entity List, revises the first sentence of the introductory text of the Entity List to add a reference to part 746. This clarification to the introductory text will make it clear that this Supplement lists certain entities subject to license requirements for specified items under this part 744 and part 746 of the EAR.

#### *Clarification to Russian Industry Sector Sanctions*

In § 746.5 (Russian industry sector sanctions), this final rule revises the second sentence of paragraph (a)(2) for the additional prohibition on those informed by BIS to add the term “end-use” after the term “end-user.” This change clarifies that the additional prohibition described in this paragraph (a)(2), as part of the BIS “is informed” process, may be based on an end-user or end-use when BIS determines there is an unacceptable risk of use in, or diversion to, the activities specified in paragraph (a)(1) of this section in Russia. This clarification does not change the scope of § 746.5, but rather

clarifies the cases in which BIS will use the “is informed” process to assist exporters, reexporters, and transferors to “know” when an export, reexport, or transfer (in-country) is subject to the license requirements specified in § 746.5.

#### **Export Administration Act**

Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013) and as extended by the Notice of August 7, 2014, 79 FR 46959 (August 11, 2014), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act. BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222 as amended by Executive Order 13637.

#### **Rulemaking Requirements**

1. 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, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to nor be subject to a penalty for failure to comply with a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid Office of Management and Budget (OMB) Control Number. This regulation involves collections previously approved by OMB under control number 0694–0088, Simplified Network Application Processing System, which includes, among other things, license applications and carries a burden estimate of 43.8 minutes for a manual or electronic submission. Total burden hours associated with the PRA and OMB control number 0694–0088 are not expected to increase as a result of this rule. You may send comments regarding

the collection of information associated with this rule, including suggestions for reducing the burden, to Jasmeet K. Seehra, Office of Management and Budget (OMB), by email to *Jasmeet.K.Seehra@omb.eop.gov*, or by fax to (202) 395-7285.

3. This rule does not contain policies with Federalism implications as that term is defined in Executive Order 13132.

4. For the Entity List changes in this final rule, the provisions of the Administrative Procedure Act (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public comment and a delay in effective date are inapplicable because this regulation involves a military or foreign affairs function of the United States. (See 5 U.S.C. 553(a)(1)). BIS implements this rule to protect U.S. foreign policy interests by preventing items from being exported, reexported, or transferred (in country) for use in, or diversion to, the activities specified in the Russian industry sector sanctions at the Russian field being added to the Entity List. If this rule were delayed to allow for notice and comment and a delay in effective date, then persons working on or in the Russian field being added to the Entity List by this action would continue to be able to receive items subject to the EAR without a license and to conduct activities contrary to the Russian industry sector sanctions. In addition, publishing a proposed rule would give parties trying to export, reexport, or transfer (in-country) to this location notice of the U.S. Government's intention to place this Russian field on the Entity List and would create an incentive for persons located at this Russian field to accelerate receiving items subject to the EAR to conduct activities that are contrary to the to the Russian industry sector sanctions, and/or to take steps to set up additional aliases and other measures to try to limit the impact of the listing on the Entity List. Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule. Because a notice of proposed rulemaking and an

opportunity for public comment are not required to be given for this rule by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are not applicable. Accordingly, no regulatory flexibility analysis is required and none has been prepared.

5. For the clarification to Russian industry sector sanctions and clarification to the introductory text of the Entity List, the Department finds that there is good cause under 5 U.S.C. 553(b)(B) to waive the provisions of the Administrative Procedure Act requiring prior notice and the opportunity for public comment because allowing for notice and comment would be contrary to the public interest. The revisions to § 746.5(a)(2) and the introductory text to Supplement No. 4 to Part 744, facilitate public understanding of existing interpretations of current EAR provisions, and therefore prior notice and the opportunity for public comment would prevent BIS promulgating these revisions as soon as possible so that the public will be aware of the correct text and meaning of these current EAR provisions.

BIS finds good cause to waive the 30-day delay in effectiveness under 5 U.S.C. 553(d)(3). As mentioned previously, the revisions described here made by this rule consist of minor clarifications that need to be in place as soon as possible to avoid confusion by the public regarding the intent and meaning of these changes to the EAR.

Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for these amendments by 5 U.S.C. 553, or by any other law, the analytical requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, are not applicable.

**List of Subjects**

*15 CFR Part 744*

Exports, Reporting and recordkeeping requirements, Terrorism.

*15 CFR Part 746*

Exports, Reporting and recordkeeping requirements.

Accordingly, parts 744 and 746 of the Export Administration Regulations (15 CFR parts 730-774) are amended as follows:

**PART 744—[AMENDED]**

■ 1. The authority citation for 15 CFR part 744 continues to read as follows:

**Authority:** 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 3201 *et seq.*; 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of August 7, 2014, 79 FR 46959 (August 11, 2014); Notice of September 17, 2014, 79 FR 56475 (September 19, 2014); Notice of November 7, 2014, 79 FR 67035 (November 12, 2014); Notice of January 21, 2015, 80 FR 3461 (January 22, 2015).

■ 2. Supplement No. 4 to part 744 is amended by:

- a. Adding introductory text;
- b. Removing from the table the text below the headings and above the entry for “Afghansistan”; and
- c. Adding under Russia, in alphabetical order, the entity “Yuzhno-Kirinskoye Field, in the Sea of Okhotsk”.

The additions read as follows:

**Supplement No. 4 to Part 744—Entity List**

This Supplement lists certain entities subject to license requirements for specified items under this part 744 and part 746 of the EAR. License requirements for these entities include exports, reexports, and transfers (in-country) unless otherwise stated. This list of entities is revised and updated on a periodic basis in this Supplement by adding new or amended notifications and deleting notifications no longer in effect.

Country	Entity	License requirement	License review policy	Federal Register citation
* RUSSIA .....	* Yuzhno-Kirinskoye Field, in the Sea of Okhotsk.	* For all items subject to the EAR. (See § 746.5 of the EAR).	* Presumption of denial .....	* 80 FR [INSERT FR PAGE NUMBER]; 8/7/15.
* *	* *	* *	* *	* *

**PART 746—[AMENDED]**

■ 3. The authority citation for 15 CFR part 746 continues to read as follows:

**Authority:** 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 22 U.S.C. 287c; Sec 1503, Pub. L. 108–11, 117 Stat. 559; 22 U.S.C. 6004; 22 U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 12854, 58 FR 36587, 3 CFR, 1993 Comp., p. 614; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13338, 69 FR 26751, 3 CFR, 2004 Comp., p. 168; Presidential Determination 2003–23 of May 7, 2003, 68 FR 26459, May 16, 2003; Presidential Determination 2007–7 of December 7, 2006, 72 FR 1899 (January 16, 2007); Notice of August 7, 2014, 79 FR 46959 (August 11, 2014); Notice of May 6, 2015, 80 FR 26815 (May 8, 2015).

■ 4. Section 746.5 is amended by revising paragraph (a)(2) to read as follows:

**§ 746.5 Russian industry sector sanctions.**

(a) \* \* \*

(2) *Additional prohibition on those informed by BIS.* BIS may inform persons, either individually by specific notice or through amendment to the EAR, that a license is required for a specific export, reexport, or transfer (in-country) or for the export, reexport, or transfer (in-country) of specified items to a certain end-user or end-use, because there is an unacceptable risk of use in, or diversion to, the activities specified in paragraph (a)(1) of this section in Russia. Specific notice is to be given only by, or at the direction of, the Deputy Assistant Secretary for Export Administration. When such notice is provided orally, it will be followed by a written notice within two working days signed by the Deputy Assistant Secretary for Export Administration. However, the absence of any such notification does not excuse persons from compliance with the license requirements of paragraph (a)(1) of this section.

\* \* \* \* \*

Dated: July 30, 2015.

**Eric L. Hirschhorn,**

*Under Secretary of Commerce for Industry and Security.*

[FR Doc. 2015–19274 Filed 8–6–15; 8:45 am]

**BILLING CODE 3510–33–P**

**DEPARTMENT OF HOMELAND SECURITY****U.S. Customs and Border Protection****DEPARTMENT OF THE TREASURY****19 CFR Parts 181 and 191**

[CBP Dec. 15–11]

**RIN 1515–AE02**

**Liberalization of Certain Documentary Evidence Required as Proof of Exportation on Drawback Claims**

**AGENCY:** U.S. Customs and Border Protection, Department of Homeland Security; Department of the Treasury.

**ACTION:** Final rule.

**SUMMARY:** This document amends U.S. Customs and Border Protection (CBP) regulations by removing some of the requirements for documentation used to establish proof of exportation for drawback claims. Currently, claimants must provide originally signed documentary evidence or a certified copy of such documentary evidence to establish the date and fact of exportation of articles for drawback purposes. This document also amends various sections of title 19 of the Code of Federal Regulations (CFR) to reflect that there is no longer a legal requirement that the export invoice for mail shipments be certified. Additionally, this document amends Appendix B to part 191 of title 19 so that the Appendix reflects previous regulatory amendments closing four drawback offices. Finally, this document amends CBP regulations to reflect the change from the legacy agency name of U.S. Customs Service to the current agency name of U.S. Customs and Border Protection and to make other non-substantive editorial changes.

**DATES:** This final rule is effective on August 7, 2015.

**FOR FURTHER INFORMATION CONTACT:** For legal aspects, Carrie L. Owens, Chief, Entry Process & Duty Refunds Branch, Regulations and Rulings, Office of International Trade, (202) 325–0266. For operational aspects, Celestine L. Harrell, Chief, Post Release and Trade Processes Branch, Office of International Trade, (202) 863–6937.

**SUPPLEMENTARY INFORMATION:****Background**

This document amends the U.S. Customs and Border Protection (CBP) regulations by: (1) Removing some of the requirements for drawback claimants to establish proof of exportation; (2) conforming Appendix B

to part 191 of the CBP regulations to previous regulatory changes reflecting the closing of four drawback offices; (3) updating the regulations to reflect that CBP is now part of the Department of Homeland Security; and (4) making other non-substantive editorial and nomenclature changes.

*Easing the Requirements for Establishing Proof of Exportation*

This document amends title 19 of the Code of Federal Regulations (19 CFR) by making amendments to 19 CFR parts 181 and 191, specifically, sections 19 CFR 181.47, 191.72 and 191.74 to align CBP documentation requirements with current business practices related to the documents used to establish the date and fact of exportation for purposes of drawback. In order to qualify for drawback, claimants must establish that articles are exported or destroyed. When drawback is claimed for exported goods, the claimant must submit documentation that establishes fully the date and fact of exportation and the identity of the exporter. *See* 19 CFR 191.72. For certain types of drawback claims subject to the North American Free Trade Agreement (NAFTA), documentation must also establish the identity and location of the ultimate consignee of the exported goods. *See* 19 CFR 181.47 (b)(2)(ii)(G).

The documents for establishing exportation include, but are not limited to: a bill of lading, air waybill, freight waybill, Canadian Customs manifest, and/or cargo manifest. *See* 19 CFR 191.72(a). If the export is a mail shipment, vessel supply, or transfer to a foreign trade zone, other procedures to establish exportation may apply. *See* 19 CFR 191.72 (c)–(e). Current CBP regulations specify that the documents listed in paragraph (a) must be either originally signed or certified copies thereof. *See* 19 CFR 191.72(a). Additionally, certain claims subject to NAFTA require that the claimant produce an originally signed document or a certified copy of such document. *See* 19 CFR 181.47(b)(2)(ii)(G).

Acquiring pen and ink signatures for the original documentation or certified copies of such documentation is time consuming and often unrealistic for the trade. CBP realizes the difficulty of having to provide a pen and ink signature for documents when these documents are issued electronically and do not contain an actual pen and ink signature. As a consequence, drawback claims are often denied when claimants can produce only documentary evidence that does not contain a signature or copies of such documents that are not certified.

As such, CBP is amending its regulations by removing the requirement that the documentary evidence that establishes the date and fact of exportation for drawback eligibility be originally signed or that any copy of such documentary evidence must be certified. CBP will now allow claimants to provide unsigned originals or copies of documentary evidence as proof of export for drawback eligibility. Therefore, copies of original documentary evidence will no longer need to be certified.

Additionally, pursuant to 19 CFR 191.72(c), CBP currently requires a certified export invoice for mail shipments and references section 191.74. Even though section 191.72(c) cites to section 191.74 as a reference for the “certified export invoice” requirement for mail shipments, the regulatory text of 19 CFR 191.74 does not require a claimant to submit a certified copy of the export invoice, but only requires that the claimant provide the official postal records. There is no reference to “export invoice” in section 191.74. Further, the only reference to “certification” is in the title heading to section 191.74. Accordingly, CBP is removing the phrase “Certification of” from the heading text to section 191.74 as it is misleading as to what that regulation requires. Thus, CBP is clarifying that claimants submitting postal records in support of exportation in accordance with section 191.74 may submit either originals or uncertified copies of official postal records by clearly stating that within the text of section 191.74. Further, CBP is revising section 191.72(c) to accurately reflect the plain language of section 191.74 by requiring evidence of official postal records (originals or copies) that demonstrate exportation by mail.

Other non-substantive editorial changes to reflect the plain English mandate are made to these regulatory sections, 19 CFR 181.47, 191.72 and 191.74.

#### *Conforming Amendments*

CBP inadvertently failed to remove from Appendix B to part 191 references to certain drawback offices when the agency previously amended the regulations to close four drawback offices. Three drawback offices were closed in 2003 (Boston, MA; New Orleans, LA; and Miami, FL) and one in 2010 (Long Beach, CA). See *Consolidation of Customs Drawback Centers: Final rule*, 68 FR 3381, dated January 24, 2003; and *Further Consolidation of CBP Drawback Centers: Final rule*, 75 FR 24392, dated May 5, 2010. Accordingly, this document

amends Appendix B, Sections II through V within part 191 of 19 CFR to reflect the closure of those four drawback offices by removing the reference to eight drawback offices and by removing the references to the locations of the four closed offices (that is, Boston, MA; Long Beach, CA; Miami, FL; and New Orleans, LA).

#### *Nomenclature Changes*

On November 25, 2002, the President signed into law the Homeland Security Act of 2002 (Pub. L. 107–296, 116 Stat. 2135). Accordingly, as of March 1, 2003, the former U.S. Customs Service of the Department of the Treasury was transferred to DHS and reorganized to become CBP. Accordingly, this document further amends § 181.47 to reflect the change from the legacy agency name, U.S. Customs Service, to the current name, U.S. Customs and Border Protection or CBP.

#### **Discussion of Changes**

##### *Part 181*

Section 181.47 of the CBP regulations (19 CFR 181.47) pertains to the documents required for a NAFTA drawback claim. Paragraph (b)(2)(ii)(G) of § 181.47 is amended by removing the requirement that copies of the exemplar documents in that paragraph be certified.

In addition, section 181.47 contains the legacy agency name of Customs. Accordingly, § 181.47 is amended to remove the outdated information and replace it with the current agency name CBP in §§ 181.47(b)(2), 181.47(b)(2)(i)(A), 181.47(b)(2)(i)(B), 181.47(b)(2)(i)(F), 181.47(b)(2)(ii)(A), 181.47(b)(2)(ii)(B), 181.47(b)(2)(ii)(C), 181.47(b)(2)(ii)(D), 181.47(b)(2)(ii)(E), 181.47(b)(2)(iii)(A), 181.47(b)(2)(iii)(B), and 181.47(b)(2)(iii)(D). Additionally, the word “shall” is replaced with either “must”, “will” or “is”, as appropriate, in paragraphs (a), (b)(1), (b)(2)(i), (b)(2)(i)(E), (b)(2)(ii), (b)(2)(ii)(B), (b)(2)(ii)(G), (b)(2)(ii)(H), (b)(2)(iii), (b)(2)(iv), (b)(2)(v), and (c) of § 181.47 to conform with the plain English mandate.

##### *Part 191*

Section 191.72 of the CBP regulations (19 CFR 191.72) pertains to exportation procedures for drawback. Section 191.72(a) is amended by removing the terms “originally signed” and “certified” from the list of acceptable documentary evidence for establishing the date and fact of exportation for drawback eligibility. Section 191.72(c) is revised to reflect the requirements of section 191.74 and to reflect that the

postal records for export shipments no longer have to be certified. Section 191.74 is amended by removing the words “Certification of” from the heading text because the text of 191.74 does not require a claimant to submit a certified copy of the postal record and the title heading cannot impose a legal requirement that is not also reflected in the regulatory text. CBP is also making it clear that claimants may submit either originals or copies of official postal records by adding the parenthetical phrase “(originals or copies)” after the phrase “official postal records” in section 191.74.

This document also makes non-substantive amendments to Appendix B, Sections II through V within part 191 of 19 CFR as discussed above.

#### **Inapplicability of Notice and Delayed Effective Date**

Because the amendments in parts 181 and 191 of 19 CFR set forth in this document merely relieve a burden on the public and the amendments to the Appendix of part 191 conform the regulations to previous regulatory changes to reflect the consolidation of drawback offices, CBP finds that good cause exists for dispensing with notice and public procedure as unnecessary under 5 U.S.C. 553(b)(B). For this same reason, pursuant to 5 U.S.C. 553(d)(3), CBP finds good cause for dispensing with the requirement for a delayed effective date.

#### **Regulatory Flexibility Act**

Because this document is not subject to the notice and public procedure requirements of 5 U.S.C. 553, it is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

#### **Executive Order 12866**

These amendments do not meet the criteria for a “significant regulatory action” as specified in Executive Order 12866, as supplemented by Executive Order 13563.

#### **Signing Authority**

This regulation is being issued in accordance with 19 CFR 0.1(a)(1), pertaining to the authority of the Secretary of the Treasury (or that of his delegate) to approve regulations concerning drawback.

#### **List of Subjects**

##### *19 CFR Part 181*

Administrative practice and procedure, Customs duties and inspection, Exports, Imports, Reporting and recordkeeping requirements.

19 CFR Part 191

Claims, Customs duties and inspection, Exports, Reporting and recordkeeping requirements.

**Amendments to the CBP Regulations**

For the reasons set forth above, parts 181 and 191 of the CBP Regulations (19 CFR parts 181 and 191) and Appendix B to part 191 of 19 CFR are amended as set forth below:

**PART 181—NORTH AMERICAN FREE TRADE AGREEMENT**

■ 1. The general authority citation for part 181 continues to read as follows:

**Authority:** 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1624, 3314.

\* \* \* \* \*

**§ 181.47 [Amended]**

■ 2. In § 181.47:

- a. Paragraph (a) is amended by:
  - (i) In the first sentence, by removing the word “shall” and adding, in its place, the word “will”;
  - (ii) In the second sentence, by removing the word “shall” each place it occurs and adding, in its place, the word “must”; and
  - (iii) In the third sentence, by removing the word “shall” and adding, in its place, the word “will”;
- b. Paragraph (b)(1) is amended by removing the word “shall” each place it occurs and adding, in its place, the word “must”;
- c. Paragraph (b)(2) introductory text is amended by removing the word “Customs” and adding, in its place, the term “CBP”;
- d. Paragraph (b)(2)(i) is amended by removing the word “shall” and adding, in its place, the word “must”;
- e. Paragraphs (b)(2)(i)(A), (b)(2)(i)(B) and (b)(2)(i)(F) are amended by removing the word “Customs” and adding, in its place, the term “CBP”;
- f. Paragraphs (b)(2)(i)(E) and (b)(2)(ii) introductory text are amended by removing the word “shall” and adding, in its place, the word “must”;
- g. Paragraph (b)(2)(ii)(A) is amended by removing the word “Customs” and adding, in its place, the term “CBP”; and by removing the word “shall” and adding, in its place, the word “must”;
- h. Paragraph (b)(2)(ii)(B) is amended by:
  - (i) Removing the first and third occurrence of the word “Customs” and adding, in its place, the term “CBP”;
  - (ii) Removing the second occurrence of the word “Customs” and adding, in

its place, the words “the CBP-assigned”; and

- (iii) Removing the word “shall” and adding, in its place, the word “must”;
- i. Paragraphs (b)(2)(ii)(C), (b)(2)(ii)(D) and (b)(2)(ii)(E) are amended by removing the word “Customs” and adding, in its place, the term “CBP”;
- j. Paragraph (b)(2)(ii)(G) is revised;
- k. Paragraph (b)(2)(ii)(H) is amended by removing the phrase “shall be” and adding, in its place, the word “is”;
- l. Paragraph (b)(2)(iii) is amended by removing the word “shall” and adding, in its place, the word “must”;
- m. Paragraphs (b)(2)(iii)(A), (b)(2)(iii)(B), and (b)(2)(iii)(D) are amended by removing the word “Customs” each place it appears and adding, in its place, the term “CBP”;
- n. Paragraph (b)(2)(iv) is amended by:
  - (i) Removing the first occurrence of the word “shall” and adding, in its place, the word “will”; and
  - (ii) Removing the second occurrence of the word “shall” and adding, in its place, the word “must”;
  - o. Paragraph (b)(2)(v) is amended by removing the word “shall” and adding, in its place, the word “will”; and
  - p. Paragraph (c) introductory text is amended by removing the word “shall” and adding, in its place, the word “must”.

The revision reads as follows:

**§ 181.47 Completion of claim for drawback.**

\* \* \* \* \*

- (b) \* \* \*
- (2) \* \* \*
- (ii) \* \* \*

(G) *Evidence of exportation.*

Acceptable documentary evidence of exportation of goods to Canada or Mexico may include originals or copies of any of the following documents that are issued by the exporting carrier: bill of lading, air waybill, freight waybill, export ocean bill of lading, Canadian customs manifest, and cargo manifest. Supporting documentary evidence must establish fully the time and fact of exportation, the identity of the exporter, and the identity and location of the ultimate consignee of the exported goods;

\* \* \* \* \*

**PART 191—DRAWBACK**

■ 3. The general authority citation for part 191 continues to read as follows:

**Authority:** 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1313, 1624.

\* \* \* \* \*

**§ 191.72 [Amended]**

4. In § 191.72:

- a. The introductory paragraph is amended by removing the word “shall” and adding, in its place, the word “must” in the first two sentences; and
- b. Paragraphs (a) and (c) are revised to read as follows:

**§ 191.72 Exportation procedures.**

\* \* \* \* \*

(a) Documentary evidence of exportation (originals or copies) issued by the exporting carrier, such as a bill of lading, air waybill, freight waybill, Canadian Customs manifest, and/or cargo manifest;”

\* \* \* \* \*

(c) Official postal records (originals or copies) which evidence exportation by mail (§ 191.74);

\* \* \* \* \*

**§ 191.74 [Amended]**

■ 5. In § 191.74:

- a. The section heading is revised;
- b. In the first sentence, add the parenthetical “(originals or copies)” after the phrase “the official postal records”; and
- c. The last sentence is amended by removing the parenthetical “(see § 191.51(a))” and adding, in its place, the parenthetical “(see § 191.51(a))”.

The revision reads as follows:

**§ 191.74 Exportation by mail.**

\* \* \* \* \*

**Appendix B to Part 191 [Amended]**

■ 6. In Appendix B to Part 191, Sections II through V, under the headings titled, “CBP OFFICE WHERE DRAWBACK CLAIMS WILL BE FILED” remove the parenthetical “(The 8 offices where drawback claims can be filed are located at: Boston, MA; New York, NY; Miami, FL; New Orleans, LA; Houston, TX; Long Beach, CA; Chicago, IL; San Francisco, CA)” each place it appears and adding, in its place, the parenthetical “(The four offices where drawback claims can be filed are located at: New York, NY; Houston, TX; Chicago, IL; San Francisco, CA)”.

**R. Gil Kerlikowske,**

*Commissioner, U.S. Customs and Border Protection.*

Approved: August 4, 2015.

**Timothy E. Skud,**

*Deputy Assistant Secretary of the Treasury.*

[FR Doc. 2015–19466 Filed 8–6–15; 8:45 am]

**BILLING CODE 9111–14–P**



**DEPARTMENT OF THE TREASURY****Alcohol and Tobacco Tax and Trade Bureau****27 CFR Part 9**

[Docket No. TTB–2015–0002; T.D. TTB–129; Ref: Notice No. 146]

RIN 1513–AC12

**Establishment of the Squaw Valley-Miramonte Viticultural Area**

**AGENCY:** Alcohol and Tobacco Tax and Trade Bureau, Treasury.

**ACTION:** Final rule; Treasury decision.

**SUMMARY:** The Alcohol and Tobacco Tax and Trade Bureau (TTB) establishes, through this final rule, the approximately 44,690-acre “Squaw Valley-Miramonte” viticultural area in Fresno County, California. The viticultural area does not overlap any established viticultural area. TTB designates viticultural areas to allow vintners to better describe the origin of their wines and to allow consumers to better identify wines they may purchase.

**DATES:** This final rule is effective September 8, 2015.

**FOR FURTHER INFORMATION CONTACT:** Karen A. Thornton, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005; phone 202–453–1039, ext. 175.

**SUPPLEMENTARY INFORMATION:****Background on Viticultural Areas***TTB Authority*

Section 105(e) of the Federal Alcohol Administration Act (FAA Act), 27 U.S.C. 205(e), authorizes the Secretary of the Treasury to prescribe regulations for the labeling of wine, distilled spirits, and malt beverages. The FAA Act provides that these regulations should, among other things, prohibit consumer deception and the use of misleading statements on labels and ensure that labels provide the consumer with adequate information as to the identity and quality of the product. The Alcohol and Tobacco Tax and Trade Bureau (TTB) administers the FAA Act pursuant to section 1111(d) of the Homeland Security Act of 2002, codified at 6 U.S.C. 531(d). The Secretary has delegated various authorities through Treasury Department Order 120–01, dated December 10, 2013, to the TTB Administrator to perform the functions and duties in the administration and enforcement of this law.

Part 4 of the TTB regulations (27 CFR part 4) authorizes TTB to establish definitive viticultural areas and regulate the use of their names as appellations of origin on wine labels and in wine advertisements. Part 9 of the TTB regulations (27 CFR part 9) sets forth standards for the preparation and submission of petitions for the establishment or modification of American viticultural areas (AVAs) and lists the approved AVAs.

*Definition*

Section 4.25(e)(1)(i) of the TTB regulations (27 CFR 4.25(e)(1)(i)) defines a viticultural area for American wine as a delimited grape-growing region having distinguishing features, as described in part 9 of the regulations, and a name and a delineated boundary, as established in part 9 of the regulations. These designations allow vintners and consumers to attribute a given quality, reputation, or other characteristic of a wine made from grapes grown in an area to the wine’s geographic origin. The establishment of AVAs allows vintners to describe more accurately the origin of their wines to consumers and helps consumers to identify wines they may purchase. Establishment of an AVA is neither an approval nor an endorsement by TTB of the wine produced in that area.

*Requirements*

Section 4.25(e)(2) of the TTB regulations (27 CFR 4.25(e)(2)) outlines the procedure for proposing an AVA and provides that any interested party may petition TTB to establish a grape-growing region as an AVA. Section 9.12(c) of the TTB regulations (27 CFR 9.12(c)) prescribes standards for petitions for the establishment or modification of AVAs. Petitions to establish an AVA must include the following:

- Evidence that the area within the proposed AVA boundary is nationally or locally known by the AVA name specified in the petition;
- An explanation of the basis for defining the boundary of the proposed AVA;
- A narrative description of the features of the proposed AVA affecting viticulture, including climate, geology, soils, physical features, and elevation, that make the proposed AVA distinctive and distinguish it from adjacent areas outside the proposed AVA boundary;
- The appropriate United States Geological Survey (USGS) map(s) showing the location of the proposed AVA, with the boundary of the proposed AVA clearly drawn thereon; and

- A detailed narrative description of the proposed AVA boundary based on USGS map markings.

**Squaw Valley-Miramonte Petition**

TTB received a petition from Christine Flannigan, owner of the Sierra Peaks Winery and Purgatory Vineyards, on behalf of the Squaw Valley Grape Growers Group, proposing the establishment of the “Squaw Valley-Miramonte” AVA in Fresno County, California, approximately 40 miles east of the city of Fresno. The proposed AVA is a largely rural region in the foothills of the Sierra Nevada Mountains and does not overlap any established AVAs. To the northwest, west, and south of the proposed AVA is the San Joaquin Valley. The Sequoia National Forest is adjacent to the northern and eastern boundaries of the proposed AVA.

The proposed Squaw Valley-Miramonte AVA contains approximately 44,690 acres and has 3 bonded wineries and 5 commercially producing vineyards, covering a total of 7.5 acres, distributed across the proposed AVA. The petition states that vineyards within the proposed AVA are small due to the region’s steep and rugged terrain, which requires most vineyard work to be done by hand rather than by machine.

According to the petition, the distinguishing features of the proposed AVA include its climate, topography, and soils. Daytime temperatures within the proposed AVA are generally cooler than in the neighboring San Joaquin Valley to the south, west, and northwest. However, nighttime temperatures are usually warmer within the proposed AVA than within the San Joaquin Valley because cool air drains off the slopes of the proposed AVA at night and settles in the valley. The cool daytime temperatures and warm nighttime temperatures during the growing season produce higher levels of sugar and anthocyanins (pigments responsible for the color of grape skins) at harvest than occur in grapes grown in the warmer San Joaquin Valley. The temperatures in the proposed AVA also contribute to later harvest dates than in the San Joaquin Valley. The proposed AVA also receives significantly more rainfall than the San Joaquin Valley, but less than the regions to the north and east of the proposed AVA, within the Sequoia National Forest. The high rainfall amounts within the proposed AVA increase the risk of erosion, so vineyard owners plant ground cover between the vineyard rows to help hold the soil in place.

The topography of the proposed AVA consists of steep and rugged hillsides

covered with boulders and oak woodlands. Elevations range from 1,600 to 3,500 feet, and slope angles in the vineyards range from 15 to 40 percent. As a result of the steep terrain, mechanized vineyard equipment is not practical, so almost all vineyard work is done by hand. Therefore, the vineyards in the proposed AVA are much smaller than those in the neighboring San Joaquin Valley, where the terrain is much lower and flatter. To the north and east of the proposed AVA, the terrain becomes too steep for commercial viticulture.

The majority of the soils within the proposed Squaw Valley-Miramonte AVA are derived from granitic material, mainly quartz diorite. The three most common soil series are the Vista, Sierra, and Auberry series. All three soil series are described as having good drainage, which reduces the risk of root disease. The soils within the proposed AVA have pH levels ranging from a slightly acidic 5.6 to a neutral 7.3, levels which are adequate for viticulture and do not promote overly vigorous vine or canopy growth. The soils within the proposed AVA are severely deficient in nitrogen, a nutrient necessary for vine growth, and therefore require supplementation. Additionally, soils in some of the vineyards within the proposed AVA have an excess of potassium, which interferes with the vines' ability to uptake magnesium. As a result, magnesium must be added to the soil in these vineyards. To the north of the proposed AVA, the soils are primarily of the Coarsegold and Trabuco series, which are derived from weathered schist and igneous rock, respectively. The most common soil series east of the proposed AVA are the Holland series, derived from weathered granitic rock, and the Aiken series, derived from volcanic rocks. These soils are more acidic than the soils within the proposed AVA due to deep mats of decomposing needle litter from conifer trees. South and west of the proposed AVA, within the San Joaquin Valley, alluvial soils such as San Joaquin loam and San Joaquin sandy loam become common, as are soils of the Hanford and Greenfield series. These soils are all less acidic and have finer textures than the soils of the proposed AVA.

#### Notice of Proposed Rulemaking and Comments Received

TTB published Notice No. 146 in the *Federal Register* on January 22, 2015 (80 FR 3184), proposing to establish the Squaw Valley-Miramonte AVA. In the notice, TTB summarized the evidence from the petition regarding the name, boundary, and distinguishing features

for the proposed AVA. The notice also compared the distinguishing features of the proposed AVA to the surrounding areas. In Notice No. 146, TTB solicited comments on the accuracy of the name, boundary, and other required information submitted in support of the petition. The comment period closed on March 23, 2015. TTB received no comments in response to Notice No. 146.

#### TTB Determination

After careful review of the petition, TTB finds that the evidence provided by the petitioner supports the establishment of the Squaw Valley-Miramonte AVA. Accordingly, under the authority of the FAA Act, section 1111(d) of the Homeland Security Act of 2002, and part 4 and part 9 of the TTB regulations, TTB establishes the "Squaw Valley-Miramonte" AVA in Fresno County, California, effective 30 days from the publication date of this document.

#### Boundary Description

See the narrative description of the boundary of the AVA in the regulatory text published at the end of this final rule.

#### Maps

The petitioner provided the required maps, and they are listed below in the regulatory text.

#### Impact on Current Wine Labels

Part 4 of the TTB regulations prohibits any label reference on a wine that indicates or implies an origin other than the wine's true place of origin. For a wine to be labeled with an AVA name or with a brand name that includes an AVA name, at least 85 percent of the wine must be derived from grapes grown within the area represented by that name, and the wine must meet the other conditions listed in 27 CFR 4.25(e)(3). If the wine is not eligible for labeling with an AVA name and that name appears in the brand name, then the label is not in compliance and the bottler must change the brand name and obtain approval of a new label. Similarly, if the AVA name appears in another reference on the label in a misleading manner, the bottler would have to obtain approval of a new label. Different rules apply if a wine has a brand name containing an AVA name that was used as a brand name on a label approved before July 7, 1986. See 27 CFR 4.39(i)(2) for details.

With the establishment of this AVA, its name, "Squaw Valley-Miramonte," will be recognized as a name of viticultural significance under 27 CFR

4.39(i)(3). The text of the regulation clarifies this point. Consequently, wine bottlers using the name "Squaw Valley-Miramonte" in a brand name, including a trademark, or in another label reference as to the origin of the wine, will have to ensure that the product is eligible to use the AVA name as an appellation of origin. TTB is not designating either "Squaw Valley" or "Miramonte," standing alone, as terms of viticultural significance because both of these names are also associated with multiple locations within the United States outside the AVA.

#### Regulatory Flexibility Act

TTB certifies that this regulation will not have a significant economic impact on a substantial number of small entities. The regulation imposes no new reporting, recordkeeping, or other administrative requirement. Any benefit derived from the use of an AVA name would be the result of a proprietor's efforts and consumer acceptance of wines from that area. Therefore, no regulatory flexibility analysis is required.

#### Executive Order 12866

It has been determined that this final rule is not a significant regulatory action as defined by Executive Order 12866 of September 30, 1993. Therefore, no regulatory assessment is required.

#### Drafting Information

Karen A. Thornton of the Regulations and Rulings Division drafted this final rule.

#### List of Subjects in 27 CFR Part 9

Wine.

#### The Regulatory Amendment

For the reasons discussed in the preamble, TTB amends title 27, chapter I, part 9, Code of Federal Regulations, as follows:

#### PART 9—AMERICAN VITICULTURAL AREAS

- 1. The authority citation for part 9 continues to read as follows:

Authority: 27 U.S.C. 205.

#### Subpart C—Approved American Viticultural Areas

- 2. Subpart C is amended by adding § 9.251 to read as follows:

##### § 9.251 Squaw Valley-Miramonte.

(a) *Name.* The name of the viticultural area described in this section is "Squaw Valley-Miramonte." For purposes of part 4 of this chapter, "Squaw Valley-

Miramonte” is a term of viticultural significance.

(b) *Approved maps.* The six United States Geological Survey (USGS) 1:24,000 scale topographic maps used to determine the boundary of the Squaw Valley-Miramonte viticultural area are titled:

- (1) Orange Cove North, Calif., 1966;
  - (2) Pine Flat Dam, Calif., 1965;
- photinspected 1978;
- (3) Luckett Mtn., Calif., provisional edition 1987;
  - (4) Verplank Ridge, Calif., provisional edition 1987;
  - (5) Miramonte, Calif., 1966; and
  - (6) Tucker Mtn., Calif., 1966.

(c) *Boundary.* The Squaw Valley-Miramonte viticultural area is located in Fresno County, California. The boundary of the Squaw Valley-Miramonte viticultural area is as described below:

(1) The beginning point is located on the Orange Cove North map, at the southwest corner of section 21, T14S/R25E. From the beginning point, proceed north-northwesterly in a straight line to the marked 3,355-foot elevation point on Bear Mountain, section 5, T14S/R25E; then

(2) Proceed northeast in a straight line, crossing onto the Pine Flat Dam map and over the marked 3,354-foot elevation point on Bear Mountain, section 32, T13S/R25E, and then continuing northeasterly in a straight line and crossing onto the Luckett Mountain map, proceed to the marked 3,489-foot summit of Dalton Mountain, section 22, T13S/R25E; then

(3) Proceed easterly in a straight line to the Sequoia National Forest boundary line at the northwest corner of section 28, T13S/R26E; then

(4) Proceed east along the Sequoia National Forest boundary line, crossing onto the Verplank Ridge map, and continue south, then east, then south along the national forest boundary line, crossing onto the Miramonte map, and then continue south, then east along the national forest boundary line to the northeast corner of section 5, T14S/R27E; then

(5) Proceed south along the eastern boundary lines of sections 5, 8, and 17, T14S/R27E, to the southeast corner of section 17; then

(6) Proceed east along the northern boundary line of section 21, T14S/R27E, to the northeast corner of that section; then

(7) Proceed south along the eastern boundary lines of sections 21, 28, and 33, T14S/R27E, to the Fresno-Tulare County boundary line at the southeast corner of section 33; then

(8) Proceed west along the Fresno-Tulare County boundary line, crossing

onto the Tucker Mountain map, to the southwest corner of section 34, T14S/R26E; then

(9) Proceed north along the western boundary lines of sections 34, 27, 22, and 15, T14S/R26E, to the northwest corner of section 15; then

(10) Proceed west along the southern boundary lines of sections 9, 8, and 7, T14S/R26E, and sections 12 and 11, T14S/R25E, to the southwest corner of section 11; then

(11) Proceed south along the eastern boundary lines of sections 15 and 22, T14S/R25E, to the southeast corner of section 22; then (12) Proceed west along the southern boundary line of section 22, T14S/R25E, and, crossing onto the Orange Cove North map, continue west along the southern boundary line of section 21, T14S/R25E, returning to the beginning point.

Signed: June 11, 2015.

**John J. Manfreda,**  
*Administrator.*

Approved: June 17, 2015.

**Timothy E. Skud,**  
*Deputy Assistant Secretary (Tax, Trade, and Tariff Policy).*

[FR Doc. 2015-19454 Filed 8-6-15; 8:45 am]

**BILLING CODE 4810-31-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 117

[Docket No. USCG-2015-0741]

#### Drawbridge Operation Regulation; Gulf Intracoastal Waterway, Galveston, TX

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of deviation from drawbridge regulations.

**SUMMARY:** The Coast Guard has issued a temporary deviation from the operating schedule that governs the operation of the Galveston Causeway Railroad Vertical Lift Bridge across the Gulf Intracoastal Waterway, mile 357.2 west of Harvey Locks, at Galveston, Galveston County, Texas. The deviation is necessary in order to conduct maintenance on the bridge. This deviation allows the bridge to remain temporarily closed to navigation for eight hours on consecutive days during day light hours and will operate normally at all other times.

**DATES:** This deviation is effective from August 31 through September 5, 2015. This deviation will be enforced from 7:30 a.m. to 11:30 and then again from

1:30 p.m. to 5:30 p.m., daily, beginning August 31 through September 5, 2015.

**ADDRESSES:** The docket for this deviation, [USCG-2015-0741] is available at <http://www.regulations.gov>. Type the docket number in the “SEARCH” box and click “SEARCH.” Click on Open Docket Folder on the line associated with this deviation. You may also visit the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary deviation, call or email Jim Wetherington, Bridge Administration Branch, Coast Guard; telephone 504-671-2128, email [james.r.wetherington@uscg.mil](mailto:james.r.wetherington@uscg.mil). If you have questions on viewing the docket, call Cheryl F. Collins, Program Manager, Docket Operations, telephone 202-366-9826.

**SUPPLEMENTARY INFORMATION:** The BNSF Railway Company requested a temporary deviation from the operating schedule of the Galveston Causeway Railroad Vertical Lift Bridge across the Gulf Intracoastal Waterway, mile 357.2 west of Harvey Locks, at Galveston, Galveston County, Texas.

The bridge has a vertical clearance of 8.0 feet above mean high water, elevation 3.0 feet (NAVD88), in the closed-to-navigation position and 73 feet above mean high water in the open-to-navigation position. In accordance with 33 CFR 117.5, the draw shall open on signal for the passage of vessels.

This temporary deviation allows the vertical lift bridge to remain closed to navigation from 7:30 a.m. to 11:30 and then again from 1:30 p.m. to 5:30 p.m., daily, beginning August 31 through September 5, 2015. During this time, the bridge owner will complete cable lubing, welding joints and replacing span guide bearings. If the vessel can safely pass without an opening, the vessel may pass at the slowest safe speed. The bridge can open in case of emergency.

Navigation at the site of the bridge consists mainly of tows with barges and some recreational pleasure craft. Based on known waterway users, as well as coordination with those waterway users, it has been determined that this closure will not have a significant effect on these vessels. No alternate routes are available.

In accordance with 33 CFR 117.35, the draw bridge must return to its regular operating schedule immediately

at the end of the effective period of this temporary deviation.

This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: August 3, 2015.

**David M. Frank,**  
Bridge Administrator, Eighth Coast Guard District.

[FR Doc. 2015-19377 Filed 8-6-15; 8:45 am]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF HOMELAND SECURITY

### Coast Guard

#### 33 CFR Part 117

[Docket No. USCG-2015-0624]

#### Drawbridge Operation Regulation; Willamette River at Portland, OR

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notice of deviation from drawbridge regulation.

**SUMMARY:** The Coast Guard has issued a temporary deviation from the operating schedule that governs four Multnomah County bridges: the Broadway Bridge, mile 11.7, Burnside Bridge, mile 12.4, Morrison Bridge, mile 12.8, and Hawthorne Bridge, mile 13.1, all crossing the Willamette River at Portland, OR. This deviation is necessary to accommodate the annual Portland Providence Bridge Pedal event. This deviation allows the bridges to remain in the closed-to-navigation position to allow safe roadway movement of event participants.

**DATES:** This deviation is effective from 6 a.m. on August 9, 2015, to 12:30 p.m. on August 9, 2015.

**ADDRESSES:** The docket for this deviation, [USCG-2015-0624] is available at <http://www.regulations.gov>. Type the docket number in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this deviation. You may also visit the Docket Management Facility in Room W12-140 on the ground floor of the Department of Transportation West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

**FOR FURTHER INFORMATION CONTACT:** If you have questions on this temporary deviation, call or email Mr. Steven Fischer, Bridge Administrator, Thirteenth Coast Guard District; telephone 206-220-7282, email [d13-pf-d13bridges@uscg.mil](mailto:d13-pf-d13bridges@uscg.mil). If you have

questions on viewing the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone 202-366-9826.

#### SUPPLEMENTARY INFORMATION:

Multnomah County has requested a temporary deviation from the operating schedule for the Broadway Bridge, mile 11.7, Burnside Bridge, mile 12.4, Morrison Bridge, mile 12.8, and Hawthorne Bridge, mile 13.1, all crossing the Willamette River at Portland, OR. The requested deviation is to accommodate the annual Providence Bridge Pedal event. To facilitate this event, the draws of the bridges will be maintained in the closed-to-navigation positions as follows: The Broadway Bridge, mile 11.7, provides a vertical clearance of 90 feet in the closed position; Burnside Bridge, mile 12.4, provides a vertical clearance of 64 feet in the closed position; Morrison Bridge, mile 12.8, provides a vertical clearance of 69 feet in the closed position; and Hawthorne Bridge, mile 13.1, provides a vertical clearance of 49 feet in the closed position; all clearances are referenced to the vertical clearance above Columbia River Datum 0.0. The normal operating schedule for all four bridges is set in 33 CFR 117.897, and states that the bridges need not open from 7 a.m. to 9 a.m., and from 4 p.m. to 6 p.m. Monday through Friday. These four bridges need not open for vessel traffic from 6 a.m. on August 9, 2015, to 12:30 p.m. on August 9, 2015. This deviation period is from 6 a.m. on August 9, 2015, to 12:30 p.m. August 9, 2015. The deviation allows the Broadway Bridge, Burnside Bridge, Morrison Bridge, and the Hawthorne Bridge all crossing the Willamette River, to remain in the closed-to-navigation position and need not open for maritime traffic from 6 a.m. to 12:30 p.m. on August 9, 2015. The four bridges shall operate in accordance to 33 CFR 117.897 at all other times. Waterway usage on this part of the Willamette River includes vessels ranging from commercial tug and barge to small pleasure craft.

Vessels able to pass through the bridge in the closed-to-navigation positions may do so at any time. The bridges will be able to open for emergencies and there is no immediate alternate route for vessels to pass. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridges so that vessels can arrange their transits to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridges must return to their regular operating schedules immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: July 17, 2015.

**Steven M. Fischer,**  
Bridge Administrator, Thirteenth Coast Guard District.

[FR Doc. 2015-19373 Filed 8-6-15; 8:45 am]

**BILLING CODE 9110-04-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 42 CFR Part 110

RIN 0906-AA79

#### Countermeasures Injury Compensation Program: Pandemic Influenza Countermeasures Injury Table

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services (HHS).

**ACTION:** Final rule.

**SUMMARY:** HHS is establishing the Pandemic Influenza Countermeasures Injury Table as authorized by the Public Readiness and Emergency Preparedness Act (PREP Act). Through this final rule, the Secretary of the U.S. Department of Health and Human Services (Secretary) adds regulations for the purpose of creating Covered Countermeasures Injury Tables. The pandemic influenza countermeasures are identified in Secretarial declarations relating to pandemic influenza, including influenza caused by the 2009 H1N1 pandemic influenza virus (hereafter referred to as the 2009 H1N1 virus) and other potential pandemic strains, such as H5N1 avian influenza.

**DATES:** This rule is effective September 8, 2015.

**FOR FURTHER INFORMATION CONTACT:** Dr. Avril M. Houston, Director, Division of Injury Compensation Programs, Healthcare Systems Bureau, HRSA, Parklawn Building, Room 11C-26, 5600 Fishers Lane, Rockville, MD 20857, or by telephone (855) 266-2427. This is a toll-free number.

**SUPPLEMENTARY INFORMATION:** On March 30, 2014, HHS published the Notice of Proposed Rulemaking (NPRM) in the **Federal Register** to amend the Countermeasures Injury Compensation Program's (CICP or Program) implementing regulation and establish a table of injuries resulting from the administration or use of covered

pandemic influenza countermeasures. The NPRM provided a 60-day comment period resulting in HHS receipt of five sets of comments—one set from a physicians' organization and four sets from individuals. HHS carefully considered these comments when developing this final rule. In "Section III, Comments and Responses" of this final rule, the comments are summarized and HHS provides responses to them.

## I. Background

The Public Readiness and Emergency Preparedness Act of 2005 (PREP Act) directs the Secretary to establish, through regulation, a Covered Countermeasures Injury Table (Table) identifying serious physical injuries that are presumed to be directly caused by the administration or use of covered countermeasures identified in PREP Act declarations issued by the Secretary.

The Secretary may only add to a Table injuries that are directly caused by the administration or use of the covered countermeasure based on "compelling, reliable, valid, medical and scientific evidence."<sup>1</sup> This Table informs the public about serious physical injuries known to be directly caused by covered countermeasures through support by compelling, reliable, valid, medical and scientific evidence. In addition, this Table creates a rebuttable presumption of causation for eligible individuals whose injuries are listed on a Table and meet the requirements of a Table.

The PREP Act authorizes both liability protections and compensation based on the terms of the PREP Act declarations, but this final rule concerns only the compensation program, not the liability protections set forth therein.

The Secretary published the interim final rule implementing the Program on October 15, 2010.<sup>2</sup> The final rule, which was published on October 7, 2011, explains the Program's policies, procedures, and requirements. Title 42 of the Code of Federal Regulations (CFR) § 110.20(a) states that individuals must establish that a covered injury occurred in order to be eligible for benefits under the Program. A covered injury is death or a serious injury determined by the Secretary to be: (1) An injury meeting the requirements of a Table, which is presumed to be the direct result of the administration or use of a covered countermeasure unless the Secretary determines there is another more likely cause; or (2) an injury (or its health complications) that is the direct result of the administration or use of a covered

countermeasure. This includes a covered countermeasure causing a serious aggravation of a pre-existing condition.<sup>3</sup> In general, only injuries that warranted hospitalization (whether or not the person was actually hospitalized), or injuries that led to a significant loss of function or disability are considered serious injuries.<sup>4</sup>

Individuals with injuries not meeting the requirements listed on the Table may still pursue their claims as non-Table injuries under the Program. In this instance, the requester does not receive the presumption of causation for a Table injury and must demonstrate that the use or administration of the covered countermeasure directly caused the injury. Proof of a causal association for the non-Table injury must be based on compelling, reliable, valid, medical and scientific evidence.

## II. Summary of the Final Rule

Through this final rule, the Secretary will be adding subpart K to 42 CFR part 110, which had been reserved for the purpose of creating a Covered Countermeasures Injury Table. The Table established in this final rule is limited to pandemic influenza covered countermeasures. These countermeasures are identified in Secretarial declarations relating to pandemic influenza, including influenza caused by the 2009 H1N1 virus, and other potential pandemic strains, such as H5N1 avian influenza. The Secretary may create and publish Tables in the **Federal Register** through separate amendments to 42 CFR part 110 in the future. Tables may be created for other countermeasures in accordance with the PREP Act. To date, declarations have been issued with respect to countermeasures against pandemic influenza A viruses, anthrax, botulism, smallpox, acute radiation syndrome, and the Ebola virus.

Through the Pandemic Influenza Countermeasures Injury Table Final Rule, the Secretary provides, as authorized by statute, a Table for several covered countermeasures listing serious physical injuries. The serious physical injuries included on the Table are injuries that are supported by compelling, reliable, valid, medical and scientific evidence showing that the administration or use of the covered countermeasures directly causes such injuries. The Table lists the serious injuries directly caused by a specific countermeasure, the time interval within which the first symptom or manifestation of onset of injury must

appear, and the definition of the injury. Table definitions are included to further explain each covered injury and the level of severity necessary to qualify as a Table injury.

The injuries, time intervals, definitions, and requirements reflect the Secretary's efforts to identify those serious physical injuries causally related to the covered countermeasures. The causal linkages between the covered countermeasures and these associated injuries are based on compelling, reliable, valid, medical and scientific evidence. The Secretary will stay informed of updates in the scientific and medical field concerning new information about causal associations between injuries and covered countermeasures.

In this final rule, the Secretary has made the following changes to the Qualifications and Aids to Interpretation (QAI) of the Table for purposes of clarity.

a. Changed section (b)(4)(i) by adding an accent over the "e" in Guillain-Barre Syndrome (GBS). The revised section term reads, "Guillain-Barré Syndrome." In the first sentence, added "currently is known to encompass" after "that" and delete "encompasses." The revised sentence states, "GBS is an acute monophasic peripheral neuropathy that currently is known to encompass a spectrum of four clinicopathological subtypes described below." In the fourth sentence, changed "nine" to "9." The revised sentence states, "Treatment related fluctuations in all subtypes of GBS can occur within 9 weeks of GBS symptom onset and recurrence of symptoms after this time frame would not be consistent with GBS."

b. Changed section (b)(4)(iv) by adding "The results of both . . ." to the beginning of the second sentence. The revised sentence states, "The results of both CSF and electrophysiologic studies are frequently normal in the first week of illness in otherwise typical cases of GBS."

c. Deleted section (b)(4)(v) which states, "For all types of GBS, the onset of symptoms less than three days (72 hours) after exposure to the influenza vaccine excludes vaccine exposure as a cause" because timeframes for serious physical injuries to be Table injuries are listed in the Table, not in the QAI.

d. Changed section (b)(4)(vi) to (b)(4)(v) since (b)(4)(v) has been deleted as stated above and added to the beginning of the first sentence of section (b)(4)(v), "For GBS to qualify as a Table injury." The revised sentence states, "For GBS to qualify as a Table injury, there must not be a more likely alternative diagnosis for the weakness."

<sup>1</sup> 42 U.S.C. 247d-6e(b)(5)(A).

<sup>2</sup> 42 CFR part 110.

<sup>3</sup> 42 CFR 110.3(g)(2).

<sup>4</sup> 42 CFR 110.3(z).

e. Changed section (b)(5)(i)(A) by adding “or” after “tube;”. The revised statement states, “(A) trauma or necrosis from an endotracheal tube; or.”

f. Changed section (b)(6)(i) by deleting “Definition -” before “VAP” at the beginning of the first sentence. In the fourth sentence, changed the phrase “radiographic infiltrate in the lungs that is consistent with pneumonia” to “radiographic infiltrate that is in the lungs and consistent with pneumonia.”

g. Changed section (b)(7) by adding “To qualify as Table injuries,” before “these” to the beginning of the last sentence. The revised sentence states, “To qualify as Table injuries, these manifestations must occur in patients who are being mechanically ventilated at the time of initial manifestation of the VILI.” VILI is Ventilator-Induced Lung Injury.

h. Changed section (b)(8) by adding “who are” after “patients” and before “under” to the first sentence. The revised sentence states, “Bleeding events are defined as excessive or abnormal bleeding in patients who are under the pharmacologic effects of anticoagulant therapy provided for extracorporeal membrane oxygenation (ECMO) treatment.”

### III. Comments and Responses

The NPRM set forth a 60-day public comment period, which ended on May 30, 2014. During this comment period, HHS received five sets of comments—one set from a physicians’ organization and four sets from individuals. Below is a summary of the comments and HHS’s responses.

#### 1. Anaphylaxis

*Comment:* A commenter suggested expanding to 12 hours the time frame within which the first symptom or manifestation of anaphylaxis must appear, stating that some cases of anaphylaxis may exhibit a late phase response up to 8–12 hours after exposure, and thus the 0–4 hour time frame is not long enough.

*Response:* HHS respectfully disagrees with this comment. There is no consensus within the medical and scientific community about the time frame in which the late phase response starts. As stated in the NPRM, anaphylaxis after immunization is serious, but it occurs rarely. After initial treatment and clinical improvement, some patients with allergic reactions may develop a late phase or “biphasic” reaction, which may be more severe than the initial presentation. Little is known of the pathophysiology of biphasic reactions. The variations and the subjective nature of definitions used

for determining the incidence of biphasic reactions in various studies are likely a major contributor to differing results, ranging from a 0.5 percent to 20 percent incidence rate. This makes comparisons of data across studies problematic. Previous guidelines have advocated the monitoring of patients post-anaphylaxis, with recommended durations varying between 4 and 24 hours. This is likely a testament to the uncertainty in the literature. Hence there is no compelling, reliable, valid, medical and scientific evidence upon which to base a Table time frame for biphasic anaphylactic reactions. HHS recognizes the occurrence of biphasic anaphylactic reactions in a minority of cases. Therefore, the Program will consider a claim for anaphylaxis occurring after the 4-hour time frame leading to a serious injury or death on a case-by-case basis as a non-Table claim.

#### 2. Pandemic Influenza Intranasal Vaccines

*Comment:* A commenter asked if a child would be eligible to receive compensation if he/she is injured from the intranasal vaccine, which was administered because the child was advised by his/her doctor to have the intranasal vaccine, even if perhaps, the child would have been more suited for the vaccine injection.

*Response:* Under the CICIP, any person who meets the appropriate declaration’s definition of covered population, is administered or used a covered countermeasure in accordance with the terms of that declaration (or in good faith belief of such), and is seriously injured as a direct result of the countermeasure, may be eligible for CICIP benefits.

#### 3. Antiviral Usage in Individuals Younger Than 2 Years of Age

*Comment:* A commenter was concerned that the guidelines for administration of Tamiflu (oseltamivir), Relenza (zanamivir), and peramivir for infants are not uniform. The commenter stated that the Food and Drug Administration has approved Tamiflu for children as young as 2 weeks of age but that the Centers for Disease Control and Prevention (CDC) recommends Tamiflu, through its safety profile, for treatment of both term and preterm infants from birth, as benefits for therapy are likely to outweigh possible risks of treatment. The commenter suggested that this rule establish the minimum age for administration of these countermeasures to children so that children are not denied compensation because of conflicting

policy recommendations about the appropriate administration of these antiviral medications.

*Response:* The CICIP is not authorized to establish age ranges for the administration of any drug, and therefore, cannot do so through this rule, as suggested by the commenter. The Program can only provide benefits to the population of individuals set forth in the applicable Secretarial declaration.

#### 4. Incorporation of Children and Infants in Overall Guidelines

*Comment:* A commenter made the statement that his organization “firmly believes that the Table should better incorporate the needs of children.” The commenter wants HHS and HRSA to ensure that children are being considered in all aspects of the proposed countermeasures, as well as in this Table.

*Response:* As indicated above, Secretarial declarations describe the covered countermeasures and the covered population. Under the CICIP, any person who meets the definition of the covered population in the relevant declaration, who receives or uses a covered countermeasure in accordance with the terms of that declaration (or in good faith belief of such), and is seriously injured as a direct result of the countermeasure may be eligible for CICIP benefits.

#### 5. Guillain-Barré Syndrome

*Comment:* One commenter was concerned that the description of Guillain-Barré Syndrome (GBS) is incomplete because it does not address the fact that GBS affects the peripheral nervous system.

*Response:* HHS respectfully disagrees with this comment. The description of GBS as stated in the NPRM and final rule is complete and explicitly addresses that GBS affects the peripheral nervous system. It is an acute monophasic peripheral neuropathy that currently is known to encompass a spectrum of four clinicopathological subtypes described in the Qualifications and Aids to Interpretation section of the Table. GBS may manifest with weakness, abnormal sensations, and/or abnormality in the autonomic (involuntary) nervous system.

*Comment:* A commenter was concerned that this allegedly incomplete description of GBS may make it difficult for requesters to prove injuries such as Miller-Fisher Syndrome or other variants of GBS that include attacks that lead to organ damage. Another commenter noted that the variants of GBS should be considered.

*Response:* HHS respectfully disagrees with the comments that the variants of GBS were not considered. The Table, including its Qualifications and Aids to Interpretation, explicitly addresses how variants of GBS, including Miller-Fisher Syndrome, can meet the Table requirements. GBS may present as one of a spectrum of four clinicopathological subtypes or variants. The most common type in North America and Europe, comprising more than 90 percent of cases, is acute inflammatory demyelinating polyneuropathy (AIDP), which has the pathologic and electrodiagnostic features of focal demyelination of motor and sensory peripheral nerves and roots.

Another subtype called acute motor axonal neuropathy (AMAN) is generally seen in other parts of the world and is predominated by axonal damage that primarily affects motor nerves. AMAN lacks features of demyelination. The axon is a portion of the nerve cell that transmits nerve impulses away from the nerve cell body. Another less common subtype of GBS includes acute motor and sensory neuropathy (AMSAN), which is an axonal form of GBS that is similar to AMAN, but also affects the axons of sensory nerves and roots.

According to the Brighton Collaboration, Fisher Syndrome (FS), also known as Miller-Fisher Syndrome, is a subtype of GBS characterized by ataxia, areflexia, and ophthalmoplegia, and overlap between FS and GBS may be seen with limb weakness.

GBS is proposed for inclusion on the Table because it is a serious physical injury, and the fact that it may be directly caused by the use of the monovalent 2009 H1N1 influenza vaccine (hereafter 2009 H1N1 vaccine) is supported by compelling, reliable, valid, medical and scientific evidence. Further, GBS is characterized by various degrees of weakness, sensory abnormality and autonomic dysfunction due to damage to peripheral nerves and nerve roots. These variants or subtypes of GBS were addressed fully in the NPRM and are adopted in the final rule.

Furthermore, as explained above, the description of GBS as stated in the NPRM, and adopted in this final rule, is complete. To the extent that one comment suggested that organ damage should be included as a Table injury, HHS respectfully disagrees. Although demyelination of peripheral nerves or axonal damage can lead to disruption of organ function, they do not lead directly to organ damage. At this time, there is no compelling, reliable, valid, medical and scientific evidence to support including organ damage on the Table.

*Comment:* A commenter was concerned that the 3- to 42-day window of GBS onset is unreasonable because some cases of GBS have been reported to have an onset outside of this interval. The commenter cited the article, “Chart-Confirmed Guillain-Barré Syndrome After 2009 H1N1 Influenza Vaccination Among the Medicare Population, 2009–2010, *American Journal of Epidemiology*, (2014), 179(5): 660.”

*Response:* HHS respectfully disagrees with this comment. The study that was cited by the commenter and published in the *American Journal of Epidemiology* looked at the risk of GBS development within 119 days of vaccination. The researchers found a slightly increased statistically significant risk of GBS only within the 6-week period after 2009 H1N1 vaccination when compared with the post-vaccination control period.

As stated in the NPRM, multiple studies performed to monitor the safety of 2009 H1N1 vaccine provide evidence that demonstrates a small statistically significant increased risk of GBS in the 6 weeks following administration of the 2009 H1N1 vaccine.<sup>5</sup> Additionally, a meta-analysis was performed of the Emerging Infections Program, the Vaccine Safety Datalink, and the Post-Licensure Rapid Immunization Safety Monitoring System data, together with additional data from safety surveillance studies performed by the Centers for Medicare & Medicaid Services, the Department of Defense, and the Department of Veterans Affairs, which analyzed data from 23 million vaccinated people. The meta-analysis found that the 2009 H1N1 inactivated vaccine was associated with a small increased risk of GBS within 6 weeks of vaccination.

The symptoms of GBS do not develop immediately after exposure to the causative agent. The immune system requires a specified time to complete the steps leading to nerve injury and dysfunction and the early symptoms of GBS. A minimum of 3 days would be necessary from the time of exposure and immune system stimulation to the first symptoms of GBS. Therefore, onset of

<sup>5</sup> Lawrence B. Schonberger, *et al.*, “Guillain-Barré Syndrome Following Vaccination in the National Influenza Immunization Program, United States, 1976–1977, *American Journal of Epidemiology*, 25 Apr. 1979, 118; IOM, “Immunization Safety Review: Influenza Vaccines and Neurological Complications,” (Washington, DC: The National Academies Press, 2004) 25; Sharon K. Greene, *et al.*, “Risk of Confirmed Guillain-Barré Syndrome Following Receipt of Monovalent Inactivated Influenza A (H1N1) and Seasonal Influenza Vaccines in the Vaccine Safety Datalink Project, 2009–2010; and *American Journal of Epidemiology*, Jun. 1, 2012, 1100.

GBS within less than 72 hours or 3 days of immunization would be strong evidence that the vaccine is not the causative agent.<sup>6</sup>

HHS believes that the *American Journal of Epidemiology* study cited by the commenter is consistent with the other studies referenced above in indicating that the window of onset for GBS on the Table is appropriate based on current compelling, reliable, valid medical and scientific evidence.

#### 6. Comparison of CICP Table Injuries to the VICP Table Injuries

*Comment:* A commenter compared the CICP Table injuries with the National Vaccine Injury Compensation Program (VICP) Table injuries because the 2009 H1N1 strain has been included in the seasonal influenza vaccine since 2010 and questioned why the Tables are different.

*Response:* The VICP and CICP are different programs authorized by two distinct federal statutes. The VICP covers certain vaccines that are recommended by the CDC for routine administration to children and are subject to an excise tax, whereas the CICP covers certain countermeasures, including pandemic influenza vaccines, as identified in Secretarial declarations. Accordingly, the VICP covers seasonal influenza vaccines, such as the quadravalent influenza vaccine, and the CICP covers pandemic vaccines, such as the 2009 monovalent H1N1 vaccine. Presently, the VICP’s Table does not include any associated injuries for seasonal influenza vaccines.

#### 7. West Nile Virus (WNV)

*Comment:* A commenter stated “I strongly believe it is beneficial to have an injury compensation program implemented for those who have been extremely touched by West Nile and other harmful influenzas . . .” HHS’ understanding is that the commenter wants a compensation program established that would cover the adverse effects of the underlying pandemic or epidemic condition itself.

*Response:* Injuries from the WNV or any influenza infection are not covered by the CICP. As stated in the NPRM, only serious injuries directly caused by the administration or use of the covered countermeasure—not injuries that result from the disease (or health condition or threat to health) itself—are covered injuries. For more information, see 42 CFR 110.20(d).

<sup>6</sup> *Peripheral Neuropathy*, 4th edition, 2005; Dyck & Thomas, eds. 626.

#### 8. Notification to Individuals Who Have Been Deemed Ineligible for Compensation

*Comment:* A commenter suggested that HHS inform all individuals who have previously applied but were deemed ineligible for compensation that they can reapply for compensation.

*Response:* HHS agrees with the commenter. Previous requesters, who were deemed ineligible for compensation, will be notified of the new Table by its publication in the **Federal Register**. The published final rule also will be posted on the CICP Web site at [www.hrsa.gov/cicp](http://www.hrsa.gov/cicp). Such requesters may have an additional 1-year filing deadline from the effective date of the Table amendment or publication. This additional filing deadline will apply only if the new or amended Table enables a requester, who could not establish a Table injury before the new or amended Table, to establish a covered injury.<sup>7</sup>

#### IV. Regulatory Impact Analysis

HHS has examined the impact of this rulemaking as required by Executive Order 12866 on Regulatory Planning and Review, Executive Order 13563 on Improving Regulation and Regulatory Review, the Congressional Review Act (5 U.S.C. 804(2)), the Regulatory Flexibility Act (RFA), section 202 of the Unfunded Mandates Reform Act of 1995, section 654(c) of the Treasury and General Government Appropriations Act of 1999, and Executive Order 13132 on Federalism.

Executive Order 12866 requires that all regulations reflect consideration of alternatives, costs, benefits, incentives, equity, and available information. Regulations must meet certain standards, such as avoiding an unnecessary burden. Regulations that are “significant” because of cost, adverse effects on the economy, inconsistency with other agency actions, effects on the budget, or novel legal or policy issues, require special analysis. In 2011, President Obama supplemented and reaffirmed Executive Order 12866. This rulemaking is not being treated as a significant regulatory action under section 3(f) of Executive Order 12866. Accordingly, the final rule has not been reviewed by the Office of Management and Budget.

Executive Order 13563 provides that, to the extent feasible and permitted by law, the public must be given a meaningful opportunity to comment on any proposed regulations, with at least a 60-day comment period. In addition,

to the extent feasible and permitted by law, agencies must provide timely on-line access to both proposed and final rules of the rulemaking docket on Regulations.gov, including relevant scientific and technical findings, in an open format that can be searched and downloaded. Federal agencies must consider approaches to maintain the freedom of choice and flexibility, including disclosure of relevant information to the public. Regulations must be guided by objective scientific evidence, easy to understand, consistent, and written in plain language. Furthermore, Federal agencies must attempt to coordinate, simplify, and harmonize regulations to reduce costs and promote certainty for the public.

In this final rule, the Secretary specifies a Table identifying serious physical injuries that shall be presumed to result from the administration or use of the covered countermeasures, and the time interval in which the onset of the first symptom or manifestation of each such serious physical injury must manifest in order for such presumption to apply. The Secretary is also specifying Table definitions and requirements. This final rule would have the effect of affording certain persons a presumption that particular serious physical injuries were sustained as the result of the administration or use of covered pandemic influenza countermeasures. The Table will establish a presumption of causation and relieve requesters of the burden of demonstrating causation for covered injuries listed on the Table. However, this presumption is rebuttable based on the Secretary’s review of the evidence. In addition, this Table may afford some requesters a new filing deadline.

Other than showing that a serious physical injury or death directly resulted from an injury included on the Table, individuals may, in the alternative, be eligible for compensation if they otherwise meet the CICP’s requirements and can show a causation-in-fact relationship between an injury or death and a covered countermeasure. This rule is based upon legal authority.

Because any resources required to implement the regulatory requirements imposed by the Program are not required by virtue of the establishment of a Table, and because the Secretary conducted an independent analysis concerning any burdens associated with the implementation of the Program when the Secretary published the companion regulation setting forth the Program’s administrative

implementation,<sup>8</sup> the Secretary has determined that no resources are required to implement the provisions included in this final rule. Therefore, in accordance with the Regulatory Flexibility Act of 1980 (RFA) and the Small Business Regulatory Enforcement Fairness Act of 1996, which amended the RFA, the Secretary certifies that this rule will not have a significant impact on a substantial number of small entities.

The Secretary has also determined that this rule does not meet the criteria for a major rule as defined by Executive Order 12866 and would have no major effect on the economy or Federal expenditures. The Secretary has determined that this rule is not a “major rule” within the meaning of the statute providing for Congressional Review of Agency Rulemaking, 5 U.S.C. 801. Similarly, it will not have effects on State, local, and tribal governments or on the private sector such as to require consultation under the Unfunded Mandates Reform Act of 1995. This final rule comports with the 2011 supplemental requirements.

#### Unfunded Mandates Reform Act of 1995

The Secretary has determined that this final rule will not have effects on State, local, and tribal governments or on the private sector such as to require consultation under the Unfunded Mandates Reform Act of 1995.

#### Federalism Impact Statement

The Secretary has also reviewed this final rule in accordance with Executive Order 13132 regarding federalism, and has determined that it does not have “federalism implications.” This final rule will not “have substantial direct effects on the States, or on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.”

#### Impact on Family Well-Being

This final rule will not adversely affect the following elements of family well-being: family safety, family stability, marital commitment; parental rights in the education, nurture, and supervision of their children; family functioning, disposable income, or poverty; or the behavior and personal responsibility of youth, as determined under section 654(c) of the Treasury and General Government Appropriations Act of 1999. In fact, this rule may have a positive impact on the disposable

<sup>7</sup> 42 CFR 110.42(f).

<sup>8</sup> 75 FR 64955.



income and poverty elements of family well-being to the extent that injured persons or their families may receive medical, lost employment income, and/or death benefits paid under this part without imposing a corresponding burden on them.

**Paperwork Reduction Act of 1995, as Amended**

This final rule has no information collection requirements.

**List of Subjects in 42 CFR Part 110**

Anaphylaxis, Anticoagulation, Antiviral, Avian, Benefits, Biologics, Bleeding, Bursitis, Compensation, Countermeasure, Declaration, Deltoid, Diagnostics, Device, Eligibility, Extra-Corporeal Membrane Oxygenation (ECMO), Fisher Syndrome, Guillain-Barré Syndrome, 2009 H1N1, Influenza,

Injury Table, Immunization, Oseltamivir, Pandemic, Peramivir, Public Readiness and Emergency Preparedness Act (PREP Act), Radiation syndrome, Respiratory protection, Relenza, Respirator, Respirator support, Tamiflu, Tracheal Stenosis, Vaccine, Vasovagal Syncope, Ventilator, Ventilator-Associated Pneumonia and Tracheobronchitis, Ventilator-Induced Lung Injury, Zanamivir.

Dated: July 24, 2015.

**James Macrae,**

*Acting Administrator, Health Resources and Services Administration.*

Approved: July 30, 2015.

**Sylvia M. Burwell,**

*Secretary.*

Therefore, for the reasons stated, the Department of Health and Human

Services amends 42 CFR part 110 as follows:

**PART 110—COUNTERMEASURES INJURY COMPENSATION PROGRAM**

■ 1. The authority citation for part 110 continues to read as follows:

**Authority:** 42 U.S.C. 247d–6e.

■ 2. Add § 110.100 to subpart K to read as follows:

**§ 110.100 Injury Tables.**

(a) *Pandemic influenza countermeasures injury table.*

Covered countermeasures under Secretarial declarations	Serious physical injury (illness, disability, injury, or condition) <sup>1</sup>	Time interval (for first symptom or manifestation of onset of injury after administration or use of covered countermeasure, unless otherwise specified)
I. Pandemic influenza vaccines administered by needle into or through the skin.	A. Anaphylaxis ..... B. Deltoid Bursitis ..... C. Vasovagal Syncope .....	A. 0–4 hours. B. 0–48 hours. C. 0–1 hour.
II. Pandemic influenza intranasal vaccines .....	A. Anaphylaxis .....	A. 0–4 hours.
III. Pandemic influenza 2009 H1N1 vaccine .....	A. Guillain-Barré Syndrome .....	A. 3–42 days (not less than 72 hours and not more than 42 days).
IV. Oseltamivir Phosphate (Tamiflu) when administered or used for pandemic influenza.	A. Anaphylaxis .....	A. 0–4 hours.
V. Zanamivir (Relenza) when administered or used for pandemic influenza.	A. Anaphylaxis .....	A. 0–4 hours.
VI. Peramivir when administered or used for 2009 H1N1 influenza.	A. Anaphylaxis .....	A. 0–4 hours.
VII. Pandemic influenza personal respiratory protection devices.	A. No condition covered <sup>2</sup> .....	A. Not applicable.
VIII. Pandemic influenza respiratory support devices.	A. Postintubation Tracheal Stenosis .....  B. Ventilator-Associated Pneumonia and Ventilator-Associated Tracheobronchitis.  C. Ventilator-Induced Lung Injury .....	A. 2–42 days (not less than 48 hours and not more than 42 days) after extubation (removal of a tracheostomy or endotracheal tube). B. More than 48 hours after intubation (placement of an endotracheal or tracheostomy tube) and up to 48 hours after extubation (removal of the tube). C. Throughout the time of intubation (breathing through an endotracheal or tracheostomy tube) and up to 48 hours after extubation (removal of the tube).
IX. Pandemic influenza respiratory support device: Extra-corporeal membrane oxygenation (ECMO).	A. Bleeding Events .....	A. Throughout the time of anticoagulation treatment for ECMO therapy, including the time needed to clear the effect of the anticoagulant treatment from the body.
X. Pandemic influenza diagnostic testing devices.	A. No condition covered .....	A. Not applicable.

<sup>1</sup> Serious physical injury as defined in 42 CFR 110.3(z). Only injuries that warranted hospitalization (whether or not the person was actually hospitalized) or injuries that led to a significant loss of function or disability will be considered serious physical injuries.

<sup>2</sup> The use of “No condition covered” in the Table reflects that the Secretary at this time does not find compelling, reliable, valid, medical and scientific evidence to support that any serious injury is presumed to be caused by the associated covered countermeasure. For injuries alleged to be due to covered countermeasures for which there is no associated Table injury, requesters must demonstrate that the injury occurred as the direct result of the administration or use of the covered countermeasure. See 42 CFR 110.20(b), (c).

(b) *Qualifications and aids to interpretation (table definitions and requirements).* The following definitions and requirements shall apply to the

Table set forth in this subpart and only apply for purposes of this subpart.

(1) *Anaphylaxis.* Anaphylaxis is an acute, severe, and potentially lethal systemic reaction that occurs as a single

discrete event with simultaneous involvement of two or more organ systems. Most cases resolve without *sequelae*. Signs and symptoms begin minutes to a few hours after exposure.

Death, if it occurs, usually results from airway obstruction caused by laryngeal edema or bronchospasm and may be associated with cardiovascular collapse. Other significant clinical signs and symptoms may include the following: Cyanosis, hypotension, bradycardia, tachycardia, arrhythmia, edema of the pharynx and/or trachea and/or larynx with stridor and dyspnea. There are no specific pathological findings to confirm a diagnosis of anaphylaxis.

(2) *Deltoid bursitis*. Deltoid bursitis is an inflammation of the bursa that lies beneath the deltoid muscle and between the acromion process and the rotator cuff. Subdeltoid bursitis manifests with pain in the lateral aspect of the shoulder similar to rotator cuff tendonitis. The presence of tenderness on direct palpation beneath the acromion process distinguishes this bursitis from rotator cuff tendonitis. Similar to tendonitis, isolated bursitis will have full passive range of motion. Other causes of bursitis such as trauma (other than from vaccination), metabolic disorders, and systemic diseases such as rheumatoid arthritis, dialysis, and infection will not be considered Table injuries. This list is not exhaustive. The deltoid bursitis must occur in the same shoulder that received the pandemic influenza vaccine.

(3) *Vasovagal syncope*. Vasovagal syncope (also sometimes called neurocardiogenic syncope) means loss of consciousness (fainting) and loss of postural tone caused by a transient decrease in blood flow to the brain occurring after the administration of an injected countermeasure. Vasovagal syncope is usually a benign condition but may result in falling and injury with significant *sequelae*. Vasovagal syncope may be preceded by symptoms such as nausea, lightheadedness, diaphoresis, and/or pallor. Vasovagal syncope may be associated with transient seizure-like activity, but recovery of orientation and consciousness generally occurs simultaneously. Loss of consciousness resulting from the following conditions will not be considered vasovagal syncope: Organic heart disease; cardiac arrhythmias; transient ischemic attacks; hyperventilation; metabolic conditions; neurological conditions; psychiatric conditions; seizures; trauma; and situational as can occur with urination, defecation, or cough. This list is not complete. Episodes of recurrent syncope occurring after the applicable time period are not considered to be *sequelae* of an episode of syncope meeting the Table requirements.

(4) *Guillain-Barré Syndrome (GBS)*. (i) GBS is an acute monophasic peripheral neuropathy that currently is known to

encompass a spectrum of four clinicopathological subtypes described below. For each subtype of GBS, the interval between the first appearance of symptoms and the nadir of weakness is between 12 hours and 28 days. This is followed in all subtypes by a clinical plateau with stabilization at the nadir of symptoms, or subsequent improvement without significant relapse. Death may occur without a clinical plateau. Treatment related fluctuations in all subtypes of GBS can occur within 9 weeks of GBS symptom onset and recurrence of symptoms after this time frame would not be consistent with GBS.

(ii) The most common subtype in North America and Europe, comprising more than 90 percent of cases, is acute inflammatory demyelinating polyneuropathy (AIDP) which has the pathologic and electrodiagnostic features of focal demyelination of motor and sensory peripheral nerves and nerve roots. Another subtype called acute motor axonal neuropathy (AMAN) is generally seen in other parts of the world and is predominated by axonal damage that primarily affects motor nerves. AMAN lacks features of demyelination. Another less common subtype of GBS includes acute motor and sensory neuropathy (AMSAN), which is an axonal form of GBS that is similar to AMAN, but also affects the sensory nerves and roots. AIDP, AMAN, and AMSAN are typically characterized by symmetric motor flaccid weakness, sensory abnormalities, and/or autonomic dysfunction caused by autoimmune damage to peripheral nerves and nerve roots. The diagnosis of AIDP, AMAN, and AMSAN requires bilateral flaccid limb weakness and decreased or absent deep tendon reflexes in weak limbs; a monophasic illness pattern; an interval between onset and nadir of weakness between 12 hours and 28 days; subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse); and, the absence of an identified more likely alternative diagnosis. Death may occur without a clinical plateau.

(iii) Fisher syndrome (FS), also known as Miller-Fisher Syndrome, is a subtype of GBS characterized by ataxia, areflexia, and ophthalmoplegia, and overlap between FS and AIDP may be seen with limb weakness. The diagnosis of FS requires bilateral ophthalmoparesis; bilateral reduced or absent tendon reflexes; ataxia; the absence of limb weakness (the presence of limb weakness suggests a diagnosis of AIDP); a monophasic illness pattern; an

interval between onset and nadir of weakness between 12 hours and 28 days; subsequent clinical plateau (the clinical plateau leads to either stabilization at the nadir of symptoms, or subsequent improvement without significant relapse); no alteration in consciousness; no corticospinal track signs; and, the absence of an identified more likely alternative diagnosis. Death may occur without a clinical plateau.

(iv) Evidence that is supportive, but not required, of a diagnosis of all subtypes of GBS includes electrophysiologic findings consistent with GBS or an elevation of cerebral spinal fluid (CSF) protein with a total CSF white blood cell count below 50 cells per microliter. The results of both CSF and electrophysiologic studies are frequently normal in the first week of illness in otherwise typical cases of GBS.

(v) For GBS to qualify as a Table injury there must not be a more likely alternative diagnosis for the weakness. Exclusionary criteria for the diagnosis of all subtypes of GBS include the ultimate diagnosis of any of the following conditions: Chronic immune demyelinating polyradiculopathy (“CIDP”), carcinomatous meningitis, brain stem encephalitis (other than Bickerstaff brainstem encephalitis), myelitis, spinal cord infarct, spinal cord compression, anterior horn cell diseases such as polio or West Nile virus infection, subacute inflammatory demyelinating polyradiculoneuropathy, multiple sclerosis, cauda equina compression, metabolic conditions such as hypermagnesemia or hypophosphatemia, tick paralysis, heavy metal toxicity (such as arsenic, gold, or thallium), drug-induced neuropathy (such as vincristine, platinum compounds, or nitrofurantoin), porphyria, critical illness neuropathy, vasculitis, diphtheria, myasthenia gravis, organophosphate poisoning, botulism, critical illness myopathy, polymyositis, dermatomyositis, hypokalemia, or hyperkalemia. The above list is not exhaustive.

(5) *Tracheal stenosis*. (i) Postintubation tracheal stenosis means an iatrogenic (caused by medical treatment) and symptomatic stricture of the airway (narrowing of the windpipe) resulting from:

(A) Trauma or necrosis from an endotracheal tube; or

(B) Stomal injury from a tracheostomy; or

(C) A combination of the two.

(ii) Tracheal stenosis or narrowing due to tumors (malignant or benign), infections of the trachea (such as

tuberculosis, fungal diseases), radiotherapy, tracheal surgery, trauma, congenital, and inflammatory or autoimmune diseases will not be considered post-intubation tracheal stenosis. Post-intubation tracheal stenosis requires either tracheostomy with placement of a tracheostomy tube or endotracheal intubation. Diagnosis requires symptoms of upper airway obstruction such as stridor (inspiratory wheeze) or exertional dyspnea (increased shortness of breath with exertion), and positive radiologic studies showing abnormal narrowing of the trachea or bronchoscopic evaluation that demonstrates abnormal narrowing.

(6) *Ventilator-Associated Pneumonia (VAP) and Ventilator-Associated Tracheobronchitis (VAT)*. (i) VAP is defined as an iatrogenic pneumonia caused by the medical treatment of mechanical ventilation. Similarly, VAT is an iatrogenic infection of the trachea and/or bronchi caused by mechanical ventilation. The initial manifestation of VAP and VAT must occur more than 48 hours after intubation (placement of the breathing tube) and up to 48 hours after extubation (removal of the breathing tube). VAP will be considered to be present when the patient demonstrates a new or progressive radiographic infiltrate that is in the lungs and consistent with pneumonia, fever, leukocytosis (increased white blood cell count) or leucopenia (decreased white blood cell count), purulent (containing pus) tracheal secretions from a tracheal aspirate, and a positive lower respiratory tract culture. The positive lower respiratory tract culture is a diagnostic requirement only if there has not been a change in antibiotics in the 72 hours prior to collection of the culture. In addition, a tracheal aspirate that does not demonstrate bacteria or inflammatory cells in a patient without a change in antibiotics in the previous 72 hours is unlikely to be VAP and shall not be considered a condition set forth in the Table.

(ii) VAT will be considered to be present when the patient demonstrates fever, leukocytosis or leucopenia, purulent tracheal secretions, and a positive tracheal aspirate culture in the absence of a change of antibiotics within the 72 hours prior to culture. Tracheal colonization with microorganisms is common in intubated patients, but in the absence of clinical findings is not a sign of VAT.

(7) *Ventilator-Induced Lung Injury (VILI)*. VILI results from mechanical trauma such as volutrauma leading to rupture of alveoli (air sacs in the lungs where oxygen and carbon dioxide are exchanged with the blood) with

subsequent abnormal leakage of air. VILI manifests as iatrogenic pneumothorax (abnormal air from alveolar rupture in the pleural space), pneumomediastinum (abnormal air from alveolar rupture in the mediastinum (middle part of the chest between the lungs)), pulmonary interstitial emphysema (abnormal air in the lung interstitial space between the alveoli), subpleural air cysts (an extreme form of pulmonary emphysema where the abnormal air in the interstitial space has pooled into larger pockets), subcutaneous emphysema (abnormal air from alveolar rupture that has dissected into the skin), pneumopericardium (abnormal air from alveolar rupture that has traveled to the pericardium (covering of the heart)), pneumoperitoneum (abnormal air from alveolar rupture that has moved into the abdominal space), or systemic air embolism (abnormal air from alveolar rupture that has moved into the blood). To qualify as Table injuries, these manifestations must occur in patients who are being mechanically ventilated at the time of initial manifestation of the VILI.

(8) *Bleeding events*. Bleeding events are defined as excessive or abnormal bleeding in patients who are under the pharmacologic effects of anticoagulant therapy provided for extracorporeal membrane oxygenation (ECMO) treatment.

(c) *Covered countermeasures*. The Office of the Secretary publishes Secretarial declarations on the following covered countermeasures in the **Federal Register**:

- (1) Pandemic influenza vaccines;
- (2) Tamiflu;
- (3) Relenza;
- (4) Peramivir;
- (5) Personal respiratory protection devices;
- (6) Respiratory support devices;
- (7) Diagnostic testing devices.

[FR Doc. 2015-19228 Filed 8-6-15; 8:45 am]

**BILLING CODE 4165-15-P**

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

#### 50 CFR Part 17

[Docket No. FWS-R2-ES-2014-0008; 4500030113]

RIN 1018-BA32

#### Endangered and Threatened Wildlife and Plants; 4(d) Rule for the Georgetown Salamander

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Final rule.

**SUMMARY:** We, the U.S. Fish and Wildlife Service, finalize a rule under authority of section 4(d) of the Endangered Species Act of 1973, as amended, that provides measures that are necessary and advisable to provide for the conservation of the Georgetown salamander (*Eurycea naufragia*), a species that occurs in Texas. This final 4(d) rule will provide the Service the opportunity to work cooperatively, in partnership with the local community and State agencies, on conservation of the Georgetown salamander and the ecosystems on which it depends.

This 4(d) rule is necessary and advisable to provide for the conservation of the Georgetown salamander because it strengthens water quality protection measures throughout the species' range, allows for consideration of new information to optimize conservation measures, and furthers conservation partnerships that can be leveraged to improve the status of the Georgetown salamander.

**DATES:** This rule is effective September 8, 2015.

**ADDRESSES:** This final rule, the final environmental assessment, and a list of references cited are available on the Internet at <http://www.regulations.gov> under Docket No. FWS-R2-ES-2014-0008, or by mail from the Austin Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

Comments and materials we received are available for public inspection at <http://www.regulations.gov>. All of the comments, materials, and documentation that we considered in this rulemaking are available by appointment, during normal business hours at the Austin Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

**FOR FURTHER INFORMATION CONTACT:** Adam Zerrenner, Field Supervisor, U.S. Fish and Wildlife Service, Austin Ecological Services Field Office, 10711 Burnet Rd., Suite 200, Austin, TX 78758; telephone 512-490-0057; facsimile 512-490-0974. Persons who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 800-877-8339.

#### SUPPLEMENTARY INFORMATION:

##### Previous Federal Actions

On August 22, 2012, we published a proposed rule in the **Federal Register** (77 FR 50768) to list the Georgetown salamander (*Eurycea naufragia*), Salado salamander (*Eurycea chisholmensis*), Jollyville Plateau salamander (*Eurycea*

*tonkawae*), and Austin blind salamander (*Eurycea waterlooensis*) as endangered species and to designate critical habitat for these species under the Endangered Species Act of 1973, as amended (Act) (16 U.S.C. 1533 *et seq.*). The Federal lists of endangered and threatened species and other protective regulations for listed species under the Act are in part 17 of title 50 of the Code of Federal Regulations (CFR). On February 24, 2014, we published a final determination to list the Georgetown salamander and the Salado salamander as threatened species under the Act (79 FR 10236) and a proposed rule under section 4(d) of the Act (a proposed 4(d) rule) for the Georgetown salamander (79 FR 10077) at 50 CFR 17.43. On April 9, 2015, we revised the proposed 4(d) rule for the Georgetown salamander and reopened the public comment period for 30 days, ending May 11, 2015 (80 FR 19050). Please see the final listing determination (79 FR 10236) for additional information concerning previous Federal actions for the Georgetown salamander.

### Background

The Georgetown salamander is entirely aquatic and depends on water from the Edwards Aquifer in sufficient quantity and quality to meet the species' life-history requirements for survival, growth, and reproduction. Degradation of habitat, in the form of reduced water quality and quantity and disturbance of spring sites, is the main threat to this species. For more information on the Georgetown salamander and its habitat, please refer to the February 24, 2014, final listing determination (79 FR 10236).

The Act does not specify particular prohibitions, or exceptions to those prohibitions, for threatened species. Instead, under section 4(d) of the Act, the Secretary of the Interior has the discretion to issue such regulations as she deems necessary and advisable to provide for the conservation of such species. The Secretary also has the discretion to prohibit by regulation, with respect to any threatened wildlife species, any act prohibited under section 9(a)(1) of the Act. Exercising this discretion, the Service developed general prohibitions (50 CFR 17.31) and exceptions to those prohibitions (50 CFR 17.32) under the Act that apply to most threatened wildlife species. Alternately, for other threatened species, under the authority of section 4(d) of the Act, the Service may develop specific prohibitions and exceptions that are tailored to the specific conservation needs of the species. In such cases, some of the prohibitions and

authorizations under 50 CFR 17.31 and 17.32 may be appropriate for the species and incorporated into a rule under section 4(d) of the Act. However, these rules, known as 4(d) rules, will also include provisions that are tailored to the specific conservation needs of the threatened species and may be more or less restrictive than the general provisions at 50 CFR 17.31.

### Summary of Changes From the Revised Proposed Rule

Based on information we received in both public comment periods on the proposed 4(d) rule (see Summary of Comments and Recommendations), we revised the provisions of the 4(d) rule to provide greater clarity around the activities that are covered and not covered by this rule.

### Provisions of the 4(d) Rule for the Georgetown Salamander

Under section 4(d) of the Act, the Secretary may publish a rule that modifies the standard protections for threatened species and that contains prohibitions tailored to the conservation of the species and that are determined to be necessary and advisable. Under this 4(d) rule, the Service provides that all of the prohibitions under 50 CFR 17.31 and 17.32 are necessary and advisable and, therefore, apply to the Georgetown salamander, except as noted below. This 4(d) rule will not remove or alter in any way the consultation requirements under section 7 of the Act.

#### *City of Georgetown Unified Development Code (UDC)*

For activities outside of habitat occupied by the Georgetown salamander, the final 4(d) rule provides that take of Georgetown salamanders that is incidental to regulated activities (as defined in title 30, Texas Administrative Code, section 213.3(28)) that are conducted consistent with the water quality regulations contained in chapter 11.07 of the City of Georgetown Unified Development Code (UDC 11.07) (<https://udc.georgetown.org/>) will not be prohibited under the Act. The water quality regulations in UDC 11.07 were finalized on February 24, 2015. Chapter 11.07 of the UDC describes stream and spring buffers, water quality best management practices, and geologic assessments that are required for property development within the Northern Edwards Aquifer Recharge Zone and the City of Georgetown.

"Regulated activities" are defined in title 30, Texas Administrative Code, section 213.3(28) as any construction-related or post-construction activities on

the Recharge Zone of the Edwards Aquifer having the potential for polluting the Edwards Aquifer and hydrologically connected surface streams. "Regulated activities" do not include the clearing of vegetation without soil disturbance, agricultural activities, oil and gas activities, routine maintenance of existing structures that does not involve additional site disturbance, and construction of single-family residences on lots larger than 2 hectares (ha) (5 acres (ac)). More specific details on spring and stream buffers can be found in sections 11.07.003A. and B. of the UDC.

When a property owner submits a development application for a regulated activity on a tract of land located over the Edwards Aquifer Recharge Zone, that individual is required to submit a geologic assessment to the City of Georgetown. The geologic assessment identifies and describes all springs and streams on any subject property, and the UDC establishes buffer zones around identified springs and streams. For springs, the buffer encompasses 50 meters (m) (164 feet (ft)) extending from the approximate center of the spring outlet that is identified in a geologic assessment. For streams, the boundaries of the buffer must coincide with either the boundaries of the Federal Emergency Management Agency (FEMA) one percent floodplain or a calculated one percent floodplain, whichever is smaller. In the absence of a FEMA floodplain or calculated one percent floodplain, these stream buffers may be no smaller than 61 m (200 ft) wide with at least 23 m (75 ft) from the centerline of the stream. Section 11.07.003 of the UDC states that no "regulated activities" may be conducted within the spring and stream buffers.

In addition to the establishment of these spring and stream buffers, the UDC outlines water quality best management practices designed to minimize sediment runoff, increase the removal of total suspended solids, prevent an increase in flow rates, and ensure spill containment for new or expanded roadways. These regulations in chapter 11.07 of the UDC are designed to reduce water quality degradation that may occur as a result of development. By reducing further water quality degradation that may result from development, these protective measures are also expected to reduce degradation to Georgetown salamander habitat that may occur.

The UDC 11.07 also outlines exemptions from the requirement to prepare a geologic assessment, the process by which a landowner may request a variance to the spring and

stream buffer requirements, and exemptions to the spring and stream buffer requirements of section 11.07.003. Small (less than 2-ha (5-ac)) single-family and two-family residential developments are exempt from submitting a geologic assessment; however, these developments are required to implement UDC water quality measures. Landowners may request to the City of Georgetown a variance from the spring and stream buffer requirements in UDC 11.07 if: The variance is not contrary to the public interest; due to special conditions, a literal enforcement of the ordinance would result in unnecessary hardship; and the spirit of the ordinance is observed and substantial justice is done, in accordance with UDC section 2.05.010.A.6. These variances and exemptions apply only to sites not occupied by Georgetown salamanders.

Properties with a site occupied by the Georgetown salamander are exempt from the spring and stream buffer requirements in chapter 11.07. Rather, UDC Appendix A outlines conservation measures (which are voluntary under the UDC) to be implemented when undertaking regulated activities that occur on a tract of land with an occupied site or within 984 ft (300 m) of an occupied site. An "occupied site" is defined in the UDC as any spring identified as a critical habitat unit by the Service for the Georgetown salamander and includes the following sites: Cobb Well, Cobb Springs, Cowen Creek Spring, Bat Well Cave, Walnut Spring, Twin Spring, Hogg Hollow Spring, Cedar Hollow Spring, Knight (Crockett Garden) Spring, Cedar Breaks Hiking Trail Spring, Water Tank Cave, Avant's (Capitol Aggregates), Buford Hollow Springs, Swinbank Spring, Shadow Canyon, San Gabriel Spring, and Garey Ranch Springs. For the purposes of this 4(d) rule, however, we define an occupied site to be any site where Georgetown salamanders have been found in the past or new sites found in the future.

For activities involving habitat occupied by the Georgetown salamander, the final 4(d) rule provides that take of the Georgetown salamander that is incidental to regulated activities that are conducted consistent with the guidelines described in Appendix A of the UDC will not be prohibited under the Act. Similar to chapter 11.07 of the UDC, the guidelines in Appendix A establish stream and spring buffers and allowable activities within those buffers; however, the measures described in Appendix A create larger, more protective buffers than those that appear in chapter 11 for unoccupied sites. First,

Appendix A establishes a "No-Disturbance Zone" in the stream or waterway into which a spring drains directly; this zone extends 80 m (264 ft) upstream and downstream from the approximate center of the spring outlet of an occupied site and is bounded by the top of the bank. No regulated activities may occur within the "No-Disturbance Zone." In addition, Appendix A establishes a "Minimal-Disturbance Zone" for the subsurface area that drains to the spring(s) at an occupied site; this zone consists of the area within 300 m (984 ft) of the approximate center of the spring outlet of an occupied site, except those areas within the "No-Disturbance Zone." Most regulated activities are also prohibited in the "Minimal-Disturbance Zone," but single-family developments, limited parks and open space development, and wastewater infrastructure will be allowed. For additional details on the buffers around occupied sites and prohibited actions, please refer to the UDC Appendix A.

In general, this 4(d) rule does not apply to deviations from the water quality measures in UDC 11.07 and Appendix A. Any variance from the measures and guidelines described in UDC 11.07 (non-occupied sites) is not covered by this final 4(d) rule, unless that variance has been granted by the City of Georgetown. In addition, variances from the spring and stream buffer requirements of UDC 11.07 may be granted by the City of Georgetown only if the variance is not contrary to the public interest, if due to special conditions a literal enforcement of the ordinance would result in unnecessary hardship, and if the spirit of the ordinance is observed and substantial justice is done, in accordance with UDC section 2.05.010.A.6. Projects involving habitat occupied by the Georgetown salamander (which are not eligible for variances) where the project proponent chooses not to follow the voluntary guidelines in Appendix A of the UDC, may work with the Service to pursue take coverage by developing a habitat conservation plan (HCP) in accordance with section 10 of the Act.

Section 11.07.008 of the UDC also establishes an Adaptive Management Working Group (Working Group) that is responsible for reviewing data on a regular basis and making recommendations for specific changes in the management directions related to the voluntary conservation measures for occupied sites in Appendix A. Adaptive management for preservation of the Georgetown salamander is one of the duties tasked to the Working Group. The adaptive management described in the

UDC specifically applies to the guidelines (*i.e.*, conservation measures) found in Appendix A; therefore, the guidelines described in Appendix A may change over time if they would result in equal or better conservation benefits to the Georgetown salamander, as determined by the Service. For example, if experience gained during implementation of the guidelines or new scientific information suggests that a buffer distance was either too small, or larger than needed, to achieve the intended benefits, that buffer distance could be modified. However, the activities covered under Appendix A (*i.e.*, regulated activities) are not subject to change under the adaptive management provisions described in the UDC. In other words, exercising of adaptive management under this 4(d) rule cannot expand the scope of the covered activities beyond regulated activities (as defined in title 30, Texas Administrative Code, section 213.3(28)). The Working Group will develop an annual report regarding the preservation of the Georgetown salamander, continuous monitoring of the Georgetown salamander, assessment of research priorities, and the effectiveness of the water quality regulations and guidelines. Copies of the February 24, 2015, dated UDC 11.07 and Appendix A are available at <http://www.regulations.gov> at Docket No. FWS-R2-ES-2014-0008. Any revisions to Appendix A will be made available at <https://udc.georgetown.org/udc-amendments/>.

#### Determination

Section 4(d) of the Act states that "the Secretary shall issue such regulations as [s]he deems necessary and advisable to provide for the conservation" of species listed as threatened species. Conservation is defined in the Act to mean "to use and the use of all methods and procedures which are necessary to bring any endangered species or threatened species to the point at which the measures provided pursuant to [the Act] are no longer necessary."

The courts have recognized the extent of the Secretary's discretion under this standard to develop rules that are appropriate for the conservation of a species. For example, the Secretary may find that it is necessary and advisable not to include a taking prohibition, or to include a limited taking prohibition. See *Alsea Valley Alliance v. Lautenbacher*, 2007 U.S. Dist. Lexis 60203 (D. Or. 2007); *Washington Environmental Council v. National Marine Fisheries Service*, and 2002 U.S. Dist. Lexis 5432 (W.D. Wash. 2002). In addition, as affirmed in *State of Louisiana v. Verity*,

853 F.2d 322 (5th Cir. 1988), the rule need not address all the threats to the species. As noted by Congress when the Act was initially enacted, “once an animal is on the threatened list, the Secretary has an almost infinite number of options available to him [her] with regard to the permitted activities for those species. [S]he may, for example, permit taking, but not importation of such species,” or she may choose to forbid both taking and importation but allow the transportation of such species, as long as the prohibitions, and exceptions to those prohibitions, will “serve to conserve, protect, or restore the species concerned in accordance with the purposes of the Act” (H.R. Rep. No. 412, 93rd Cong., 1st Sess. 1973).

Section 9 prohibitions make it illegal for any person subject to the jurisdiction of the United States to take (including harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect; or attempt any of these), import or export, ship in interstate commerce in the course of commercial activity, or sell or offer for sale in interstate or foreign commerce any wildlife species listed as an endangered species, without written authorization. It also is illegal under section 9(a)(1) of the Act to possess, sell, deliver, carry, transport, or ship any such wildlife that is taken illegally. Prohibited actions consistent with section 9 of the Act are outlined for threatened wildlife in 50 CFR 17.31(a) and (b). For the Georgetown salamander, the Service has determined that a 4(d) rule tailored to its specific conservation needs is necessary and advisable, as discussed below. This final 4(d) rule provides that all prohibitions in 50 CFR 17.31(a) and (b) will apply to the Georgetown salamander, except as described below.

Under this final 4(d) rule, incidental take of the Georgetown salamander will not be considered a violation of section 9 of the Act if the take occurs on any non-Federal land and from regulated activities that are conducted consistent with the water quality protection measures contained in chapter 11.07 and Appendix A of the City of Georgetown Unified Development Code. This final 4(d) rule refers to the definition of “regulated activities” in title 30, Texas Administrative Code, section 213.3(28), which is any construction-related or post-construction activities on the recharge zone of the Edwards Aquifer having the potential for polluting the Edwards Aquifer and hydrologically connected surface streams. We have determined that this provision is necessary and advisable for the conservation of the

Georgetown salamander, as explained in the paragraphs that follow.

The local community in the City of Georgetown and Williamson County has expressed a desire to design and implement a local solution to conserving the natural resources in their county, including water quality and the Georgetown salamander (City of Georgetown Resolution No. 082812–N). All currently known locations for the Georgetown salamander are within the jurisdiction of the City of Georgetown, making the city an appropriate entity to manage conservation measures that protect Georgetown salamander habitat. Because impervious cover levels within most of the watersheds known to be occupied by the Georgetown salamander are still relatively low, a window of opportunity exists to design and implement measures to protect water quality and, therefore, conserve the salamander. The City and County’s approach for accomplishing this conservation goal includes regulatory and non-regulatory actions, as described below. Regulatory actions include passage of the Edwards Aquifer Recharge Zone Water Quality Ordinance (Ordinance No. 2013–59) by the Georgetown City Council on December 20, 2013, and the revisions to their UDC (chapter 11.07) finalized on February 24, 2015. Their approach also includes non-regulatory actions, such as the technical guidance provided in Appendix A of the UDC, which outlines additional conservation measures to protect water quality and to avoid direct destruction of occupied sites.

Habitat modification, in the form of degraded water quality and quantity and disturbance of spring sites, is the primary threat to the Georgetown salamander. The conservation measures in both chapter 11.07 and Appendix A of the UDC provide a variety of water quality protection measures, such as the creation of buffers around springs and streams where regulated activities are prohibited, designed to lessen impacts to the water quality of springs and streams in the Edwards Aquifer Recharge Zone. The UDC is applied throughout the watersheds that contain the Georgetown salamander. Absent this 4(d) rule, the status quo would be to address development impacts through traditional tools (that is, sections 7 and 10 of the Act) that are generally applied at the project-by-project scale. The watershed-level approach in UDC 11.07 and Appendix A works to avoid incremental environmental degradation that may go unnoticed on a small, individual project scale. Through this final 4(d) rule, we can achieve a greater level of conservation for the Georgetown

salamander than we could without it because it encourages rangewide implementation of water quality protective measures that are aimed at addressing the primary threat of habitat modification and degradation for Georgetown salamanders. The majority of Georgetown salamanders occur within 164 ft (50 m) of a spring outlet (Pierce *et al.* 2010, p. 294; TPWD 2011, p. 3); this coincides with the spring and stream buffers for unoccupied sites. We also believe the salamander populations exist through underground conduits that may extend 300 m (984 ft) around cave or spring points; this area coincides with the size of the “Minimal-Disturbance Zones” for occupied sites. By limiting development activities within these respective areas, the measures in the UDC 11.07 and Appendix A are expected to limit water quality degradation in areas that may provide suitable surface or subsurface habitat for the Georgetown salamander now and in the future.

Although the areas that provide recharge and the source water for specific areas occupied by the salamander have not been precisely delineated, the watershed-level approach makes it likely that unknown recharge areas are receiving water quality protection under the UDC. This is because the UDC prohibits regulated activities within buffers around all streams located within the recharge zone and the City of Georgetown jurisdiction. In karst aquifer systems, streams often contain important recharge features called swallow holes or swallets, which allow the stream to continue flowing underground in a conduit and feed the larger aquifer or even small springs directly (White 1998, p. 172). For example, in the Barton Springs Segment of the Edwards Aquifer, hydrologists generally agree that most of the aquifer’s recharge comes via these streambed recharge features (Mahler *et al.* 2011, p. 4). Although similar research is lacking in the Northern Segment of the Edwards Aquifer, it is likely that the aquifer feeding Georgetown salamander habitat works in a similar way because both areas are karst aquifer systems, thereby making the stream buffers of the UDC crucial in protecting groundwater quality.

This watershed-level approach also includes an adaptive management component that will allow the Adaptive Management Working Group (Working Group) to evaluate the response of salamander populations to management actions and quickly respond and recommend adjustments, if necessary, to management strategies to protect water

quality consistent with conserving the Georgetown salamander. The UDC formalizes the Working Group with representatives from the City of Georgetown, Williamson County, Texas Commission on Environmental Quality, Texas Parks and Wildlife Department, university scientists, private real estate developers, and the Service. The role of the Working Group is to:

- Review scientific information to understand the latest science on watershed management practices and the conservation of the Georgetown salamander;
- Recommend support for additional Georgetown salamander scientific studies and oversee a long-term monitoring program to ensure that salamander abundance at monitored locations is stable or improving;
- Conduct and evaluate water quality trend analysis as part of its long-term monitoring program to ensure water quality conditions do not decline and, in turn, result in impacts to salamander abundance; and
- Develop recommendations for changes to the UDC Appendix A for occupied sites if scientific and monitoring information indicates that water quality and salamander protection measures need changes to minimize impacts to salamander populations and to help attain the goal of species conservation.

While a window of opportunity exists to design and implement conservation measures to conserve the Georgetown salamander, human population levels and development are expected to increase rapidly in Williamson County (Texas State Data Center 2012, pp. 166–167). The success of the local community's efforts depends on their robust adaptive management program. The program is designed to monitor and quickly assess the effectiveness of the identified conservation measures and strategies and to be able to respond quickly and adapt the conservation measures and strategies to provide equal or better conservation benefits to the Georgetown salamander. The adaptive management approach will ensure that the water quality protective measures are serving their intended purpose of conserving the Georgetown salamander, thereby providing for the conservation of the species. Changes to UDC Appendix A that are agreed upon by the Working Group through the adaptive management process, provide equal or greater conservation benefits to the Georgetown salamander, and approved by the Service would be covered under this 4(d) rule.

By not prohibiting incidental take resulting from regulated activities

conducted in accordance with the UDC 11.07 and Appendix A, the Service is supporting and encouraging a local solution to conservation of the Georgetown salamander. This final 4(d) rule will provide the Service the opportunity to work cooperatively, in partnership with the local community and State agencies, on conservation of the Georgetown salamander and the ecosystems on which it depends. Leveraging our conservation capacity with that of the State, local governments, and the conservation community at large may make it possible to attain biological outcomes larger than those we could attain ourselves due to the watershed-scale protection the UDC requires. Further, our local partners are best able to design solutions that minimize socioeconomic impacts, thereby encouraging participation in measures that will protect water quality and conserve the Georgetown salamander. In addition, by not prohibiting incidental take resulting from regulated activities conducted in accordance with UDC 11.07 and Appendix A, the Service is providing a streamlining mechanism for compliance with the Act for those project proponents who comply with the protective measures in UDC 11.07 and Appendix A and, thus, are considered covered by this final 4(d) rule. Project proponents who comply with these protective measures, as outlined in this final rule, can implement their projects without any potential delay from seeking incidental take coverage from the Service, while also minimizing water quality degradation. This approach provides greater regulatory certainty and streamlines compliance for project proponents and thus is likely to result in increased implementation of water quality protective measures that benefit salamanders.

In summary, this 4(d) rule is necessary and advisable to provide for the conservation of the Georgetown salamander because it strengthens water quality protection measures throughout the species' range, allows for consideration of new information to optimize conservation measures, and furthers conservation partnerships that can be leveraged to improve the status of the Georgetown salamander. Implementation of water quality protection measures throughout the range of the species will provide greater protection for the species than would project-by-project efforts, and provide protections to recharge areas that we may not be able to protect under our traditional tools (*e.g.*, sections 7 and 10 of the Act). Further, water quality

protection is a crucial element of conservation for the Georgetown salamander. Because the best available information does not allow us to determine the exact amount of water quality protection needed to satisfy the life requirements of the Georgetown salamander, the adaptive management approach incorporated into UDC Appendix A provides a pathway to achieving our conservation goals for the species in the face of scientific uncertainty. Finally, this approach also encourages further cooperation between the Service and local government entities, enhancing our ability to work collaboratively with partners to further Georgetown salamander conservation.

If an activity that may affect the species is not regulated by UDC 11.07 or is not in accordance with UDC 11.07 and Appendix A, or a person or entity is not in compliance with all terms and conditions of UDC 11.07 and Appendix A and the activity would result in an act that would be otherwise prohibited under 50 CFR 17.31, then the general provisions of 50 CFR 17.31 and 17.32 for threatened species apply. In such circumstances, the prohibitions of 50 CFR 17.31 would be in effect, and authorization under 50 CFR 17.32 would be required. In addition, nothing in this 4(d) rule affects in any way other provisions of the Act, such as the designation of critical habitat under section 4, recovery planning provisions of section 4(f), and consultation requirements under section 7.

#### Summary of Comments and Recommendations

We requested written comments from the public on the proposed 4(d) rule for the Georgetown salamander during two comment periods: February 24 to April 25, 2014, and April 9 to May 11, 2015. We also contacted appropriate Federal, State, and local agencies; scientific organizations; and other interested parties and invited them to comment on the proposed 4(d) rule, draft environmental assessment, and chapter 11.07 and Appendix A of the UDC during the respective comment periods.

Over the course of the two comment periods, we received 39 comment submissions. All substantive information provided during these comment periods has either been incorporated directly into this final rule or is addressed below. Comments from peer reviewers and State agencies are grouped separately.

#### Peer Review Comments

In accordance with our peer review policy published on July 1, 1994 (59 FR 34270), we solicited expert opinion

from five knowledgeable individuals with scientific expertise that are familiar with the species, the geographic region in which the species occurs, and conservation biology principles. We received responses from two of the five peer reviewers. We reviewed all comments received from the peer reviewers for substantive issues and new information. These comments are addressed in the following summary and incorporated into the final rule as appropriate.

(1) *Comment:* An additional buffer specifically associated with where Georgetown salamanders are found, to minimize direct impacts by people (and domestic pets), is critical. Fencing is often an effective way to mark the boundaries (and potentially reduce their footprint) of such a protective buffer.

*Our response:* We agree that additional measures to protect Georgetown salamanders from the threat of trampling by people, pets, feral hogs, and livestock may contribute to the conservation of the species. However, as noted above, this 4(d) rule does not provide incidental take authority for all types of activities that may constitute take or harm of Georgetown salamanders. Rather, the 4(d) rule will promote the conservation of the species by helping to alleviate negative impacts that can occur from the threat of water quality degradation as a result of urbanization.

(2) *Comment:* I am uncertain as to whether the fixed-width buffers are appropriate in all localities to achieve the desired level of protection. Protection of surface and groundwater resources in karstified area can be quite challenging, and, therefore, simplified metrics such as horizontal setbacks may not achieve the desired results. Adequate buffers would require an understanding of both the detailed hydrogeology and the dispersal patterns of the listed species. For the former, I would expect that areas upgradient of springs (a more immediate source of recharge) would be more important than downgradient areas, all else being equal, to the maintenance of adequate springflow. For the latter, I would expect that downgradient areas (where the emergent surface water flows) would be more important than upgradient areas for the direct support of habitat. How these two attributes interact to define a truly “critical” area of influence is undoubtedly complex, and a fixed-width buffer may be the best alternative at the present time. However, I would hope that improved understanding of these interactions would be a focus of the adaptive management effort.

*Our response:* We agree and expect that improving the understanding of the detailed hydrogeology and dispersal patterns of the species will be a focus of the Working Group. Please see our response to *Comment #8*.

(3) *Comment:* The stormwater-management requirements for protection of the Edwards Aquifer (UDC) are laudable, but they lag behind the current understanding, and readily available applications, of what constitutes stormwater “best management practices” of the 21st century. Particularly given the importance of maintaining aquifer recharge, I would expect to see on-site retention of the 95th percentile storm (as is already mandated for federal facilities) rather than just 85 percent reduction in total suspended solids.

*Our response:* Because the on-site retention of the 95th percentile storm is a different type of stormwater measurement than 85 percent reduction in total suspended solids, it is difficult to compare the two in terms of water quality protection. However, we recognize that there may be more stringent water quality regulations that aim to remove more contaminants from stormwater runoff than the UDC. The adaptive management process will monitor the status of the species in response to implementation of the UDC and modify the regulations if more protective measures are needed to further reduce impacts to the species. At this time, we have determined that the UDC and Appendix A, which include the 85 percent reduction, are necessary and advisable for the conservation of the species (see Determination section above).

(4) *Comment:* I recommend that there should be no exemptions to the water quality regulations. Every proposed change in land use should have some form of review to ensure compatibility with management goals.

*Our response:* In general, deviations from the water quality regulations described in UDC 11.07 and the voluntary guidelines described in Appendix A of the UDC will not be covered under this 4(d) rule. Non-regulated activities, for example, are exempt from UDC 11.07 and are, therefore, not covered under this 4(d) rule. However, variances from UDC 11.07 may be granted by the City of Georgetown in special circumstances. These variances from the spring and stream buffer requirements apply only to non-occupied sites and undergo review by the City of Georgetown staff and may be granted only if the variance is not contrary to the public interest, due to special conditions a literal

enforcement of this regulation would result in unnecessary hardship, and the spirit of the regulation is observed and substantial justice is done, in accordance with UDC Section 2.05.010.A.6. No variances to Appendix A, which covers all occupied sites, of the UDC will be covered under this 4(d) rule. Individual variances to UDC 11.07 that have been approved by the City of Georgetown can be tracked by the Working Group and incorporated into their discussions and recommendations on the adaptive management needed to attain conservation goals.

(5) *Comment:* Geologic and soil studies should be performed by the community to delineate locations where shallow soil cover prevents conventional onsite wastewater disposal. Green infrastructure and low-impact development should be required everywhere in Georgetown, Texas. This includes new development, redevelopment, and restoration projects.

*Our response:* We agree that groundwater vulnerability studies and low-impact development will be beneficial for the Georgetown salamander and its habitat. These are helpful suggestions for the Working Group to consider as they evaluate the effectiveness of the UDC conservation measures.

(6) *Comment:* The community should track water quality and flow at selected springs and streams in order to develop long-term databases able to detect changes.

*Our response:* We agree that water quality and quantity monitoring conducted in a manner that is able to detect changes needs to be a priority for the Working Group. Williamson County is currently monitoring salamander abundance and basic water chemistry (for example, temperature, dissolved oxygen, and specific conductance) at three sites with plans to add more monitoring sites in the future.

#### *Comments From States*

(7) *Comment:* We urge the Service to finalize and implement this proposed rule as efficiently as possible while following a transparent process in order to provide regulatory certainty.

*Our response:* By requesting input from the public on this 4(d) rule during two public comment periods, one 60-day and a second 30-day, we believe the rulemaking process has been transparent.

(8) *Comment:* Spring buffers and other water quality protection policies should be aligned with the hydrogeology that most directly influences conditions for the species’ survival. It also appears that the current buffer strategy may unduly



restrict landowners in some areas that do not influence survival conditions for the species while potentially not affording protection to other areas that do influence survival conditions. We believe the proposed rule affords the [Adaptive Management] Working Group the latitude to study these spring buffers and offer alternative recommendations if new science dictates that changes should be made.

*Our response:* The specific hydrogeology (for example, recharge area) for each site occupied by the Georgetown salamander has not been determined. The Act requires that we use the best available information and does not require that we conduct research to develop new science. In the absence of this information, we believe a fixed-width buffer is the best alternative for protecting these sites. As new information is discovered, the conservation measures can be modified through the adaptive management process.

(9) *Comment:* Conservation measures detailed in the UDC are limited to "Occupied Sites" with currently known populations. Conservation measures would not apply to newly discovered occupied sites. Since newly discovered sites could be important to the recovery of the species, we request that the Service clarify the applicability of the 4(d) rule to these sites and the role the Working Group should play in this regard.

*Our response:* In this final rule, we have clarified that any site determined to be occupied by Georgetown salamanders in the future will be considered "occupied" and the protective measures outlined in Appendix A of the UDC must be followed in order to be covered under this 4(d) rule. We recommend that the Working Group make efforts to survey suitable habitat within the range of the Georgetown salamander to identify all sites occupied by the species.

(10) *Comment:* It is unclear whether a landowner owning a newly discovered site occupied by Georgetown salamanders outside the City of Georgetown's extra-territorial jurisdiction would be covered for incidental take if [s]he were to conduct activities consistent with the conservation measures contained in the UDC. Regulatory predictability and incidental take coverage for all affected landowners are important for the ultimate recovery of the species.

*Our response:* Regulated activities located outside of the City of Georgetown's jurisdiction are not covered by the UDC. Therefore, only incidental take from those activities that

are in the City of Georgetown's jurisdiction are potentially exempt from take prohibitions through this 4(d) rule. All currently known Georgetown salamander sites are covered by the UDC.

#### *Public Comments*

(11) *Comment:* The proposed revised 4(d) rule states that the boundaries of the stream buffer coincides with the boundaries of the FEMA or calculated floodplain, but may be no smaller than [61 m (200 ft)] in width. It should be noted that, while the stream buffer varies depending on the size of the stream (size of the stream is based on the size of the drainage area, which influences the size of the floodplain), there may be situations under the UDC where the stream buffer is smaller than [61 m (200 ft)] in width.

*Our response:* Per the UDC 11.07, only stream buffers without FEMA or calculated floodplains may be no smaller than 61 m (200 ft) in width. We have made the appropriate clarification in this final rule.

(12) *Comment:* The proposed exemption from prohibitions, as it will be outlined in § 17.43(e)(2) of [title 50 of] the CFR, states that "incidental take of the Georgetown salamander will not be considered a violation of section 9 of the Act if the take occurs on privately owned, State, or county land. . . ." This exemption must include, at a minimum, city-owned property.

*Our response:* We have edited the exemption to include all non-Federal land.

(13) *Comment:* The proposed rule, if finalized, could not be amended substantially unless and until the Service allowed for public comment and input. Public input would not be allowed to a greater degree in connection with an incidental take permit than it has been in connection with the proposed rule.

*Our response:* This is correct. Future changes to the content of this 4(d) rule require a public notice and comment period. However, future changes related to the conservation of the Georgetown salamander may be made to the conservation measures in UDC Appendix A, without public notice and comment, if they are agreed upon by the Working Group through the adaptive management process outlined in the UDC, provide equal or greater conservation benefits to the Georgetown salamander, and are approved by the Service.

(14) *Comment:* The proposed rule does not exempt any set of activities in the "red zone." The proposed rule does not pick apart who is regulated or not.

Rather, it focuses on actual implementation of water quality measures consistent with those set forth in the UDC and listed in the proposed rule. A non-regulated entity can presumably meet the standard set forth in the proposed rule, not because such an activity is exempt from regulations, but because it would have affirmatively implemented the water quality measure set forth in the proposed rule and UDC. While it is true that the UDC applies only to regulated activities, the exemption from take in the proposed rule applies to all activities (and only those activities), regulated or not, that are consistent with the conservation measures in the UDC; that is, activities for which the project proponent has performed a geologic assessment, abided by the limitations described in the UDC for no-disturbance and minimal-disturbance zones, established buffers around springs and streams, etc.

*Our response:* The UDC 11.07 and Appendix A were specifically designed for regulated activities. Other kinds of non-regulated activities could have different impacts not addressed with this set of measures. Non-regulated activities that voluntarily follow the UDC 11.07 or Appendix A are not covered by this final 4(d) rule, and project proponents may choose to work with the Service to obtain take coverage.

(15) *Comment:* The Service should permit take under section 10 rather than adopt a special 4(d) rule because the resulting HCP cannot be weakened through amendment (unlike the City of Georgetown UDC), the section 10 process provides greater protections for the salamanders compared to the City of Georgetown UDC, and the process provides an open process in which the public can be involved.

*Our response:* Section 10 permits are voluntary, are tailored towards individual applicants, would only cover known occupied sites, and have different criteria for permit issuance than the Act requires for issuance of a 4(d) rule. It is not certain that the Service would receive applications for section 10 permits that would provide greater protections for the Georgetown salamander over the entire range of the species. The 4(d) rule provides a landscape-level approach that is consistently implemented throughout the range of the Georgetown salamander, including unoccupied sites.

While it is true that the conservation measures in UDC Appendix A may be revised, those changes would not be covered under this 4(d) rule unless they are agreed upon by the Working Group through the adaptive management process outlined in the UDC, provide

equal or greater conservation benefits to the Georgetown salamander, and are approved by the Service. In addition, we have a “No Surprises” policy for section 10 incidental take permits, which states, if unforeseen circumstances occur during the life of an HCP, the Service will not require additional lands, additional funds, or additional restrictions on lands or other natural resources released for development or use, from any permittee, who in good faith is adequately implementing or has implemented an approved HCP. This policy makes HCPs less flexible in terms of requiring more stringent conservation measures over time in response to new information. Given the amount of uncertainty in how best to protect Georgetown salamander habitat quality at individual sites, the flexibility provided in the adaptive management approach of the UDC is desirable.

We believe the development of this 4(d) rule has been an open process comparable to that of a section 10 permit process. In addition, the process of amending the UDC is very transparent, involving monthly meetings of the Unified Development Code Advisory Committee that are open to the public with minutes and agendas posted online (<https://government.georgetown.org/unified-development-code-advisory-board-2/>).

(16) *Comment:* The 4(d) rule allows degradation of water quality and, therefore, is not necessary and advisable for the conservation of the Georgetown salamander.

*Our response:* The protective measures provided for in the 4(d) rule are intended to address the threat of water quality degradation from urbanization throughout the range of the species. We have found that the 4(d) rule positively contributes to the recovery of the Georgetown salamander by addressing the primary threat to the species and that these measures are “necessary and advisable for the conservation” of the Georgetown salamander (see Determination section above).

(17) *Comment:* Numerous activities that may degrade water quality are entirely exempted and, therefore, allowed within the zones and buffers described in the City of Georgetown UDC. The Service should exempt only “regulated activities” because those are the only activities that are actually regulated by the UDC. In this way, threats such as oil and gas activities, agricultural operations, and residential developments on lots greater than 2 ha (5 ac), which are currently unregulated and, therefore, do not contribute to the conservation of the salamander, would

not receive the benefit of protection from incidental take.

*Our response:* We agree and have clarified this issue in the final 4(d) rule. Also, please see our response to *Comment #14*.

(18) *Comment:* Because the proposed special rule references the Ordinance instead of prescribing all the necessary conservation measures, the City could receive the benefits of protection from section 9 even if the City weakens the Ordinance through amendment. To solve this problem, the Service must use the section 10 process, describe all the necessary conservation measures in the Ordinance, or modify the 4(d) rule to state on its face what is and what is not authorized. At a bare minimum, the agency must specifically reference the version of the Ordinance adopted on December 20, 2013.

*Our response:* The final rule clarifies that modifications to UDC Appendix A are covered under the 4(d) rule only if they are agreed upon by the Working Group through the adaptive management process, provide equal or greater conservation benefits to the Georgetown salamander, and are approved by the Service. In order to allow this important adaptive management process to be implemented, we have revised the final 4(d) rule to note that the provisions apply only to Service-endorsed versions of UDC 11.07 and Appendix A.

(19) *Comment:* It concerns us that the proposed 4(d) special rule is proceeding without scientific peer review.

*Our response:* Although our February 24, 2014, proposed 4(d) rule announced that we were not conducting a peer review, we did conduct a peer review of the proposed 4(d) rule during the second comment period (April 9, 2015, to May 11, 2015). We requested peer review from five water quality protection experts and received reviews from two of the five. The peer reviews, along with the other comments and materials we received, are available on the Internet at <http://www.regulations.gov> under Docket No. FWS-R2-ES-2014-0008.

(20) *Comment:* The UDC will not protect the quantity of spring flows or threats to water quality from points more distant than 50–300 m (164–984 ft) from spring sites. The UDC on which the proposed 4(d) rule is based does not adequately protect groundwater quality, including recharge features, caves, conduits, or local aquifers. The only substantive contribution made by the UDC is to decrease the probability of wholesale destruction by physical disturbance of occupied springs, but

that is just one of many threats to the species.

*Our response:* We believe the regulations in the UDC provide some protections to recharge features and water quality in the aquifer as a whole, primarily through the required stream buffers. Although the UDC addresses water quality, regulating every threat to the species is outside the scope of the UDC. In addition, as affirmed in *State of Louisiana v. Verity*, 853 F.2d 322 (5th Cir. 1988), the rule need not address all the threats to the species. Activities that are not covered by this 4(d) rule and that may result in take to the species would need to be covered through sections 7 or 10 of the Act.

(21) *Comment:* The UDC does not specify whether any new population discoveries in the future will be treated as “Edwards Springs” with a 50-m (164-ft) buffer or as occupied sites with a 300-m (984-ft) buffer. Furthermore, the UDC does not require population surveys for salamander presence in currently occupied sites or at sites that are currently thought to be unoccupied. Therefore, it provides zero protection for spring sites that are determined in the future to be occupied by salamanders.

*Our response:* We have clarified in the final 4(d) rule that any site determined to be occupied by Georgetown salamanders in the future will be considered “occupied” and require the protective measures outlined in Appendix A of the UDC to be covered under this 4(d) rule.

(22) *Comment:* Under the 4(d) rule, the Service should allow the City of Georgetown to conduct all technical reviews related to compliance with the UDC, including review and approval of subdivision plats, site plans, or other plans to be in compliance with the UDC. The UDC already requires that all development within the salamanders’ known distribution may not begin until a geologic assessment has been conducted and accepted by the City and all project plats, site plans, and infrastructure construction plans reflect occupied springs and required buffers. The City of Georgetown is the logical entity to conduct this review under the UDC, as City staff are the most knowledgeable about local codes, ordinances, and environmental conditions and will ensure technical reviews comply with the UDC.

*Our response:* The City of Georgetown will implement and enforce the regulations in chapter 11.07 of the UDC. The City, with assistance of the Working Group (comprising representatives from the City of Georgetown, Williamson County, Texas Commission on

Environmental Quality, Texas Parks and Wildlife Department, university scientists, private real estate developers, and the Service), will also review and approve projects that wish to follow the guidelines described in Appendix A of the UDC. The Service has no intention of reviewing individual projects unless the developers wish to obtain an incidental take permit through section 10, or if a Federal nexus exists through section 7, instead of following the UDC.

(23) *Comment:* The required buffers will not infringe too seriously on Georgetown residents. The “Minimal-Disturbance Zone” will allow those who wish to live near rivers and springs that are the salamander’s habitats to do so, as long as the residential areas are low density. Recreational activities like fishing or boating would not be severely limited either, as the “No-Disturbance Zone” on the river stretches only [80 m (262 ft)] in either direction. This is a significant buffer for the salamander, but it is not a far distance for humans to traverse.

*Our response:* The “No-Disturbance Zone” of Appendix A of the UDC does not apply to recreation activities. Only regulated activities (as defined in title 30, Texas Administrative Code, section 213.3(28)) are prohibited within this zone.

(24) *Comment:* Stream buffers of at least 23 m (75 ft) may not be large enough to considerably reduce water pollution. Salamanders are affected by slight changes in pH and increase of chemicals in the water. The small population sizes of Georgetown salamanders greatly increase their risk of extinction. Therefore, more studies on the biology and population demographics of this species should be performed before additional urban development is allowed near these crucial habitat sites.

*Our response:* The adaptive management process is a component of chapter 11.07 and Appendix A of the UDC that allows changes to the regulations in response to new information. If there is adequate evidence that the current regulations are not protective enough for the Georgetown salamander, the Working Group will recommend changes to the UDC that meet the overall management goals.

(25) *Comment:* This plan essentially provides a loophole for developers to continue construction if they survey the area themselves. There is no outside authority to check if salamander habitat will be disturbed. This could potentially allow for corrupt results of the investigation to be passed off as legitimate.

*Our response:* This 4(d) rule does not provide a loophole, because all individual project proponents continue to be responsible for determining impacts on listed species and seeking the appropriate take coverage based on their determination.

(26) *Comment:* If the development is single-family residential, two-family residential, or on a lot smaller than 2 ha (5 ac), the assessment from the Federal Government would be waived. Any construction, no matter how small it may be, will have an impact on the environment.

*Our response:* There is no Federal Government assessment that would be waived from residential developments. Geologic assessments (which have to be completed under the UDC 11.07 regulations) are not required to be submitted to the City of Georgetown if the proposed development is a small (less than 2-ha (5-ac)) single-family and two-family residential development located in a small (25.9-ha (64-ac)) watershed. However, these developments are required to implement all other UDC water quality measures.

#### Required Determinations

##### *Regulatory Planning and Review (Executive Orders 12866 and 13563)*

Executive Order 12866 provides that the Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget will review all significant rules. OIRA has determined that this rule is not significant.

Executive Order 13563 reaffirms the principles of E.O. 12866 while calling for improvements in the nation’s regulatory system to promote predictability, to reduce uncertainty, and to use the best, most innovative, and least burdensome tools for achieving regulatory ends. The executive order directs agencies to consider regulatory approaches that reduce burdens and maintain flexibility and freedom of choice for the public where these approaches are relevant, feasible, and consistent with regulatory objectives. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open exchange of ideas. We have developed this final 4(d) rule in a manner consistent with these requirements.

##### *Regulatory Flexibility Act*

Under the Regulatory Flexibility Act (RFA; 5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of

1996), whenever an agency must publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effects of the rule on small entities (small businesses, small organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of the agency certifies the rule will not have a significant economic impact on a substantial number of small entities. SBREFA amended the RFA to require Federal agencies to provide a statement of the factual basis for certifying that the rule will not have a significant economic impact on a substantial number of small entities. Thus, for a regulatory flexibility analysis to be required, impacts must exceed a threshold for “significant impact” and a threshold for a “substantial number of small entities.” See 5 U.S.C. 605(b). Based on the information that is available to us at this time, we certify that this regulation will not have a significant economic impact on a substantial number of small entities. The following discussion explains our rationale.

On February 24, 2014 (79 FR 10236), we published the final determination to list the Georgetown salamander as a threatened species. That rule became effective on March 26, 2014. As a result, the Georgetown salamander is currently covered by the full protections of the Act, including the full section 9 prohibitions that make it illegal for any person subject to the jurisdiction of the United States to take (harass, harm, pursue, hunt, shoot, wound, kill, trap, capture, or collect, or attempt to engage in any such conduct), import or export, ship in interstate commerce in the course of commercial activity, or sell or offer for sale in interstate or foreign commerce any wildlife species listed as an endangered species, without written authorization. It also is illegal under section 9(a)(1) of the Act to possess, sell, deliver, carry, transport, or ship any such wildlife that is taken illegally. Prohibited actions consistent with section 9 of the Act are outlined for threatened species in 50 CFR 17.31(a) and (b). This final 4(d) rule states that all prohibitions in 50 CFR 17.31(a) and (b) will apply to the Georgetown salamander, except regulated activities that are conducted consistent with the water quality protective measures contained in Chapter 11.07 and Appendix A of the Unified Development Code, which would result in a less restrictive regulation under the Act, as it pertains to the Georgetown

salamander, than would otherwise exist. For the above reasons, we certify that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, a final regulatory flexibility analysis is not required.

#### *Unfunded Mandates Reform Act*

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we make the following findings:

(a) This final rule will not produce a Federal mandate. In general, a Federal mandate is a provision in legislation, statute, or regulation that would impose an enforceable duty upon State, local, or Tribal governments, or the private sector, and includes both “Federal intergovernmental mandates” and “Federal private sector mandates.” These terms are defined in 2 U.S.C. 658(5)–(7). “Federal intergovernmental mandate” includes a regulation that “would impose an enforceable duty upon State, local, or [T]ribal governments” with two exceptions. It excludes “a condition of Federal assistance.” It also excludes “a duty arising from participation in a voluntary Federal program,” unless the regulation “relates to a then-existing Federal program under which \$500,000,000 or more is provided annually to State, local, and [T]ribal governments under entitlement authority,” if the provision would “increase the stringency of conditions of assistance” or “place caps upon, or otherwise decrease, the Federal Government’s responsibility to provide funding,” and the State, local, or Tribal governments “lack authority” to adjust accordingly. At the time of enactment, these entitlement programs were: Medicaid; AFDC work programs; Child Nutrition; Food Stamps; Social Services Block Grants; Vocational Rehabilitation State Grants; Foster Care, Adoption Assistance, and Independent Living; Family Support Welfare Services; and Child Support Enforcement. “Federal private sector mandate” includes a regulation that “would impose an enforceable duty upon the private sector, except (i) a condition of Federal assistance or (ii) a duty arising from participation in a voluntary Federal program.”

(b) This 4(d) rule promulgates that all prohibitions in 50 CFR 17.31(a) and (b) will apply to the Georgetown salamander, except activities that are conducted consistent with the water quality protection measures contained in Chapter 11.07 and Appendix A of the Unified Development Code, which would result in a less restrictive regulation under the Act, as it pertains to the Georgetown salamander, than

would otherwise exist. As a result, we do not believe that this rule would significantly or uniquely affect small governments. Therefore, a Small Government Agency Plan is not required.

#### *Takings*

In accordance with Executive Order 12630, this final rule will not have significant takings implications. We have determined that the rule has no potential takings of private property implications as defined by this Executive Order because this 4(d) rule will result in a less-restrictive regulation under the Endangered Species Act than would otherwise exist. A takings implication assessment is not required.

#### *Federalism*

In accordance with Executive Order 13132, this final 4(d) rule does not have significant Federalism effects. A federalism summary impact statement is not required. This rule will not have substantial direct effects on the State, on the relationship between the Federal Government and the State, or on the distribution of power and responsibilities among the various levels of government.

#### *Civil Justice Reform*

In accordance with Executive Order 12988, the Office of the Solicitor has determined that this final rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order.

#### *Energy Supply, Distribution or Use (Executive Order 13211)*

Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking actions that significantly affect energy supply, distribution, and use. For reasons discussed within this final rule, we believe that the rule will not have any effect on energy supplies, distribution, and use. Therefore, this action is not a significant energy action, and no Statement of Energy Effects is required.

#### *Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)*

This rule does not contain collections of information that require approval by the Office of Management and Budget (OMB) under the Paperwork Reduction Act. This rule will not impose recordkeeping or reporting requirements on State or local governments, individuals, businesses, or organizations. 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.

#### *National Environmental Policy Act (42 U.S.C. 4321 et seq.)*

We have prepared a final environmental assessment, as defined under the authority of the National Environmental Policy Act of 1969. For information on how to obtain a copy of the final environmental assessment, see **ADDRESSES**, above.

#### *Government-to-Government Relationship With Tribes*

In accordance with the President’s memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination with Indian Tribal Governments), and the Department of the Interior’s manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with tribes in developing programs for healthy ecosystems, to acknowledge that tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to tribes. We determined that there are no known tribal lands within the range of the Georgetown salamander.

#### **Authors**

The primary authors of this final rule are the staff members of the Austin Ecological Services Field Office (see **FOR FURTHER INFORMATION CONTACT**).

#### **List of Subjects in 50 CFR Part 17**

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

#### **Regulation Promulgation**

Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as set forth below:

#### **PART 17—[AMENDED]**

■ 1. The authority citation for part 17 continues to read as follows:

**Authority:** 16 U.S.C. 1361–1407; 1531–1544; 4201–4245; unless otherwise noted.

■ 2. Amend § 17.43 by adding paragraph (e) to read as follows:

§ 17.43 Special rules—amphibians.

\* \* \* \* \*

(e) Georgetown salamander (*Eurycea naufragia*).

(1) *Prohibitions.* Except as noted in paragraph (e)(2) of this section, all prohibitions and provisions of §§ 17.31

and 17.32 apply to the Georgetown salamander.

(2) *Exemptions from prohibitions.* Incidental take of the Georgetown salamander will not be considered a violation of section 9 of the Act if the take occurs on non-Federal land from regulated activities that are conducted consistent with the water quality protection measures contained in chapter 11.07 and Appendix A of the

City of Georgetown (Texas) Unified Development Code (UDC), as endorsed by the U.S. Fish and Wildlife Service.

\* \* \* \* \*

Dated: July 28, 2015.

**Stephen Guertin,**

*Acting Director, U.S. Fish and Wildlife Service.*

[FR Doc. 2015-19335 Filed 8-6-15; 8:45 am]

**BILLING CODE 4310-55-P**

# Proposed Rules

Federal Register

Vol. 80, No. 152

Friday, August 7, 2015

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.

## FEDERAL TRADE COMMISSION

### 16 CFR Part 312

RIN 3084-AB20

#### Children's Online Privacy Protection Rule Proposed Parental Consent Method; Jest8 Limited, Trading as Riyo, Application for Approval of Parental Consent Method

**AGENCY:** Federal Trade Commission (FTC or Commission).

**ACTION:** Request for public comment.

**SUMMARY:** The Federal Trade Commission requests public comment concerning the proposed parental consent method submitted by Jest8 Limited, trading as Riyo ("Riyo"), under the Voluntary Commission Approval Processes provision of the Children's Online Privacy Protection Rule.

**DATES:** Written comments must be received on or before September 3, 2015.

**ADDRESSES:** Interested parties may file a comment at <http://ftcpublic.commentworks.com/ftc/riyocoppaconsent> online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write "Jest8 Limited (Trading as Riyo) Application for Parental Consent Method, Project No. P-155405" on your comment, and file your comment online at <http://ftcpublic.commentworks.com/ftc/riyocoppaconsent> by following the instructions on the web-based form. If you prefer to file your comment on paper, write "Jest8 Limited (Trading as Riyo) Application for Parental Consent Method, Project No. P-155405" on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC-5610 (Annex E), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th

Street SW., 5th Floor, Suite 5610 (Annex E), Washington, DC 20024.

**FOR FURTHER INFORMATION CONTACT:**

Miry Kim, Attorney, (202) 326-3622, or Peder Magee, Attorney, (202) 326-3538, Division of Privacy and Identity Protection, Federal Trade Commission, Washington, DC 20580.

**SUPPLEMENTARY INFORMATION:**

#### Section A. Background

On October 20, 1999, the Commission issued its final Rule<sup>1</sup> pursuant to the Children's Online Privacy Protection Act, 15 U.S.C. 6501 *et seq.*, which became effective on April 21, 2000.<sup>2</sup> On December 19, 2012, the Commission amended the Rule, and these amendments became effective on July 1, 2013.<sup>3</sup> The Rule requires certain Web site operators to post privacy policies and provide notice, and to obtain verifiable parental consent, prior to collecting, using, or disclosing personal information from children under the age of 13. The Rule enumerates methods for obtaining verifiable parental consent, while also allowing an interested party to file a written request for Commission approval of parental consent methods not currently enumerated.<sup>4</sup> To be considered, the party must submit a detailed description of the proposed parental consent method, together with an analysis of how the method meets the requirements for parental consent described in 16 CFR 312.5(b)(1).

Pursuant to Section 312.12(a) of the Rule, Riyo has submitted a proposed parental consent method to the Commission for approval. The full text of its application is available on the Commission's Web site at [www.ftc.gov](http://www.ftc.gov).

#### Section B. Questions on the Parental Consent Method

The Commission is seeking comment on the proposed parental consent method, and is particularly interested in receiving comment on the questions that follow. These questions are designed to assist the Commission's consideration of the petition and should not be construed as a limitation on the issues on which public comment may be submitted. Responses to these questions should cite the number of the question being answered. For all comments

<sup>1</sup> 64 FR 59888 (1999).

<sup>2</sup> 16 CFR part 312.

<sup>3</sup> 78 FR 3972 (2013).

<sup>4</sup> 16 CFR 312.12(a); 78 FR at 3991-3992, 4013.

submitted, please provide any relevant data, statistics, or any other evidence, upon which those comments are based.

1. Is this method, both with respect to the process for obtaining consent for an initial operator and any subsequent operators, already covered by existing methods enumerated in Section 312.5(b)(2) of the Rule?

2. If this is a new method, provide comments on whether the proposed parental consent method, both with respect to an initial operator and any subsequent operators, meets the requirements for parental consent laid out in 16 CFR 312.5(b)(1). Specifically, the Commission is looking for comments on whether the proposed parental consent method is reasonably calculated, in light of available technology, to ensure that the person providing consent is the child's parent.

3. Does this proposed method pose a risk to consumers' personal information? If so, is that risk outweighed by the benefit to consumers and businesses of using this method?

#### Section C. Invitation to Comment

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before September 3, 2015. Write "Jest8 Limited (Trading as Riyo)" Application for Parental Consent Method, Project No. P-155405" on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including, to the extent practicable, on the Commission Web site, at <http://www.ftc.gov/os/publiccomments.shtm>. As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, including medical records or other individually identifiable health information. In addition, do not include

any “[t]rade secret or any commercial or financial information which is . . . privileged or confidential,” as discussed in Section 6(f) of the FTC Act, 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).<sup>5</sup> Your comment will be kept confidential only if the FTC General Counsel, in his or her sole discretion, grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at <http://ftcpublishcommentworks.com/ftc/riyocoppaconsent>, by following the instructions on the web-based form. If this Notice appears at <http://www.regulations.gov/#!home>, you also may file a comment through that Web site.

If you file your comment on paper, write “Jest8 Limited (Trading as Riyo) Application for Parental Consent Method, Project No. P-155405” on your comment and on the envelope, and mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC-5610 (Annex E), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex E), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Web site at <http://www.ftc.gov> to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive

<sup>5</sup>In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. See FTC Rule 4.9(c), 16 CFR 4.9(c).

public comments that it receives on or before September 3, 2015. For information on the Commission’s privacy policy, including routine uses permitted by the Privacy Act, see <http://www.ftc.gov/ftc/privacy.htm>.

By direction of the Commission.

**Donald S. Clark,**  
*Secretary.*

[FR Doc. 2015-19425 Filed 8-6-15; 8:45 am]

**BILLING CODE 6750-01-P**

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

#### 26 CFR Parts 1, 25, 26, and 301

[REG-102837-15]

RIN 1545-BM68

#### Guidance Under Section 529A: Qualifies ABLE Programs; Correction

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Correction to a notice of proposed rulemaking and notice of public hearing.

**SUMMARY:** This document contains corrections to a notice of proposed rulemaking and notice of public hearing (REG-102837-15) that was published in the *Federal Register* on Monday, June 22, 2015 (80 FR 35602). The proposed regulations under section 529A of the Internal Revenue Code that provide guidance regarding programs under The Stephen Beck, Jr., Achieving a Better Life Experience Act of 2014.

**DATES:** Written or electronic comments and request for a public hearing for the notice of proposed rulemaking at 80 FR 35602, June 22, 2015, are still being accepted and must be received by September 21, 2015.

**FOR FURTHER INFORMATION CONTACT:** Taina Edlund or Terri Harris at (202) 317-4541, or Sean Barnett (202) 317-5800, or Theresa Melchiorre (202) 317-4643 (not a toll-free number).

#### SUPPLEMENTARY INFORMATION:

##### Background

The notice of proposed rulemaking that is subject of this document is under section 529A of the Internal Revenue Code.

##### Need for Correction

As published, the notice of proposed rulemaking and notice of public hearing (REG-102837-15) contains errors that may prove to be misleading and are in need of clarification.

#### Correction of Publication

Accordingly, the notice of proposed rulemaking and notice of public hearing (REG-102837-15) that are subject to FR Doc. 2015-15280 are corrected as follows:

1. On page 35603, in the preamble, second column, twelfth line, the language “Section 529(d)(2) provides that the” is corrected to read “Section 529A(d)(2) provides that the.”

2. On page 35603, in the preamble, second column, nineteenth line, the language “529(d)(3) requires qualified ABLE” is corrected to read “529A(d)(3) requires qualified ABLE.”

3. On page 35606, in the preamble, first column, second line from the bottom of the first paragraph, the language “meaning of § 1.529A-1(b)(9)(A) or” is corrected to read “meaning of § 1.529A-1 (b)(9)(i).”

#### § 1.529A-1 [Corrected]

4. On page 35612, second column, second and third line from the bottom of paragraph (b)(16), the language “within the meaning of § 1.529-1(b)(9)(A) or § 1.529-2(e)(1)(i) are not qualified” is corrected to read “within the meaning of § 1.529A-1(b)(9)(i) or § 1.529A-2(e)(1)(i) are not qualified.”

#### § 1.529A-7 [Corrected]

5. On page 35619, third column, paragraph (a)(5)(iii) the language “furnished though a Web site posting and” is corrected to read “furnished through a Web site posting and.”

**Martin V. Franks,**

*Chief, Publications and Regulations Branch,  
Legal Processing Division, Associate Chief  
Counsel (Procedure and Administration).*

[FR Doc. 2015-19369 Filed 8-6-15; 8:45 am]

**BILLING CODE 4830-01-P**

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## ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Parts 123, 131, 233, 501

[EPA-HQ-OW-2014-0461; FRL-9930-57-OW]

#### Revised Interpretation of Clean Water Act Tribal Provision

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed interpretive rule; request for comments.

**SUMMARY:** Waters on the majority of Indian reservations do not have water quality standards under the Clean Water Act to protect human health and the environment. Only 40 of over 300 federally recognized tribes with

reservations have completed the process of obtaining EPA's approval to be treated in a manner similar to a state (TAS), and adopting standards for their waters that EPA has approved. EPA proposes to streamline how tribes apply for TAS for the water quality standards program and other Clean Water Act regulatory programs. The proposal would reduce the burden on applicant tribes and advance cooperative federalism by facilitating tribal involvement in the protection of reservation water quality as intended by Congress. Since 1991, EPA has followed a cautious approach that requires applicant tribes to demonstrate inherent authority to regulate waters and activities on their reservations under principles of federal Indian common law. The Agency has consistently stated that its approach was subject to change in the event of further congressional or judicial guidance addressing tribal authority under section 518 of the Clean Water Act. Having received such guidance, EPA proposes to conclude definitively that section 518 includes an express delegation of authority by Congress to eligible Indian tribes to administer regulatory programs over their entire reservations. This reinterpretation would eliminate the need for applicant tribes to demonstrate inherent authority to regulate under the Act, thus allowing tribes to implement the congressional delegation of authority unhindered by requirements not specified in the statute. The reinterpretation would also bring EPA's treatment of tribes under the Clean Water Act in line with EPA's treatment of tribes under the Clean Air Act, which has similar statutory language addressing tribal regulation of Indian reservation areas. This action would not revise any regulatory text. Regulatory provisions would remain in effect requiring tribes to identify the boundaries of the reservation areas over which they seek to exercise authority and allowing the adjacent state(s) to comment to EPA on an applicant tribe's assertion of authority. As a streamlining step, the proposed interpretive rule would have no significant cost.

**DATES:** EPA must receive comments on this proposal on or before October 6, 2015. EPA will discuss this proposed rule and answer questions about it in a webinar during the above comment period. If you are interested, see EPA's Web site at <http://water.epa.gov/scitech/swguidance/standards/wqslibrary/tribal.cfm> for the date and time of the webinar and instructions on how to register and participate. Additionally, under the Paperwork Reduction Act,

any comments on the information collection provisions of this proposal are best assured of having full effect if the Office of Management and Budget receives a copy of your comments on or before September 8, 2015.

**ADDRESSES:** Submit your comments, identified by Docket ID No. EPA-HQ-OW-2014-0461, by one of the following methods:

- <http://www.regulations.gov>: Follow the online instructions for submitting comments.

- *Email:* [ow-docket@epa.gov](mailto:ow-docket@epa.gov).

- *Fax:* 202-566-0409

- *Mail:* Water Docket, Environmental Protection Agency, Mail Code 2822T, 1200 Pennsylvania Ave. NW., Washington, DC 20460. Attention: Docket ID No. EPA-HQ-OW-2014-0461. In addition, please mail a copy of your comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: Desk Officer for EPA, 725 17th St. NW., Washington, DC 20503.

- *Hand Delivery:* EPA Docket Center, EPA West Room 3334, 1301 Constitution Ave. NW., Washington, DC 20004, Attention: Docket ID No. EPA-HQ-OW-2014-0461. Such deliveries are only accepted during the Docket's normal hours of operation. Please make special arrangements for deliveries of boxed information.

**Instructions:** Direct your comments to Docket ID No. EPA-HQ-OW-2014-0461. EPA's policy is to include all comments received in the public docket without change and make them available online at <http://www.regulations.gov>, including any personal information provided, unless 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 <http://www.regulations.gov> or email. The <http://www.regulations.gov> Web site is an "anonymous access" system, which means EPA will not know your identity or contact information unless you provide it in the body of your comment. If you send an email comment directly to EPA without going through <http://www.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, EPA recommends that you include your name and other contact information in the body of your comment and with any

disc you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA might not be able to consider your comment. Electronic files should avoid the use of special characters, any form of encryption, and be free of any defects or viruses. For additional information about EPA's public docket visit the Docket Center homepage at <http://www.epa.gov/epahome/dockets.htm>.

**Docket:** All documents in the docket are listed in the <http://www.regulations.gov> index. Although listed in the index, some information is not publicly available (e.g., CBI or other information whose disclosure is restricted by statute). Certain other material, such as copyrighted material, will be publicly available only in hard copy. Publicly available docket materials are available either electronically in <http://www.regulations.gov> or in hard copy at the Office of Water Docket Center, EPA/DC, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC 20004. This Docket Facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744; the telephone number for the Office of Water Docket Center is (202) 566-2426.

**FOR FURTHER INFORMATION CONTACT:** Fred Leutner, Standards and Health Protection Division, Office of Science and Technology (4305T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 566-0378; fax number: (202) 566-0409; email address: [TASreinterpretation@epa.gov](mailto:TASreinterpretation@epa.gov).

**SUPPLEMENTARY INFORMATION:** This supplementary information section is organized as follows:

- I. General Information
  - A. Does this action apply to me?
  - B. What should I consider as I prepare my comments for EPA?
    1. Resubmitting Relevant Comments From Consultations and Listening Sessions
    2. Submitting CBI
    3. Tips for Preparing Your Comments
- II. What is the statutory and regulatory history of the CWA TAS provision?
  - A. Statutory History
  - B. Regulatory History
- III. How did EPA interpret the CWA TAS provision when establishing TAS regulations for CWA regulatory programs?
- IV. What developments support EPA's proposed statutory reinterpretation?
  - A. Relevant Congressional, Judicial and Administrative Developments
  - B. EPA and Tribal Experience in Processing TAS Applications for CWA Regulatory Programs



- C. Request for Reinterpretation From Tribes
- V. How does EPA propose to reinterpret the CWA TAS provision?
  - A. Statement of Proposal
  - B. Geographic Scope of TAS for Regulatory Programs
  - C. Treatment of Tribal Trust Lands
  - D. Tribal Criminal Enforcement Authority
  - E. Special Circumstances
  - F. Tribal Inherent Regulatory Authority
  - G. Existing Regulatory Requirements
- VI. How would the proposed change in interpretation affect existing EPA guidance to tribes seeking to administer CWA regulatory programs?
- VII. What are the anticipated effects of the proposed reinterpretation?
  - A. Effects on Tribes That EPA Has Previously Found Eligible for TAS
  - B. Effects on New Tribal Applications

- C. Effects on EPA-Approved State Programs
- VIII. Economic Analysis
- IX. Statutory and Executive Order Reviews
  - A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review
  - B. Paperwork Reduction Act (PRA)
  - C. Regulatory Flexibility Act (RFA)
  - D. Unfunded Mandates Reform Act (UMRA)
  - E. Executive Order 13132: Federalism
  - F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments
  - G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks
  - H. Executive Order 13211: Actions Concerning Regulations That

- Significantly Affect Energy Supply, Distribution, or Use
- I. National Technology Transfer and Advancement Act (NTTAA)
- J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

**I. General Information**

*A. Does this action apply to me?*

This action applies to tribal governments that seek eligibility to administer regulatory programs under the Clean Water Act (CWA, or the Act). The table below provides examples of entities that could be affected by this action or have an interest in it.

Category	Examples of potentially affected or interested entities
Tribes .....	Federally recognized tribes with reservations that could potentially seek eligibility to administer CWA regulatory programs, and other interested tribes.
States .....	States adjacent to potential applicant tribes.
Industry .....	Industries discharging pollutants to waters within or adjacent to reservations of potential applicant tribes.
Municipalities .....	Publicly owned treatment works or other facilities discharging pollutants to waters within or adjacent to reservations of potential applicant tribes.

If you have questions regarding the effect of this proposed action on a particular entity, please consult the person listed in the preceding **FOR FURTHER INFORMATION CONTACT** section.

*B. What should I consider as I prepare my comments for EPA?*

1. *Resubmitting Relevant Comments from Consultations and Listening Sessions.* EPA held multiple consultations and listening sessions with tribes and states concerning the issue addressed in this proposed action, and considered views and comments received from these sessions in developing this proposal. The proposed rule has evolved from the materials EPA shared at the time. Therefore, if you submitted comments based on these sessions and wish for EPA to consider them as part of the public comment opportunity for this proposed action, you must resubmit your comments to EPA in accordance with the instructions outlined in this document.

2. *Submitting CBI.* Do not submit CBI information to EPA through <http://www.regulations.gov> or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disc that you mail to EPA, mark the outside of the disc as CBI and then identify electronically within the disc the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not

contain the information claimed as CBI must be submitted for inclusion in the public docket. EPA will not disclose information so marked except in accordance with procedures set forth in 40 Code of Federal Regulations (CFR) part 2.

3. *Tips for Preparing Your Comments.* When submitting comments, remember to:

- Identify the proposed action by docket number and other identifying information (subject heading, **Federal Register** date and page number).
  - Explain why you agree or disagree, suggest alternatives, and substitute language for your requested changes.
  - Describe any assumptions and provide any technical information and/or data that you used.
    - If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
    - Provide specific examples to illustrate your concerns, and suggest alternatives.
    - Explain your views as clearly as possible.
    - Submit your comments by the date shown in the **DATES** section of this notice.

**II. What is the statutory and regulatory history of the CWA TAS provision?**

*A. Statutory History*

Congress added CWA section 518, 33 U.S.C. 1377, as part of amendments made in 1987. Section 518(e) authorizes

EPA to treat eligible Indian tribes in the same manner as it treats states for a variety of purposes, including administering each of the principal CWA regulatory programs and receiving grants under several CWA funding authorities. Section 518(e) is commonly known as the “TAS” provision, for treatment in a similar manner as a state.

Section 518(e) establishes eligibility criteria for TAS, including requirements that the tribe have a governing body carrying out substantial governmental duties and powers; that the functions to be exercised by the tribe pertain to the management and protection of water resources within the borders of an Indian reservation; and that the tribe be reasonably expected to be capable of carrying out the functions to be exercised in a manner consistent with the terms and purposes of the Act and applicable regulations. Section 518(e) also requires EPA to promulgate regulations specifying the TAS process for applicant tribes. See section II.B.

Section 518(h) defines “Indian tribe” to mean any Indian tribe, band, group, or community recognized by the Secretary of the Interior and exercising governmental authority over a federal Indian reservation. It defines “federal Indian reservation” to mean all land within the limits of any reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, and including rights-of-way running through the reservation.

### B. Regulatory History

Pursuant to section 518(e), EPA promulgated several final regulations establishing TAS criteria and procedures for Indian tribes interested in administering programs under the Act. The relevant regulations addressing TAS requirements for the principal CWA regulatory programs are:

- 40 CFR 131.8 for section 303(c) water quality standards (WQS). Final rule published December 12, 1991 (56 FR 64876); proposed rule published September 22, 1989 (54 FR 39098). Referred to hereafter as the “1991 WQS TAS rule” or “1991 TAS rule”;

- 40 CFR 131.4(c) for section 401 water quality certification, published in the 1991 WQS TAS rule;

- 40 CFR 123.31–34 for section 402 National Pollutant Discharge Elimination System (NPDES) permitting and other provisions, and 40 CFR 501.22–25 for the state sewage sludge management program. Final rule published December 22, 1993 (58 FR 67966); proposed rule published March 10, 1992 (57 FR 8522); and
- 40 CFR 233.60–62 for section 404 dredge or fill permitting. Final rule published February 11, 1993 (58 FR 8172); proposed rule published November 29, 1989 (54 FR 49180).

In 1994, EPA amended the above regulations to simplify the TAS process and eliminate unnecessary and duplicative procedural requirements. See 59 FR 64339 (December 14, 1994) (the “Simplification Rule”). For example, the Simplification Rule eliminated the need for a tribe to prequalify for TAS before applying for section 402 and section 404 permitting programs. Instead, the rule provided that a tribe would establish its TAS eligibility at the program approval stage, subject to EPA’s notice and comment procedures already established for state program approvals in 40 CFR parts 123 and 233. The rule retained the prequalification requirements (including local notice and comment procedures) for section 303(c) WQS and section 401 water quality certifications. *Id.*; see also, 40 CFR 131.8(c)(2), (3).<sup>1</sup> The TAS regulations for CWA regulatory programs have remained intact since promulgation of the Simplification Rule.

This proposed action would not address or affect the TAS requirements

<sup>1</sup> Under the CWA and EPA’s regulations, tribes can apply for TAS under CWA section 518 for the purpose of administering WQS and simultaneously submit actual standards for EPA review under section 303(c). Although they can proceed together, a determination of TAS eligibility and an approval of actual water quality standards are two distinct actions.

or review process for tribes to receive grants.<sup>2</sup> The receipt of grant funding does not involve any exercise of regulatory authority. Therefore, a determination of TAS eligibility solely for funding purposes does not, under existing regulations, require an analysis or determination regarding an applicant tribe’s regulatory authority.

### III. How did EPA interpret the CWA TAS provision when establishing TAS regulations for CWA regulatory programs?

In the 1991 WQS TAS rule, which addressed TAS for the WQS and certification programs, EPA explained that tribes must meet four criteria to be approved for TAS eligibility. Specifically, an applicant tribe must: (1) Be federally recognized, (2) carry out substantial governmental duties and powers over a “Federal Indian reservation” as defined in CWA section 518(h)(1), (3) have appropriate authority to regulate the quality of reservation waters, and (4) be reasonably expected to be capable of administering the CWA program. 54 FR at 39101.

The third of the criteria—regulatory authority—is the sole focus of the proposed change in statutory interpretation. This proposal would not affect the other TAS criteria or tribal application requirements relating to those criteria.

With regard to regulatory authority,<sup>3</sup> EPA carefully analyzed section 518 and the then-current state of judicial precedent to assess whether Congress had intended to delegate regulatory authority to eligible Indian tribes to administer CWA regulatory programs throughout their entire reservations, including over lands owned by nonmembers of the tribe within a reservation. 56 FR at 64879–81. EPA noted significant support in the CWA and its legislative history for the conclusion that Congress had in fact delegated such authority. *Id.* Section 518(e) requires only that the functions to be exercised by the applicant Indian tribe pertain to the management and protection of water resources that are “within the borders of an Indian reservation.” Section 518(h)(1) expressly defines Indian reservations as

“all land within the limits of any Indian reservation . . . notwithstanding the issuance of any patent, and including rights-of-way running through the reservation.”

EPA specifically noted the import of language in *Brendale v. Confederated Tribes and Bands of the Yakima Nation*, 492 U.S. 408, 428 (1989), where Justice White (with three additional Justices joining) identified CWA sections 518(e) and (h)(1) as an express delegation of authority to tribes, including authority over the activities of non-tribal members on their lands within a reservation. 56 FR at 64879–80. EPA agreed with commenters on the proposed rule that Justice White’s opinion indicated that at least four Supreme Court Justices would interpret the plain language of section 518 as an express delegation of regulatory authority. *Id.*

At the same time EPA recognized that Justice White’s opinion was not a majority opinion of the Supreme Court (the other five Justices did not opine on the issue) and that the interpretation of CWA section 518 was not actually before the Court in *Brendale*. *Id.* EPA also noted that while there were significant statements in the legislative history of section 518 supporting congressional intent to delegate authority to eligible tribes, the legislative history standing alone was insufficiently clear to confirm definitively such intent. *Id.* at 64879–81. EPA was also mindful that three members of Congress had submitted comments in connection with the proposed TAS rule stating their respective views that Congress did not intend to expand the scope of tribal authority over non-Indians on the reservation by passage of section 518. *Id.* Although EPA observed that subsequent statements by members of Congress must be treated cautiously and do not supplement the statute’s legislative history, EPA carefully considered the commenters’ views in forming its initial approach to tribal regulatory authority under the CWA.

Ultimately, EPA took a cautious approach in the 1991 TAS rule and stated it would await further congressional or judicial guidance on the extent to which section 518 is properly interpreted as an express congressional delegation of authority. *Id.* at 64877–81. EPA specifically stated the Agency’s interpretation that in section 518, Congress had expressed a preference for tribal regulation of surface water quality on reservations to ensure compliance with the goals of the CWA. *Id.* at 64878–79. However, until such time as EPA revisited the issue, the Agency determined it would require

<sup>2</sup> EPA has promulgated regulations governing the TAS application and review requirements for CWA grant funding programs. See, e.g., 40 CFR 35.580–588 (CWA section 106 water pollution control funding); 40 CFR 35.600–615 (CWA section 104 water quality cooperative agreements and wetlands development funding); 40 CFR 35.630–638 (CWA section 319 nonpoint source management grants).

<sup>3</sup> Tribal “regulatory authority” in this proposal refers to civil regulatory authority. See section V.D. for a discussion of tribal criminal enforcement authority.

applicant Indian tribes to demonstrate, on a case-by-case basis, their inherent authority under existing principles of federal Indian law to regulate activities under the CWA. *Id.* at 64880–81.

EPA's approach required an applicant tribe to demonstrate its inherent tribal authority over the activities of non-tribal members on lands they own in fee within a reservation ("nonmember fee lands") under the principles of *Montana v. United States*, 450 U.S. 544 (1981), and its progeny. *Montana* held that absent a federal grant of authority, tribes generally lack inherent jurisdiction over nonmember activities on nonmember fee lands, but retain inherent civil jurisdiction over nonmember activities within the reservation where (i) nonmembers enter into "consensual relationships with the tribe or its members, through commercial dealing, contracts, leases, or other arrangements" or (ii) ". . . [nonmember] conduct threatens or has some direct effect on the political integrity, the economic security, or the health or welfare of the tribe." *Id.* at 565–566; the "*Montana* test."

EPA noted that in applying the second prong of the *Montana* test and assessing the impacts of nonmember activities on a tribe, EPA will rely upon an operating rule that evaluates whether the potential impacts of regulated activities on the tribe are serious and substantial. 56 FR at 64878–79. EPA recognized that the analysis of whether the *Montana* test is met in a particular situation depends on the specific circumstances presented by the tribe's application. *Id.* at 64878. Thus, EPA's approach to the second prong of the *Montana* test involves a fact-specific inquiry to determine whether the tribe has shown that existing and potential nonmember activities within the reservation affecting water quality have or could have serious and substantial direct impacts on the political integrity, economic security, or health or welfare of the tribe.

EPA adopted an identical approach and reasoning regarding tribal inherent regulatory authority in its subsequent TAS regulations (see list of regulations in section II.B). In these rules, EPA restated that the question of whether section 518 delegated authority to tribes to administer CWA regulatory programs on their reservations was unresolved and remained subject to additional consideration in light of subsequent congressional or judicial guidance. *See, e.g.*, 58 FR at 8173–76; 58 FR at 67971, 67975–76.

#### IV. What developments support EPA's proposed statutory reinterpretation?

##### A. Relevant Congressional, Judicial and Administrative Developments

EPA has taken final action approving TAS for CWA regulatory programs for 50 tribes since the 1991 WQS TAS rule.<sup>4</sup> Three of those decisions were challenged in judicial actions. The last challenge concluded in 2002. In each of the cases, the reviewing court upheld EPA's determination with respect to the applicant tribe's inherent authority to regulate under the CWA. *Wisconsin v. EPA*, 266 F.3d 741 (7th Cir. 2001), *cert. denied*, 535 U.S. 1121 (2002) (Sokaogon Chippewa Community); *Montana v. EPA*, 137 F.3d 1135 (9th Cir.), *cert. denied*, 525 U.S. 921 (1998) (Confederated Salish and Kootenai Tribes of the Flathead Reservation); *Montana v. EPA*, 141 F.Supp.2d 1259 (D. Mont. 1998) (Assiniboine and Sioux Tribes of the Fort Peck Reservation).<sup>5</sup>

As noted in section III's discussion of the 1991 TAS rule, EPA was mindful of the statement in *Brendale* indicating that Justice White and the three other Supreme Court Justices joining his plurality opinion viewed CWA section 518 as an express congressional delegation of authority to Indian tribes. 56 FR at 64889 (citing *Brendale*, 492 U.S. at 428). EPA also recognized, however, that the statement regarding section 518 was not necessary to the plurality's decision; nor was it based on an analysis of the relevant CWA legislative history, which, as EPA noted, was inconclusive on the issue. *Id.* EPA thus opted to proceed with a cautious initial approach to tribal regulatory authority under the CWA, and await further developments that could guide the proper interpretation of section 518.

Since the 1991 TAS rule, there have been significant developments supporting the interpretive change EPA proposes. Notably, the first court to review a challenge to an EPA CWA TAS approval expressed the view that the statutory language of section 518 indicated plainly that Congress intended to delegate authority to Indian tribes to regulate their entire

reservations, including regulation of non-Indians on fee lands within a reservation. *Montana v. EPA*, 941 F. Supp. 945, 951–52 (D. Mont. 1996), *aff'd*, 137 F.3d 1135 (9th Cir.), *cert. denied*, 525 U.S. 921 (1998). In that case, the applicant tribe, participating as amicus, argued that the definition of "federal Indian reservation" in CWA section 518(h)(1)—which expressly includes all land within the limits of a reservation notwithstanding the issuance of any patent—combined with the bare requirement of section 518(e) that the functions to be exercised by the applicant tribe pertain to reservation water resources, demonstrates that section 518 provides tribes with delegated regulatory authority over their entire reservations, including over non-Indian reservation lands. *Id.* Because EPA premised its approval of the TAS application at issue upon a showing of inherent tribal authority, it was unnecessary for the district court to reach the delegation issue as part of its holding in the case. Nonetheless, the court readily acknowledged that section 518 is properly interpreted as an express congressional delegation of authority to Indian tribes over their entire reservations. The court noted that the legislative history might be ambiguous, although only tangentially so, since the bulk of the legislative history relates to the entirely separate issue of whether section 518(e) pertains to non-Indian water quantity rights, which it does not. *Id.* The court observed the established principle that Congress may delegate authority to Indian tribes—per *United States v. Mazurie*, 419 U.S. 544 (1975)—and commented favorably on Justice White's statement regarding section 518 in *Brendale*. *Id.* The court also noted that a congressional delegation of authority to tribes over their entire reservations "comports with common sense" to avoid a result where an interspersed mixing of tribal and state WQS could apply on a reservation depending on whether the waters traverse or bound tribal or non-Indian reservation land. *Id.* Having thus analyzed CWA section 518, the court concluded—albeit in dicta—that Congress had intended to delegate such authority to Indian tribes over their entire reservations.

The TAS provision of a separate statute—the Clean Air Act (CAA)—provides additional relevant insight into congressional intent. Congress added the CAA TAS provision—section 301(d)—to the statute in 1990, only three years after it enacted CWA section 518. Although CAA section 301(d) pre-dates EPA's 1991 CWA TAS rule, it was

<sup>4</sup> The site <http://water.epa.gov/scitech/swguidance/standards/wqslibrary/approvable.cfm> provides a list of tribes approved for section 303(c) water quality standards and section 401 water quality certification. To date, EPA has not approved TAS for any tribe for CWA section 402 or section 404 permitting.

<sup>5</sup> EPA was also upheld in the only case challenging the Agency's approval of actual tribal water quality standards under CWA section 303(c) (which is a distinct action from EPA's approval of tribal TAS eligibility under section 518). *City of Albuquerque v. Browner*, 97 F.3d 415 (10th Cir. 1996), *cert. denied*, 522 U.S. 965 (1997) (water quality standards of Isleta Pueblo).

not until 1998 that EPA promulgated its regulations interpreting the CAA TAS provision as an express congressional delegation of authority to eligible Indian tribes. The U.S. Court of Appeals for the DC Circuit upheld that interpretation two years later. *Arizona Public Service Co. v. EPA*, 211 F.3d 1280 (D.C. Cir. 2000) (“*APS*”), cert. denied, 532 U.S. 970 (2001). Viewed in light of the court’s careful review, the CAA TAS provision provides useful guidance regarding Congress’ understanding of the importance of uniform tribal regulation of mobile environmental pollutants within reservations. Further, that understanding can fairly be traced back to the 1987 enactment of CWA section 518. Each statute must, of course, be viewed in light of its own language and history. Relevant aspects of EPA’s interpretation of the CAA TAS provision are described below.

EPA finalized its regulations implementing CAA section 301(d) in 1998. 40 CFR part 49; 63 FR 7254 (February 12, 1998) (the “CAA Tribal Authority Rule”). The CAA TAS provision, combined with the definition of Indian tribe in CAA section 302(r), established the same basic TAS eligibility criteria for CAA purposes that apply under the CWA: *i.e.*, federal recognition, tribal government carrying out substantial duties and powers, jurisdiction, and capability. With regard to jurisdiction, EPA carefully analyzed the language and legislative history of the relevant portion of the CAA TAS provision, CAA section 301(d)(2)(B), and concluded that Congress had intended to delegate authority to eligible Indian tribes to administer CAA regulatory programs over their entire reservations irrespective of land ownership—*e.g.*, including over nonmember fee lands within the reservation. 63 FR at 7254–57. EPA determined that the language of the provision distinguished between reservation and non-reservation areas over which tribes could seek TAS eligibility and plainly indicated Congress’ intent that reservations will be under tribal jurisdiction. *Id.* By contrast, for non-reservation areas tribes would need to demonstrate their inherent authority to regulate under principles of federal Indian law. *Id.*

EPA noted at that time important similarities between the CAA and CWA TAS provisions. Most notably, the tribal provisions of both statutes expressly provided eligibility for tribal programs that pertain to the management and protection of environmental resources (*i.e.*, air and water, respectively) located on Indian reservations. *Id.* at 7256. For instance, CAA section 301(d) provides

for tribal regulation of air resources “within the exterior boundaries of the reservation” without any requirement for a demonstration by applicant tribes of separate authority over such reservation areas. CAA section 301(d)(2)(B). Similarly, CWA section 518 provides eligibility for tribal programs covering water resources “within the borders of an Indian reservation” and expressly defines Indian reservations to include all land within the reservation notwithstanding the issuance of any patent and including rights-of-way. CWA sections 518(e)(2), (h)(1). By their plain terms, both statutes thus treat reservation lands and resources the same way and set such areas aside for tribal programs. At the time EPA promulgated the CAA Tribal Authority Rule, however, EPA viewed the CAA—which also contained other provisions addressing tribal roles—and its legislative history as more conclusively demonstrating congressional intent to delegate authority to eligible tribes over their reservations. *Id.* EPA recognized that this resulted in different approaches to two similar TAS provisions and reiterated that the question remained as to whether the CWA provision is also an express delegation of authority to eligible tribes. *Id.* EPA also cited to the district court decision in *Montana v. EPA*, which, as noted above, concluded that CWA section 518 plainly appears to delegate such authority to Indian tribes. *Id.*

Several parties petitioned for judicial review of the CAA Tribal Authority Rule and challenged whether CAA section 301(d) could be properly interpreted as a delegation of authority by Congress to eligible Indian tribes. *APS*, 211 F.3d at 1287–92. The D.C. Circuit carefully analyzed CAA section 301(d), the relevant legislative history, and the judicial precedent on delegations of authority to Indian tribes and concluded that EPA’s interpretation comported with congressional intent. *Id.* The court acknowledged the similarities between the CAA and CWA TAS provisions, as well as EPA’s different approach under the CWA. *Id.* at 1291–92. However, the court also noted with significance that EPA’s approach under the CWA had not been subjected to judicial review and observed favorably the district court’s statements in *Montana v. EPA* that section 518 plainly indicates congressional intent to delegate authority to Indian tribes. *Id.* Ultimately, the D.C. Circuit recognized that EPA had taken a cautious approach under the CWA but that there was no

reason EPA must do so again under the CAA. *Id.*

A dissenting judge in the *APS* case disagreed that CAA section 301(d)(2)(B) expressed congressional intent to delegate authority to tribes over their reservations. *Id.* at 1301–05. Notably, the dissent’s view was predicated largely on the absence in section 301(d)(2)(B) of language explicitly describing the reservation areas over which tribes would exercise CAA jurisdiction as including *all* reservation lands *notwithstanding the issuance of any patent and including rights-of-way running through the reservation* (emphasis added). *Id.* The dissent viewed this language as critical to an expression of congressional intent that tribes are to exercise delegated authority over all reservation lands, including lands owned by nonmembers of the tribes. *Id.* And in the absence of such language—which the dissent referred to as “the gold standard for such delegations”—the dissent did not view CAA section 301(d)(2)(B) as expressing Congress’ intent to relieve tribes of the need to demonstrate their inherent authority to regulate under the CAA, including a demonstration of inherent authority over nonmember activities on fee lands under the Supreme Court’s *Montana* test. *Id.* at 1303–04.<sup>6</sup> Notably, the dissent observed that the key “notwithstanding” language is, in fact, included in the relevant tribal provisions of the CWA—*i.e.*, in the definition of “federal Indian reservation” in CWA section 518(h)(1). *Id.* at 1302 (referencing *Brendale*, 492 U.S. at 428). The dissent noted that in spite of the statement in *Brendale*, EPA had determined not to treat CWA section 518 as a congressional delegation; however, the dissent also observed that no court had yet resolved the issue. *Id.*

As the D.C. Circuit stated in *APS*, no court has yet reviewed EPA’s interpretation of tribal regulation under the CWA on the question of whether CWA section 518 constitutes an express delegation of authority from Congress to eligible Indian tribes to regulate water resources throughout their reservations. Importantly, members of the three courts that have considered the issue have favorably viewed such an interpretation: The U.S. Supreme Court

<sup>6</sup>The dissent in *APS* also concluded that a separate provision of the CAA—section 110(o)—expressly delegates authority to eligible Indian tribes over their entire reservations for the specific CAA program established in that provision. *Id.* at 1301–02. Section 110(o) includes the key language cited by the dissent as indicative of express congressional delegations of authority to tribes over their reservations. *Id.*

in *Brendale*, the federal district court in *Montana v. EPA*, and the D.C. Circuit in *APS*.

In light of these developments, as well as EPA's experience administratively interpreting and implementing the CAA TAS provision, it is appropriate to revisit and revise EPA's approach to TAS under the CWA. In the preambles to the CWA TAS regulations from the 1990s, EPA discussed the possibility of reinterpreting CWA section 518 as an express congressional delegation of authority to tribes based on subsequent congressional or judicial guidance. The proposed action would accomplish such a reinterpretation.

#### *B. EPA and Tribal Experience in Processing TAS Applications for CWA Regulatory Programs*

Based on EPA's experience to date, the TAS application process has become significantly more burdensome than EPA anticipated in 1991. Many authorized tribes have informed EPA that the demonstration of inherent tribal authority, including application of the *Montana* test, constituted the single greatest administrative burden in their application processes.

In the 1991 TAS rule, EPA expressed its expert view that given the importance of surface water to tribes and their members, the serious nature of water pollution impacts, and the mobility of pollutants in water, applicant Indian tribes would generally be able to demonstrate inherent regulatory authority to set WQS for reservation waters, including as applied to nonmembers on fee lands under federal Indian law principles. *Id.* at 64877–79. In light of the Agency's generalized findings regarding the relationship of water quality to tribal health and welfare, EPA noted that a tribe could likely meet the *Montana* test by making a relatively simple factual showing that (1) there are waters within the subject reservation used by the tribe or its members, (2) the waters are subject to protection under the CWA, and (3) impairment of the waters by nonmember activities on fee lands would have serious and substantial effects on tribal health and welfare. *Id.* at 64879.

EPA thus anticipated in the early 1990s that applicant tribes would face a relatively simple initial burden of supplying basic facts to demonstrate that they retain requisite inherent authority to regulate under the CWA—including regulation of nonmember activities on fee lands—under established federal Indian law principles. *Id.*

Unfortunately, EPA's expectations have not, as a general matter, been realized. Although each TAS application has varied according to the particular facts and circumstances of the applicant tribe and its reservation, the general experience confirms that demonstrations of inherent regulatory authority continue to impose unintended administrative hurdles on applicant tribes and to require substantial commitments of limited tribal and federal resources. In particular, the demonstration of inherent authority over nonmember activities on the reservation under the so-called *Montana* test has created the most significant and widespread burden and at the same time provides no information necessary for EPA's oversight of the regulatory program. Tribes have repeatedly expressed their concern that the demonstration of inherent authority on a case-by-case basis is challenging, time consuming and costly. EPA's information on the 50 tribes that it has found eligible to administer WQS and section 401 certifications indicates that tribal applications for reservations with nonmember fee lands, which require an analysis of tribal inherent authority under *Montana*, took 1.6 years longer to be approved, on average, than applications for reservations without such lands.

The elimination of such unintended administrative burdens does not, in itself, provide a legal rationale to alter EPA's interpretation of section 518. However, streamlining a TAS process that has become unnecessarily restrictive and burdensome does offer a strong policy basis for the Agency to take a careful second look at that provision and to consider—as it contemplated as early as 1991—whether intervening events have shed additional light on the appropriate statutory interpretation. Eliminating such unnecessary burdens is consistent with longstanding EPA and Executive policy to support tribal self-determination and promote and streamline tribal involvement in managing and regulating their lands and environments. *See, e.g.,* Executive Order 13175 (65 FR 67249, November 9, 2000); Presidential Memorandum: Government-to-Government Relations with Native American Tribal Governments (59 FR 22951, April 29, 1994); EPA Policy for the Administration of Environmental Programs on Indian Reservations (November 8, 1984).

As explained in section III, EPA has long interpreted the CWA as expressing Congress' preference for tribal regulation of reservation surface water

quality. *See, e.g.,* 56 FR at 64878. As explained in section IV, developments subsequent to the 1991 TAS rule definitively confirm that section 518 includes an express delegation of authority by Congress to eligible tribes to regulate water resources under the CWA throughout their entire reservations.

#### *C. Request for Reinterpretation from Tribes*

In April 2013, the National Tribal Water Council<sup>7</sup> expressed its concern in a document submitted to EPA's Office of Water<sup>8</sup> that “[c]urrently, EPA does not treat tribes and states in the same manner even though it has the authority to do so under section 518(e)(2) of the CWA.” The Council further stated that “reliance on a jurisdictional showing before granting tribal regulatory authority has prevented many tribes from establishing federally approved WQS for the waters of their reservations. This has left a significant portion of Native American communities without the protection of the CWA to safeguard their water resources.” The Council encouraged EPA to consider reinterpreting the CWA TAS provision as an express delegation of congressional authority as it did with the similar provision of the CAA and to remove the requirement for tribes to show their inherent authority.<sup>9</sup>

### **V. How does EPA propose to reinterpret the CWA TAS provision?**

#### *A. Statement of Proposal*

Based on the analysis in sections III and IV above, EPA proposes to revise its interpretation of CWA section 518 and conclude definitively that Congress expressly delegated authority to Indian tribes to administer CWA regulatory programs over their entire reservations, including over nonmember activities on fee lands within the reservation of the applicant tribe, subject to the eligibility requirements in section 518. In doing so, EPA thus proposes to exercise the

<sup>7</sup> For more information on the National Tribal Water Council, see <http://nationaltribalwatercouncil.org/>.

<sup>8</sup> *Equal Treatment for Tribes in Seeking Eligibility under EPA Regulatory Programs*, unsigned undated document, National Tribal Water Council, provided to the Office of Water in April 2013. Available at the above site.

<sup>9</sup> In addition to demonstrating their inherent regulatory authority, a number of tribes that have previously applied for TAS to administer CWA regulatory programs have asserted in their applications their view that CWA section 518 constitutes an express delegation of authority from Congress. Although EPA has not previously relied on that approach in its TAS decisions, it is noteworthy that tribes have expressed this legal interpretation in prior applications.

authority entrusted to it by Congress to implement the CWA TAS provision.

EPA's revised interpretation is, most importantly, expressed in the language of section 518. Section 518(e)(2) requires only that the functions to be exercised by the applicant Indian tribe pertain to the management and protection of water resources "within the borders of an Indian reservation." Section 518(h)(1) then defines the term "federal Indian reservation" to include all lands within the limits of any Indian reservation notwithstanding the issuance of any patent, and including rights-of-way running through the reservation. That definition is precisely the same language that the dissent in *APS* stated is the "gold standard" for an express congressional delegation of regulatory authority to tribes over their entire reservations. *APS*, 211 F.3d at 1302–03. It is also the language that the U.S. Supreme Court reviewed in finding congressional delegations to tribes in other contexts. *United States v. Mazurie*, 419 U.S. 544 (1975) (delegation of authority to tribes regarding regulation of liquor); *Rice v. Rehner*, 463 U.S. 713 (1983) (same). Although the legislative history of section 518 has, of course, remained unaltered since 1987, the plain language of the statute and the above-described developments provide ample support for the revised interpretation.

The effect of this proposal would be to relieve tribes of the need to demonstrate their inherent authority when they apply for TAS to administer CWA regulatory programs. In particular, this proposal would eliminate any need to demonstrate that the applicant tribe retains inherent authority to regulate the conduct of nonmembers of the tribe on fee lands under the test established by the Supreme Court in *Montana*. Instead, applicant tribes would be able to rely on the congressional delegation of authority in section 518 as the source of their authority to regulate their entire reservations under the CWA, without distinguishing among various categories of on-reservation land. As EPA explained in connection with the CAA, such a territorial approach that treats Indian reservations uniformly promotes rational, sound management of environmental resources that might be subjected to mobile pollutants that disperse over wide areas without regard to land ownership. See 59 FR at 43959. As specifically recognized by the district court in *Montana v. EPA*, the same holds true for regulation under the CWA. *Montana*, 941 F. Supp. at 952.

### B. Geographic Scope of TAS for Regulatory Programs

EPA's proposal would not affect—either by expanding or contracting—the geographic scope of potential tribal TAS eligibility under the CWA. Under section 518, tribes can only obtain TAS status over waters within the borders of their reservations. See, e.g., 56 FR at 64881–82. Thus, under any approach to tribal regulatory authority under the CWA, tribal TAS eligibility under the CWA is limited to Indian reservations. Tribes can seek TAS with respect to water resources pertaining to any type of on-reservation land, including, for example, reservation land held in trust by the United States for a tribe, reservation land owned by or held in trust for a member of the tribe, and reservation land owned by non-tribal members. Conversely, tribes cannot obtain TAS under the CWA for water resources pertaining to any non-reservation Indian country<sup>10</sup> or any other type of non-reservation land.<sup>11</sup> The proposed change in interpretation would not alter that basic limitation of TAS under the CWA.

### C. Treatment of Tribal Trust Lands

The proposed change in statutory interpretation would not alter the current approach to tribal trust lands. Indian reservations include trust lands validly set aside for Indian tribes even if such lands have not formally been designated as an Indian reservation. Many named Indian reservations were established through federal treaties with tribes, federal statutes, or Executive Orders of the President. Such reservations are often referred to as formal Indian reservations. Many tribes have lands that the United States holds in trust for the tribes, but that have not been formally designated as reservations. As EPA has consistently stated, and consistent with relevant judicial precedent, such tribal trust

<sup>10</sup> Indian country is defined at 18 U.S.C. 1151 as: (a) All land within the limits of any Indian reservation under the jurisdiction of the United States Government, notwithstanding the issuance of any patent, and, including rights-of-way running through the reservation; (b) all dependent Indian communities within the borders of the United States whether within the original or subsequently acquired territory thereof, and whether within or without the limits of a state; and (c) all Indian allotments, the Indian titles to which have not been extinguished, including rights-of-way running through the same. Indian reservations are thus a subset of the broader geographic area that comprises Indian country as a whole.

<sup>11</sup> Many tribes have rights to hunt, fish, gather resources, or perform other activities in areas outside of their reservations. To the extent the lands on which these rights are exercised are not Indian reservation lands as defined at 18 U.S.C. 1151(a), tribes cannot obtain TAS under the CWA for water resources pertaining to such lands.

lands are informal reservations and thus have the same status as formal reservations for purposes of the Agency's programs. See, e.g., 56 FR at 64881; 63 FR at 7257–58; *APS*, 211 F.3d at 1292–94. For CWA purposes, tribes have thus always been able to seek TAS over such trust lands, and would continue to be able to do so under this proposal. Several tribes have done so previously.

### D. Tribal Criminal Enforcement Authority

EPA's proposed change in statutory interpretation would not affect any existing limitations on tribal criminal enforcement authority. This proposal relates solely to applicant Indian tribes' civil regulatory authority to administer CWA regulatory programs on their reservations; it does not address or in any way alter the scope of tribal criminal enforcement jurisdiction. EPA has previously established regulations addressing implementation of criminal enforcement authority on Indian reservations for those CWA programs that include potential exercises of such authority. See, e.g., 40 CFR 123.34, 233.41(f). These regulations provide that the federal government will retain primary criminal enforcement responsibility in those situations where eligible tribes do not assert or are precluded from exercising such authority.

### E. Special Circumstances

There could be rare instances where special circumstances limit or preclude a particular tribe's ability to accept or effectuate the congressional delegation of authority over its reservation. For example, there could be a separate federal statute establishing unique jurisdictional arrangements for a specific state or a specific reservation that could affect a tribe's ability to exercise authority under the CWA. It is also possible that provisions in particular treaties or tribal constitutions could limit a tribe's ability to exercise relevant authority.<sup>12</sup>

<sup>12</sup> EPA takes no position in this proposal regarding whether any particular tribe or Indian reservation is subject to any potential impediment relating to the effectuation of the congressional delegation of regulatory authority or how the CWA can be interpreted vis-à-vis the alleged source of any such impediment. Any such issue would need to be addressed on a case-by-case basis and with the benefit of a full record of relevant information that would be developed during the processing of a particular TAS application. To the extent EPA is ever called upon to make a decision regarding this type of issue, such a decision would be rendered in the context of EPA's final action on a specific TAS application, and any judicial review of that decision would occur in that context.

The application requirements of existing CWA TAS regulations already require tribes to submit a statement of their legal counsel (or equivalent official) describing the basis for their assertion of authority. The statement can include copies of documents such as tribal constitutions, by-laws, charters, executive orders, codes, ordinances, resolutions, etc. See 40 CFR 131.8(b)(3)(ii); 123.32(c); 233.61(c)(2). If EPA finalizes this proposed action, the requirement for a legal counsel's statement would continue to apply and would ensure that applicant tribes appropriately rely on the congressional delegation of authority and provide any additional information that could be relevant to their ability to accept or effectuate the delegated authority. As described below in section V.G., existing CWA TAS and program regulations will also continue to provide appropriate opportunities for other potentially interested entities—such as states or other Indian tribes adjacent to an applicant tribe—to comment on an applicant tribe's assertion of authority and, among other things, inform EPA of any special circumstances that they believe could affect a tribe's ability to regulate under the CWA.

Section 10211(b) of the Safe, Accountable, Flexible, Efficient Transportation Equity Act of 2005 ("SAFETEA"), Public Law 109–59, 119 Stat. 1144 (August 10, 2005) established a unique TAS requirement with respect to Indian tribes located in the State of Oklahoma. Under section 10211(b) of SAFETEA, tribes in Oklahoma seeking TAS under a statute administered by the EPA for the purpose of administering an environmental regulatory program must, in addition to meeting applicable TAS requirements under the EPA statute, enter into a cooperative agreement with the state that is subject to EPA approval and that provides for the tribe and state to jointly plan and administer program requirements. This requirement of SAFETEA exists apart from, and in addition to, existing TAS criteria, including the TAS criteria set forth in section 518 of the CWA. EPA's proposal relates solely to the interpretation of an existing CWA TAS requirement; it would thus have no effect on the separate TAS requirement of section 10211(b) of SAFETEA.

#### F. Tribal Inherent Regulatory Authority

EPA's proposed change in statutory interpretation is not intended as any comment on the extent of tribal inherent regulatory authority. As the Agency clearly articulated in the TAS rules identified in section II.B, the importance of water resources to tribes, the serious

potential impacts of water pollution on tribes' uses of their waters, and the mobility of pollutants in water all strongly support tribes' ability to demonstrate their inherent authority to regulate surface water quality on their reservations, including the authority to regulate nonmember conduct on fee lands under the Supreme Court's test established in *Montana*. Consistent with its 1991 interpretation of section 518, EPA concluded that each of the 50 tribes it has approved for TAS for CWA regulatory programs has demonstrated its inherent regulatory authority and has demonstrated that the functions it sought to exercise pertain to the management and protection of reservation water resources. All Agency CWA TAS determinations challenged in court have been upheld.

The proposed change in interpretation would not affect these prior TAS approvals. The proposed change would, however, modify EPA's approach going forward to be consistent with Congress' intent to delegate authority to eligible tribes. It would relieve tribes of the administrative burden associated with demonstrating their inherent regulatory authority in the TAS application process. The change in interpretation does not, however, alter EPA's prior views regarding the extent of tribal inherent regulatory authority.<sup>13</sup>

#### G. Existing Regulatory Requirements

Because the proposed change in statutory interpretation is consistent with existing CWA TAS regulatory text, EPA's proposal would not revise any regulatory text in the Code of Federal Regulations.

If EPA finalizes its change in interpretation, tribes would be able to rely on the congressional delegation of authority in section 518 as the source of their authority to regulate water quality on their reservations. Aside from any special circumstances (see section V.E.), the main focus in determining the extent of an applicant tribe's jurisdiction for CWA regulatory purposes would then be identifying the geographic boundaries of the Indian reservation area (whether a formal or informal reservation) over which the congressionally delegated authority would apply. EPA's existing CWA TAS regulations already provide for applicant tribes to submit a map or legal description of the reservation area that

<sup>13</sup> In promulgating the CAA Tribal Authority Rule, the EPA similarly noted its expert view that even absent a direct delegation of authority from Congress, tribes would very likely have inherent authority over all activities within Indian reservation boundaries that are subject to CAA regulation. 59 FR at 43958 n.5.

is the subject of the TAS application. See 40 CFR 131.8(b)(3)(i); 123.32(c); 233.61(c)(1); 501.23(c). These provisions would continue to apply and would ensure that each tribe applying for a CWA regulatory program submits information adequate to demonstrate the location and boundaries of the subject reservation.

The existing regulations provide appropriate opportunities for potentially interested entities to provide input to EPA regarding any jurisdictional issues associated with a tribe's TAS application. As mentioned in section II.B. above, EPA's TAS regulations for the CWA section 303(c) WQS program include a process for notice to appropriate governmental entities—states, tribes and other federal entities located contiguous to the reservation of the applicant tribe—and provide an opportunity for such entities to provide comment on the applicant tribe's assertion of authority. EPA makes such notice broad enough that other potentially interested entities can participate in the process. 56 FR at 64884. For example, EPA routinely publishes notice of tribal TAS applications for the WQS program in relevant local newspapers covering the area of the subject reservation and in electronic media.

EPA's TAS regulations for the CWA section 402 and 404 permitting programs require an analysis of regulatory authority as part of the program approval process under 40 CFR parts 123 and 233 that are described in section II.B. As described in the Simplification Rule, EPA makes its decisions to approve or disapprove those programs as part of a public notice and comment process conducted in the **Federal Register**. 59 FR at 64340.

Thus, the regulations would continue to afford appropriate opportunities for interested parties to comment on tribal assertions of authority for all CWA regulatory programs. Because the principal jurisdictional issue under the proposed reinterpretation would be the boundaries of the subject reservation, any comments on an applicant tribe's assertion of authority would likely focus on the reservation boundaries.<sup>14</sup>

<sup>14</sup> Focusing the jurisdictional inquiry on the geographic scope of a tribe's TAS application—*i.e.*, the boundary of the reservation area that a tribe seeks to regulate—would impose no additional burden on entities that wish to comment on an applicant tribe's assertion of authority. Under any approach to tribal regulatory authority, the geographic scope of the TAS application would be a relevant jurisdictional consideration and thus an appropriate issue for potential comment during the TAS process. Commenters have, at times, raised such geographic issues in the context of previous TAS applications; EPA's proposal would not alter

However, to the extent a particular application presents a separate jurisdictional issue, the notice-and-comment process that exists in each CWA TAS regulation would also be available to raise such an issue to EPA for due consideration.

Because this proposal merely explains EPA's revised interpretation of existing statutory requirements established in the CWA tribal provision—and does not propose any changes to the existing regulatory language applicable to CWA TAS applications—an interpretive rule is the appropriate vehicle to announce EPA's revised approach. This interpretive rule is not subject to notice and comment requirements of the Administrative Procedure Act. However, EPA decided to provide notice and an opportunity for comment to increase transparency and to allow interested parties to provide their views. EPA intends this process to ensure that the Agency's decision making is well informed by stakeholder review and invites comments on all aspects of this proposal to reinterpret section 518 of the CWA as a congressional delegation of authority to eligible tribes.

#### **VI. How would the proposed change in interpretation affect existing EPA guidance to tribes seeking to administer CWA regulatory programs?**

As noted in section V.G., EPA's proposal would not revise any regulatory text. However, if EPA finalizes the proposal, the Agency would consider revising and updating some of its existing guidance to tribes and EPA regional offices on implementing the regulations.

For example, a 1998 memorandum to EPA staff (the "Cannon-Perciasepe Memorandum")<sup>15</sup> provided guidance for EPA's reviews of tribal assertions of inherent authority. The memorandum established a case-by-case process for EPA to seek comments from appropriate governmental entities and the public on EPA's proposed factual findings relating to nonmember activities on fee lands. Cannon-Perciasepe Memorandum, p. 6. The memorandum also provided detailed guidance for implementing the *Montana* test. Cannon-Perciasepe Memorandum, Att. C.<sup>16</sup>

the opportunity to do so for future applications, or any burden attendant to preparing and submitting such comments.

<sup>15</sup> "Adoption of the Recommendations from the EPA Workgroup on Tribal Eligibility Determinations," memorandum from Assistant Administrator for Water Robert Perciasepe and General Counsel Jonathan Z. Cannon to EPA Assistant Administrators and Regional Administrators, March 19, 1998.

<sup>16</sup> The "Cannon-Perciasepe" approach and related guidance to tribes are reflected in subsequent EPA

If EPA finalizes this proposal, the memorandum's *Montana* test guidance would no longer be relevant for TAS applications for CWA regulatory programs, and there would be no need for EPA to develop or seek comment on factual findings relating to tribal inherent authority. EPA would update its guidance to applicant tribes to reflect these changes consistent with the express congressional delegation of authority to eligible tribes.

#### **VII. What are the anticipated effects of the proposed reinterpretation?**

##### *A. Effects on Tribes That EPA Has Previously Found Eligible for TAS*

There would be no effect on tribes that EPA has previously found eligible for TAS for the purpose of a CWA regulatory program.

##### *B. Effects on New Tribal Applications*

If EPA finalizes this proposed interpretive rule, then after the effective date TAS applications for CWA regulatory programs would be able to rely on the delegation from Congress as the relevant source of authority supporting their eligibility. The reinterpretation should thus streamline the TAS process for many tribes seeking eligibility to administer CWA regulatory programs. EPA anticipates that this proposed action, if finalized, could significantly reduce the time and effort for tribes to develop their TAS applications, and could encourage more tribes to apply for TAS for CWA regulatory programs.

EPA advises tribes that have already initiated TAS applications for CWA regulatory programs that the reinterpretation proposed in this action has not yet taken effect. The earliest it could take effect would be 30 days after EPA issues a final interpretive rule after reviewing and considering all comments received during the public comment period (see **DATES** section at the beginning of this document). All TAS applications will be processed under the existing statutory interpretation and the current regulations and guidance noted above, unless and until EPA issues a final interpretive rule. Such tribes can, at their option, ask EPA to suspend action on their current CWA applications for regulatory programs pending a potential final interpretive rule, but EPA cannot guarantee whether or when this proposal will be finalized.

materials, including portions of the "Strategy for Reviewing Tribal Eligibility Applications to Administer EPA Regulatory Programs," memorandum from Deputy Administrator Marcus Peacock, January 23, 2008.

##### *C. Effects on EPA-Approved State Programs*

EPA's proposal would have no effect on the scope of existing state regulatory programs approved by EPA under the CWA. Generally speaking, civil regulatory jurisdiction in Indian country lies with the federal government and the relevant Indian tribe, not with the states. See, e.g., *Alaska v. Native Village of Venetie Tribal Gov't*, 522 U.S. 520, 527 n.1 (1998). Therefore, in the absence of an express demonstration of authority by a state for such areas, EPA has generally excluded Indian country from its approvals of state regulatory programs under the CWA.

The proposal relates solely to the exercise of jurisdiction by Indian tribes on their reservations; it would have no effect on the scope of existing CWA regulatory programs administered by states outside of Indian country. It would neither diminish, nor enlarge, the scope of such approved state programs.

There are uncommon situations where a federal statute other than the CWA grants a state jurisdiction to regulate in areas of Indian country. For example, in a few cases EPA has approved states to operate CWA regulatory programs in areas of Indian country where the states demonstrated jurisdiction based on such a separate federal statute. This proposal is not intended to address or affect such jurisdiction that other federal statutes provide to states.

Regulations already exist to address circumstances where a state or tribe believes that unreasonable consequences could arise or have arisen as a result of differing WQS set by states and eligible Indian tribes on common bodies of water. Section 518(e) of the CWA required EPA to provide a mechanism to address such situations. The Agency did so at 40 CFR 131.7, which establishes a detailed dispute resolution mechanism. This proposal does not affect that process; it would remain available as needed to address potential state/tribal issues.

#### **VIII. Economic Analysis**

This rule would entail no significant cost. Its only direct effect would be to reduce the administrative burden for a tribe applying to administer a CWA regulatory program, and to potentially increase the pace at which tribes seek such programs. See the discussion of administrative burden and cost in section IX.B. (Paperwork Reduction Act).



## IX. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <http://www2.epa.gov/laws-regulations/laws-and-executive-orders>.

### A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review

This action is not a significant regulatory action and was, therefore, not submitted to the Office of Management and Budget (OMB) for review.

### B. Paperwork Reduction Act (PRA)

EPA has submitted the information collection activities in this proposed interpretive rule to OMB for approval under the PRA. The Information Collection Request (ICR) document that EPA prepared has been assigned EPA ICR number 2515.01. You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

As discussed in section II.B., EPA's regulations require that a tribe seeking to administer a CWA regulatory program must submit information to EPA demonstrating that the tribe meets the statutory criteria described in section II.A. EPA requires this information in order to determine that the tribe is eligible to administer the program.

This proposed interpretive rule would streamline the application by removing the current requirement for an applicant tribe to demonstrate its inherent regulatory authority, including demonstrating that it meets the *Montana* test where relevant. As described in the ICR, this proposed rule would reduce the burden by an estimated 583 staff hours for a typical tribe, or 27 percent, and reduce the cost of an application to a typical tribe for salaries and contractor support by an estimated \$70,554 per tribe, or 39 percent.

*Respondents/affected entities:* Any federally recognized tribe with a reservation can potentially apply to administer a regulatory program under the CWA.

*Respondent's obligation to respond:* The information discussed in this rule is required from a tribe only if the tribe seeks to administer a CWA regulatory program. See EPA's regulations cited in section II.B of this notice.

*Estimated number of respondents:* The total potential pool of respondents is over 300 tribes with reservations. Although there are 566 federally recognized Indian tribes in the United States, the CWA allows only those tribes with reservations to apply for authority to administer programs. EPA estimates

that about six tribes per year would apply for a regulatory program under this proposed rule, an increase from the current rate of four tribes per year. The pace of applications could increase after the first few years as tribes become more familiar with the post-rule process.

*Frequency of response:* Application by a tribe to be eligible to administer a CWA regulatory program is a one-time collection of information.

*Total estimated burden:* 9,642 tribal staff hours per year. Burden is defined at 5 CFR 1320.3(b). EPA's ICR analysis included all administrative costs associated with TAS applications even if some of the costs are not strictly information collection costs. EPA was unable to differentiate the information collection costs consistently and reliably from other administrative costs such as program development costs.

This estimate could overstate actual burden because (a) EPA assumed that all applications are first-time applications for CWA regulatory programs, and thus the tribes submitting them would be unable to rely on materials from previous applications for different regulatory programs; (b) EPA used a liberal estimate of the annual rate of tribal applications to ensure that the ICR does not underestimate tribal burden; and (c) EPA used a simplifying steady-state assumption in estimating annualized costs.

*Total estimated cost:* \$668,292, including staff salaries and the cost of contractors supporting tribal applicants. This action does not entail capital or operation and maintenance costs.

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. The OMB control numbers for EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to EPA using the docket identified in the **ADDRESSES** section at the beginning of this rule. You can also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov), Attention: Desk Officer for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than September 8, 2015. EPA will respond to any ICR-related comments in the final rule.

### C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA. This action will not impose any requirements on small entities. This action affects only Indian tribes that seek to administer CWA regulatory programs.

### D. Unfunded Mandates Reform Act (UMRA)

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments or the private sector.

### E. Executive Order 13132: Federalism

This action would not have federalism implications. It would not have substantial direct effects 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.

This proposed action would apply only to tribal governments that seek eligibility to administer CWA regulatory programs. Although it could be of interest to some state governments, it would not apply directly to any state government or to any other entity. As discussed in section VII.C., the action would have no effect on the scope of existing state regulatory programs approved by EPA under the CWA.

In the spirit of Executive Order 13132, and consistent with EPA policy to promote communications between EPA and state and local governments, EPA consulted with representatives of state governments to obtain meaningful and timely input for consideration in this proposal. On June 18, 2014, EPA invited ten national and regional state associations<sup>17</sup> by letter to a July 8, 2014, informational meeting at EPA in Washington, DC. As a result of this meeting and other outreach, EPA participated in several follow-up meetings with interested associations

<sup>17</sup> The National Governors Association, the National Conference of State Legislatures, the Council of State Governments, the Western Governors Association, the Southern Governors Association, the Midwestern Governors Association, the Coalition of Northeastern Governors, the Environmental Council of the States, the Association of Clean Water Administrators, and the Western States Water Council. In May and June 2015, EPA held additional informational meetings with the state environmental chiefs of the National Association of Attorneys General, members of the legal network of the Environmental Council of the States, and member states of the Western Governors' Association.

and their members as well as certain individual states during the months of June–September, 2014. Records of these meetings and copies of written comments and questions submitted by states and state associations are included in the docket for this rule.

Some participants expressed concerns, which included: Whether the proposal would affect the geographic scope of TAS under the CWA; whether there is adequate evidence of congressional intent; how the proposal would affect a state's ability to dispute a TAS application; and how the proposal would affect the status of existing TAS applications. Some states also had questions about issues unique to their situations. EPA considered this input in developing the proposed rule, particularly in developing sections IV. and V.

EPA specifically solicits additional comment on this proposed action from state officials.

*F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments*

This action has tribal implications because it would directly affect tribes seeking to administer CWA regulatory programs. However, it would neither impose substantial direct compliance costs on federally recognized tribal governments, nor preempt tribal law. EPA consulted and coordinated with tribal officials under the EPA Policy on Consultation and Coordination with Indian Tribes early in the process of developing this regulation to permit them to have meaningful and timely input into its development. A summary of that consultation and coordination follows.

EPA initiated a tribal consultation and coordination process for this action by sending a “Notification of Consultation and Coordination” letter on April 18, 2014, to all 566 federally recognized tribes. EPA contacted all federally recognized tribes, even though only tribes with reservations can apply for TAS under the CWA, because it is possible that additional tribes could acquire reservation lands in the future. The letter invited tribal leaders and designated consultation representatives to participate in the tribal consultation and coordination process. EPA held two identical webinars concerning this matter for tribal representatives on May 22 and May 28, 2014. A total of 70 tribal representatives participated in the two webinars, and tribes and tribal organizations sent 23 comment letters to EPA.

All tribal comments generally supported EPA's potential

reinterpretation of section 518. Some comments expressed concerns about whether there would be adequate funding to help tribes administer CWA regulatory programs after they have TAS. EPA considered the tribal comments in developing this proposal, and will continue to consider tribal resource issues in its budgeting and planning process. However, EPA cannot assure tribes that additional funding will be available for a tribe to develop or implement the CWA regulatory program it seeks. A tribe choosing to administer such programs will need to carefully weigh its priorities and any available EPA assistance.

EPA specifically solicits additional comment on this proposed action from tribal officials.

*G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks*

EPA interprets Executive Order 13045 as applying only to those regulatory actions that concern environmental health or safety risks that EPA has reason to believe could disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health or safety risk.

*H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*

This action is not subject to Executive Order 13211 because it is not a significant regulatory action under Executive Order 12866.

*I. National Technology Transfer and Advancement Act (NTTAA)*

This rulemaking does not involve technical standards.

*J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations*

This proposed interpretive rule would not have potential disproportionately high and adverse human health or environmental effects on minority, low-income, or indigenous populations. This action would affect the procedures tribes must follow in order to seek TAS for CWA regulatory purposes and would not directly affect the level of environmental protection.

Dated: July 31, 2015.

**Gina McCarthy,**  
Administrator.

[FR Doc. 2015–19351 Filed 8–6–15; 8:45 am]

BILLING CODE 6560–50–P

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 721**

[EPA–HQ–OPPT–2014–0697; FRL–9930–33]

RIN 2070–AK50

**Trichloroethylene (TCE); Significant New Use Rule; TCE in Certain Consumer Products**

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** Under the Toxic Substance Control Act (TSCA), EPA is proposing a significant new use rule (SNUR) for trichloroethylene (TCE). The proposed significant new use is manufacture or processing for use in a consumer product, with a proposed exception for use of TCE in cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants, and pepper spray. Persons subject to the SNUR would be required to notify EPA at least 90 days before commencing any manufacturing or processing of TCE for a significant new use. The required notification would provide EPA with the opportunity to evaluate the intended use and, if necessary based on the information available at that time, an opportunity to protect against potential unreasonable risks, if any, from that activity before it occurs.

**DATES:** Comments must be received on or before October 6, 2015.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2014–0697, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001.

- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** *For technical information contact:*

Katherine Sleasman, Chemical Control Division (7405M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 564-7716; email address: [sleasman.katherine@epa.gov](mailto:sleasman.katherine@epa.gov).

*For general information contact:* The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Executive Summary**

*A. Does this action apply to me?*

You may be potentially affected by this action if you manufacture, process, or distribute in commerce chemical substances and mixtures. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Textile Product Mills (NAICS code 314).
- Wood Product Manufacturing (NAICS code 321).
- Printing and Related Support Activities (NAICS code 323).
- Chemical Manufacturing (NAICS code 325).
- Plastics and Rubber Product Manufacturing (NAICS code 326).
- Primary Metal Manufacturing (NAICS code 331).
- Fabricated Metal Product Manufacturing (NAICS code 332).
- Machinery Manufacturing (NAICS code 333).
- Computer and Electronic Product Manufacturing (NAICS code 334).
- Electrical Equipment, Appliance, and Component Manufacturing (NAICS code 335).
- Transportation Equipment Manufacturing (NAICS code 336).
- Furniture and Product Related Manufacturing (NAICS code 337).
- Miscellaneous Manufacturing (NAICS code 339).
- Clothing and Clothing Accessory Stores (NAICS code 488).
- Warehousing and Storage (NAICS code 493).

- Repair and Maintenance (NAICS code 811).
- National Security and International Affairs (NAICS code 928).

This action may also affect certain entities through pre-existing import certification and export notification rules under TSCA. Persons who import any chemical substance governed by a final SNUR are subject to the TSCA section 13 (15 U.S.C. 2612) import certification requirements and the corresponding regulations at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B. In addition, any persons who export or intend to export a chemical substance that is the subject of this proposed rule on or after September 8, 2015 are subject to the export notification provisions of TSCA section 12(b) (15 U.S.C. 2611(b)), (see 40 CFR 721.20), and must comply with the export notification requirements in 40 CFR part 707, subpart D.

If you have any questions regarding the applicability of this action to a particular entity, consult the technical information contact listed under **FOR FURTHER INFORMATION CONTACT**.

*B. What is the agency's authority for taking this action?*

Section 5(a)(2) of TSCA (15 U.S.C. 2604(a)(2)) authorizes EPA to determine that a use of a chemical substance is a "significant new use." EPA must make this determination by rule after considering all relevant factors, including those listed in TSCA section 5(a)(2). Once EPA determines that a use of a chemical substance is a significant new use, TSCA section 5(a)(1)(B) requires persons to submit a significant new use notice (SNUN) to EPA at least 90 days before they manufacture (including import) or process the chemical substance for that use (15 U.S.C. 2604(a)(1)(B)). As described in Unit V., the general SNUR provisions are found at 40 CFR part 721, subpart A.

*C. What action is the agency taking?*

EPA is proposing a SNUR for trichloroethylene (TCE). The proposed significant new use is: Manufacturing and processing for any use in a consumer product of TCE except for use in cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants, and pepper spray.

The proposed significant use EPA has identified in this unit is a use that EPA believes is not ongoing at the time of this proposed rule. EPA is requesting public comment on this proposal, and specifically on the Agency's understanding of ongoing uses for the chemical identified. EPA is particularly interested in whether there are any ongoing uses of this chemical in consumer products of which the Agency is currently unaware. EPA would welcome specific documentation of any such ongoing uses. A consumer product is defined at 40 CFR 721.3 as "a chemical substance that is directly, or as part of a mixture, sold or made available to consumers for their use in or around a permanent or temporary household or residence, in or around a school, or in recreation."

This proposed SNUR would require persons that manufacture (including import) or process any of the chemicals for a significant new use, consistent with the requirements at 40 CFR 721.25, to notify EPA at least 90 days before commencing such manufacture or process of the chemical substance for a significant new use.

*D. Why is the agency taking this action?*

This SNUR is necessary to ensure that EPA receives timely advance notice of any future manufacturing and processing of TCE for new uses that may produce changes in human and environmental exposures. The rationale and objectives for this SNUR are explained in Unit III.

*E. What are the estimated incremental impacts of this action?*

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers and processors of the chemical substance included in this proposed rule. This analysis, which is available in the docket, is discussed in Unit IX., and is briefly summarized here. In the event that a SNUN is submitted, costs are estimated to be less than \$8,900 per SNUN submission for large business submitters and \$6,500 for small business submitters. These estimates include the cost to prepare and submit the SNUN and the payment of a user fee. The proposed SNUR would require first-time submitters of any TSCA section 5 notice to register their company and key users with the CDX reporting tool, deliver a CDX electronic signature to EPA, and establish and use a Pay.gov E-payment account before they may submit a SNUN, for a cost of \$203 per firm. However, these activities are only required of first time submitters of

section 5 notices. In addition, for persons exporting a substance that is the subject of a SNUR, a one-time notice to EPA must be provided for the first export or intended export to a particular country, which is estimated to be \$83 per notification.

## II. Chemical Substance Subject to This Proposed Rule

### A. What chemical is included in the proposed SNUR?

This proposed SNUR would apply to TCE (Chemical Abstract Services Registry Number (CASRN 79-01-6) manufactured or processed for use in a consumer product except for use in cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants, and pepper spray. TCE is a volatile organic compound (VOC) that is produced and imported into the United States, with use estimated to be around 250 million pounds per year. It is a clear, colorless liquid that has a sweet odor and evaporates quickly (Ref. 1).

To ascertain if TCE is used in consumer products, EPA reviewed published literature, the National Institute of Health's (NIH) Household Product Database (HPD), Safety Data Sheets (SDSs), data submitted under EPA's Chemical Data Reporting (CDR) rule, and data submitted under EPA's Toxics Release Inventory (TRI) and communicated directly with domestic manufacturers and processors (Refs. 1 and 2). From review of these resources it was confirmed that the following consumer products containing TCE are available in retail outlets and e-commerce sites: Cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants, and pepper spray. Cleaners and solvents can be used to clean automotive parts, fabrics, and carpets. EPA does not believe that there are any other types of consumer products containing TCE (Ref. 1).

Following the release of the final risk assessment, EPA received a letter from PLZ Aeroscience Corporation on March 5, 2015, indicating their intent to reformulate their spray fixative product for consumers. Their letter states that they will no longer manufacture or process spray fixatives with TCE by September 1, 2015 (Ref. 3). EPA's review of the resources indicates this is the only TCE-containing spray fixative that is still used in a consumer product.

### B. What are the production volumes and uses of TCE?

The majority (>80%) of TCE is used as an intermediate for manufacturing

refrigerant chemicals. Much of the remainder, less than 14 percent, is used as a solvent for metals degreasing, leaving a relatively small percentage to account for all other uses, including its use in consumer products. In 2011, global consumption of TCE was 945 million pounds (lbs) and U.S. consumption was 255 million lbs. Nine companies, including domestic manufacturers and importers, reported a total production of 224.7 million lbs of TCE in 2011 to the CDR database. Based on the TRI data for 2012, 38 companies use TCE as a formulation component, 33 companies process TCE by repackaging the chemical, 28 companies use TCE as a manufacturing aid, and 1,113 companies use TCE for ancillary uses, such as degreasing. Overall, most U.S. consumption is attributable to two specific uses: As an intermediate for manufacturing the refrigerant (closed system) HFC-134a (a major alternative to CFC-12), and as a solvent for metal degreasing (Ref. 1).

### C. What are the potential health effects of TCE?

A broad set of relevant studies including epidemiologic studies, animal bioassays, metabolism studies and mechanistic studies show that TCE exposure is associated with a wide array of adverse health effects. TCE has the potential to induce neurotoxicity, immunotoxicity, developmental toxicity, liver toxicity, kidney toxicity, endocrine effects, and several forms of cancer (Ref. 1).

TCE is fat soluble (lipophilic) and easily crosses biological membranes. It is readily absorbed into the body following oral, dermal, or inhalation exposure. Following oral ingestion TCE is rapidly absorbed from the gastrointestinal tract into the systemic circulation (*i.e.*, blood), and its absorption rate is highly influenced by dose of the chemical, dosing vehicle, and stomach content. Absorption through the skin has been shown by both vapor and liquid TCE contact. Likewise, absorption following inhalation of TCE is also rapid and the inhaled absorbed dose is proportional to the exposure concentration, duration of exposure, and lung ventilation rate. Regardless of the route of exposure, TCE is widely distributed throughout the body. TCE levels can be found in many different tissues including: Brain, muscle, heart, kidney, lung, liver, and adipose tissues. Due to its lipophilicity, TCE has been found in human maternal and fetal blood and in the breast milk of lactating women (Ref. 1).

The metabolism of TCE has been extensively studied in humans and

experimental rodent models. Both humans and animals metabolize TCE to numerous toxicologically active metabolites to varying degrees. These metabolites are generated from and transported across multiple tissues and play a key role in causing TCE-associated toxic effects that target the liver and kidney (Ref. 1).

TCE is characterized as carcinogenic to humans by all routes of exposure as documented in EPA's TCE Integrated Risk Information System (IRIS) assessment (Ref. 4). This conclusion is based on strong cancer epidemiological data that reported an association between TCE exposure and the onset of various cancers, primarily in the kidney, liver and the immune system (*i.e.*, non-Hodgkin lymphoma or NHL). Further support for TCE's carcinogenic characterization comes from positive results in multiple rodent cancer bioassays in rats and mice of both sexes, similar toxicokinetics between rodents and humans, mechanistic data supporting a mutagenic mode of action for kidney tumors, and the lack of mechanistic data supporting the conclusion that any of the mode(s) of action for TCE-induced rodent tumors are irrelevant to humans. Additional support comes from the recent evaluation of TCE's carcinogenic effects by the International Agency for Research on Cancer (IARC). IARC classifies TCE as carcinogenic to humans (Ref. 5).

EPA's IRIS assessment also concluded that TCE poses a potential human health hazard for non-cancer toxicity including neurotoxicity, liver and kidney effects, immunotoxicity, reproductive, and developmental effects. Also evaluated in the IRIS assessment were TCE's and its metabolites genotoxic effects. As shown through the results of *in vitro* and *in vivo* tests, TCE has the potential to bind or induce damage to the structure of DNA or chromosomes (Ref. 4).

Neurotoxicity has been demonstrated in animal and human studies under both acute and chronic exposure conditions. Evaluation of the human studies revealed TCE-induced neurotoxic effects including alterations in trigeminal nerve and vestibular function, auditory effects, changes in vision, alterations in cognitive function, changes in psychomotor effects, and neurodevelopmental outcomes. The strongest neurological evidence of human toxicological hazard is for changes in trigeminal nerve function or morphology and impairment of vestibular function. Multiple epidemiological studies in different populations have reported TCE-induced abnormalities in trigeminal nerve

function in humans, and various human studies have consistently reported vestibular system-related symptoms such as headaches, dizziness, and nausea following TCE exposure (Ref. 1).

Animals and humans exposed to TCE consistently experience liver toxicity. Specific effects include the following structural changes: Increased liver weight, increase in deoxyribonucleic acid (DNA) synthesis (transient), enlarged hepatocytes, enlarged nuclei, and peroxisome proliferation. Several human studies reported an association between TCE exposure and significant changes in serum liver function tests used in diagnosing liver disease, or changes in plasma or serum bile acids. There was also human evidence for hepatitis accompanying immune-related generalized skin diseases, jaundice, hepatomegaly, hepatosplenomegaly, and liver failure in TCE-exposed workers. For kidney effects, studies in both humans and animals have shown changes in the proximate tubules of the kidney following exposure to TCE. TCE metabolites also appear to be the causative agents that induce renal toxicity (Ref. 1).

Immune-related effects following TCE exposures have been observed in both animal and human studies. In general, these effects were associated with inducing enhanced immune responses as opposed to immunosuppressive effects. Human studies have reported a relationship between systemic autoimmune diseases, such as scleroderma with occupational exposure to TCE. There have also been a large number of case reports in TCE-exposed workers developing a severe hypersensitivity skin disorder, often accompanied by systemic effects to the lymph nodes and other organs, such as hepatitis (Ref. 1).

The toxicological literature provides support for male and female reproductive toxicity following TCE exposure. Both the epidemiological and animal studies provide evidence of adverse outcomes to female reproductive outcomes. However, much more extensive evidence exists in support of an association between TCE exposures and male reproductive toxicity. There is evidence that the metabolism of TCE in male reproductive tract tissues is associated with adverse effects on sperm measures in both humans and animals. Furthermore, human studies support an association between TCE exposure and alterations in sperm density and quality, as well as changes in sexual drive or function and altered serum endocrine levels (Ref. 1).

An evaluation of the overall weight and strength of the evidence of the

human and animal developmental toxicity data suggests an association between pre- and/or post-natal TCE exposures and potential adverse developmental outcomes. TCE-induced heart malformations in animals have been identified as the most sensitive developmental toxicity endpoint for TCE. Human studies examined the possible association of TCE with various prenatal effects. These adverse effects of developmental TCE exposure could include death (spontaneous abortion, perinatal death, pre- or post-implantation loss, resorptions), decreased growth (low birth weight, small for gestational age), and congenital malformations, in particular cardiac defects, and postnatal effects such as growth, survival, developmental neurotoxicity, developmental immunotoxicity, and childhood cancers. There have also been some epidemiological studies that have consistently reported an increased incidence of birth defects in TCE-exposed populations from exposure to contaminated water. As for human developmental neurotoxicity, studies collectively suggest that the developing brain is susceptible to TCE toxicity. These studies have reported an association with TCE exposure and central nervous system birth defects and postnatal effects such as delayed newborn reflexes, impaired learning or memory, aggressive behavior, hearing impairment, speech impairment, encephalopathy, impaired executive and motor function and attention deficit (Ref. 1).

#### *D. What are the potential routes and sources of exposure to TCE?*

The main route of exposure for TCE is inhalation due to its chemical properties and the nature of the consumer products. However, EPA recognizes that highly volatile compounds such as TCE may also be absorbed through the skin. (Ref. 1).

In EPA's final risk assessment for TCE, EPA examined acute risks for consumer exposures in residential settings. The assessment identified risks to consumers and residential bystanders from use of solvent degreasers and protective spray coatings, also referred to as spray fixatives, because of either their high TCE content or high potential for human exposure. TCE is also present in film cleaners, and mirror edge sealants, but these products were not evaluated because of either their low TCE content, less frequent use, or low exposure potential. The final risk assessment calculated indoor air concentrations using the Exposure and Fast Assessment Screening Tool Version

2 (E-FAST2) Consumer Exposure Model (CEM) for the consumer exposure. EPA used E-FAST2 CEM because of the lack of available emissions and monitoring data for the TCE containing consumer products (Ref. 1).

For the spray fixatives and solvent degreasers used by consumers who experience exposures, there is the potential for acute risks that could result from even one improper use of these products containing TCE. Most consumers would be unaware of the potential toxicity of consumer products containing TCE. Consequently, insufficient and inadequate hazard communication may lead to incorrect use and increased consumer and bystander exposures. Even if consumers are aware of such potential hazards, they may not take appropriate precautions or research the appropriate resources in which these precautions are addressed. Of particular concern is that TCE has harmful effects that occur below the odor threshold, meaning that smelling the chemical in the home environment is not a sufficient approach to avoid hazardous effects (Ref. 1).

### **III. Rationale and Objectives**

#### *A. Rationale*

EPA is concerned about the adverse health effects of TCE resulting from commercial and consumer uses of the chemical substance identified for a risk assessment as part of EPA's Existing Chemicals Management Program. EPA identified a work plan of 83 chemicals including TCE for further assessment under the TSCA Work Plan for Chemical Assessments in March 2012, to help focus and direct the activities of its Existing Chemicals Management Program. EPA reviewed readily available information on TCE including uses, physical and chemical properties, fate, exposure potential, and associated hazards to humans and the environment. TCE was selected based on concerns for its human health hazard (e.g., human carcinogen) and its exposure profile (i.e., widely used in consumer products and detected in drinking water, indoor environments, surface water, ambient air, groundwater, and soil) using OPPT's TSCA Work Plan screening methodology (Ref. 6). In EPA's final risk assessment released on June 25, 2014, the Agency identified risks to workers using TCE and non-workers for degreasers and a spot-cleaner in dry cleaning uses, and EPA also identified health risks to consumers using spray aerosol degreasers and spray fixatives (Ref. 1).

EPA believes that any additional use of this chemical substance in consumer

products could significantly increase human exposure, and that such exposures should not occur without an opportunity for EPA review and control as appropriate. However, as discussed in Unit II, based on review of SDSs and the NIH's HPD, EPA believes that cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants, and pepper spray contain TCE. EPA believes that other consumer products do not presently contain TCE, other than spray fixative product use which will be discontinued by September 1, 2015 as described in Unit II.A.

Consistent with EPA's past practice for issuing SNURs under TSCA section 5(a)(2), EPA's decision to propose a SNUR for a particular chemical use need not be based on an extensive evaluation of the hazard, exposure, or potential risk associated with that use. Rather, the Agency action is based on EPA's determination that if the use begins or resumes, it may present a risk that EPA should evaluate under TSCA before the manufacturing or processing for that use begins. Since the new use does not currently exist, deferring a detailed consideration of potential risks or hazards related to that use is an effective use of resources. If a person decides to begin manufacturing or processing the chemical for the use, the notice to EPA allows EPA to evaluate the use according to the specific parameters and circumstances surrounding that intended use.

#### B. Objectives

Based on the considerations in Unit III.A., EPA wants to achieve the following objectives with regard to the significant new use(s) that are designated in this proposed rule:

1. EPA would receive notice of any person's intent to manufacture or process TCE for the described significant new use before that activity begins.
2. EPA would have an opportunity to review and evaluate data submitted in a SNUN before the notice submitter begins manufacturing or processing TCE for the described significant new use.
3. EPA would be able to regulate prospective manufacturers or processors of TCE before the described significant new use of the chemical substance occurs, provided that regulation is warranted pursuant to TSCA section 5(e), 5(f), 6 or 7.

#### IV. Significant New Use Determination

Section 5(a)(2) of TSCA states that EPA's determination that a use of a chemical substance is a significant new

use must be made after consideration of all relevant factors including:

1. The projected volume of manufacturing and processing of a chemical substance.
2. The extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance.
3. The extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance.
4. The reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

In addition to these factors enumerated in TSCA section 5(a)(2), the statute authorizes EPA to consider any other relevant factors.

To determine what would constitute a significant new use of TCE compounds subject to this proposed rule, as discussed in this unit, EPA considered relevant information about the toxicity of the substance, likely human exposures and environmental releases associated with possible uses, and the four factors listed in section 5(a)(2) of TSCA. EPA has preliminarily determined as the significant new use: Manufacture or processing for any use in a consumer product except for use in cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants, and pepper spray. Because TCE is not used in consumer products (with the limited exceptions of use in cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants, pepper spray, and (before September 1, 2015) spray fixatives), EPA believes new use in consumer products could increase the magnitude and duration of human exposure to TCE. Exposure to TCE through inhalation may lead to a wide array of adverse health effects, such as neurotoxicity, immunotoxicity, developmental toxicity, liver toxicity, kidney toxicity, endocrine effects, and several forms of cancer, as further explained in Unit II.C., and because of these adverse effects EPA would like the opportunity to evaluate such potential uses in consumer products for any associated risks or hazards that might exist before those uses would begin.

#### V. Applicability of General Provisions

General provisions for SNURs appear under 40 CFR part 721, subpart A. These provisions describe persons subject to the rule, recordkeeping requirements, exemptions to reporting requirements, and applicability of the rule to uses occurring before the effective date of the final rule.

Provisions relating to user fees appear at 40 CFR part 700. According to 40 CFR 721.1(c), persons subject to SNURs must comply with the same notice requirements and EPA regulatory procedures as submitters of Premanufacture Notices (PMNs) under TSCA section 5(a)(1)(A). In particular, these requirements include the information submissions requirements of TSCA section 5(b) and 5(d)(1), the exemptions authorized by TSCA section 5(h)(1), (h)(2), (h)(3), and (h)(5), and the regulations at 40 CFR part 720. Once EPA receives a SNUN, EPA may take regulatory action under TSCA section 5(e), 5(f), 6 or 7 to control the activities on which it has received the SNUN. If EPA does not take action, EPA is required under TSCA section 5(g) to explain in the **Federal Register** its reasons for not taking action.

Persons who export or intend to export a chemical substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret TSCA section 12(b) appear at 40 CFR part 707, subpart D. In accordance with 40 CFR 707.60(b) this proposed SNUR does not trigger export notification for articles. Persons who import a chemical substance identified in a final SNUR are subject to the TSCA section 13 import certification requirements, codified at 19 CFR 12.118 through 12.127; see also 19 CFR 127.28. Those persons must certify that the shipment of the chemical substance complies with all applicable rules and orders under TSCA, including any SNUR requirements. The EPA policy in support of import certification appears at 40 CFR part 707, subpart B.

#### VI. Applicability of Rule to Uses Occurring Before Effective Date of the Final Rule

As discussed in the **Federal Register** of April 24, 1990 (55 FR 17376; FRL-3658-5) (Ref. 7), EPA has decided that the intent of section 5(a)(1)(B) of TSCA is best served by designating a use as a significant new use as of the date of publication of the proposed rule rather than as of the effective date of the final rule. If uses begun after publication of the proposed rule were considered ongoing rather than new, it would be difficult for EPA to establish SNUR notice requirements, because a person could defeat the SNUR by initiating the proposed significant new use before the rule became final, and then argue that the use was ongoing as of the effective date of the final rule. Thus, persons who begin commercial manufacture or processing of the chemical substance(s) that would be regulated through this

proposed rule, if finalized, would have to cease any such activity before the effective date of the rule if and when finalized. To resume their activities, these persons would have to comply with all applicable SNUR notice requirements and wait until the notice review period, including all extensions, expires. Uses arising after the publication of the proposed rule are distinguished from uses that exist at publication of the proposed rule. The former would be new uses, the latter ongoing uses, except that uses that are ongoing as of the publication of the proposed rule would not be considered ongoing uses if they have ceased by the date of issuance of a final rule. However, recognizing the use in a consumer product of TCE in spray fixatives will cease by September 1, 2015 as described in Unit II.A., EPA considers September 1, 2015 as the date from which the significant new use with respect only to such spray fixatives would be designated. To the extent that additional ongoing uses are found in the course of rulemaking, EPA would exclude those specific uses from the final SNUR. EPA has promulgated provisions to allow persons to comply with the final SNUR before the effective date. If a person were to meet the conditions of advance compliance under 40 CFR 721.45(h), that person would be considered to have met the requirements of the final SNUR for those activities.

#### VII. Test Data and Other Information

EPA recognizes that TSCA section 5 does not usually require developing any particular test data before submission of a SNUN. There are two exceptions:

1. Development of test data is required where the chemical substance subject to the SNUR is also subject to a test rule under TSCA section 4 (see TSCA section 5(b)(1)); and
2. Development of test data may be necessary where the chemical substance has been listed under TSCA section 5(b)(4) (see TSCA section 5(b)(2)).

In the absence of a section 4 test rule or a section 5(b)(4) listing covering the chemical substance, persons are required to submit only test data in their possession or control and to describe any other data known to or reasonably ascertainable by them (15 U.S.C. 2604(d); 40 CFR 721.25, and 40 CFR 720.50). However, as a general matter, EPA recommends that SNUN submitters include data that would permit a reasoned evaluation of risks posed by the chemical substance during its manufacture, processing, use, distribution in commerce, or disposal. EPA encourages persons to consult with

the agency before submitting a SNUN. As part of this optional pre-notice consultation, EPA would discuss specific data it believes may be useful in evaluating a significant new use. SNUNs submitted for significant new uses without any test data may increase the likelihood that EPA will take action under TSCA section 5(e) to prohibit or limit activities associated with this chemical.

SNUN submitters should be aware that EPA will be better able to evaluate SNUNs that provide detailed information on:

- Human exposure and environmental releases that may result from the significant new uses of the chemical substance;
- Potential benefits of the chemical substance; and
- Information on risks posed by the chemical substances compared to risks posed by potential substitutes.

#### VIII. SNUN Submissions

EPA recommends that submitters consult with the Agency prior to submitting a SNUN to discuss what data may be useful in evaluating a significant new use. Discussions with the Agency prior to submission can afford ample time to conduct any tests that might be helpful in evaluating risks posed by the substance. According to 40 CFR 721.1(c), persons submitting a SNUN must comply with the same notice requirements and EPA regulatory procedures as persons submitting a PMN, including submission of test data on health and environmental effects as described in 40 CFR 720.50. SNUNs must be submitted on EPA Form No. 7710-25, generated using e-PMN software, and submitted to the Agency in accordance with the procedures set forth in 40 CFR 721.25 and 40 CFR 720.40. E-PMN software is available electronically at <http://www.epa.gov/opptintr/newchems>.

#### IX. Economic Analysis

##### A. SNUNs

EPA has evaluated the potential costs of establishing SNUR reporting requirements for potential manufacturers and processors of the chemical substance included in this proposed rule (Ref. 2). In the event that a SNUN is submitted, costs are estimated at approximately \$8,900 per SNUN submission for large business submitters and \$6,500 for small business submitters. These estimates include the cost to prepare and submit the SNUN, and the payment of a user fee. Businesses that submit a SNUN would be subject to either a \$2,500 user

fee required by 40 CFR 700.45(b)(2)(iii), or, if they are a small business with annual sales of less than \$40 million when combined with those of the parent company (if any), a reduced user fee of \$100 (40 CFR 700.45(b)(1)). EPA's complete economic analysis is available in the public docket for this proposed rule (Ref. 2).

##### B. Export Notification

Under section 12(b) of TSCA and the implementing regulations at 40 CFR part 707, subpart D, exporters must notify EPA if they export or intend to export a chemical substance or mixture for which, among other things, a rule has been proposed or promulgated under TSCA section 5. For persons exporting a substance that is the subject of a SNUR, a one-time notice to EPA must be provided for the first export or intended export to a particular country. The total costs of export notification will vary by chemical, depending on the number of required notifications (*i.e.*, the number of countries to which the chemical is exported). While EPA is unable to make any estimate of the likely number of export notifications for the chemical covered in this proposed SNUR, as stated in the accompanying economic analysis of this proposed SNUR, the estimated cost of the export notification requirement on a per unit basis is \$83.

#### X. Alternatives

Before proposing this SNUR, EPA considered the following alternative regulatory action: *Promulgate a TSCA Section 8(a) Reporting Rule*.

Under a TSCA section 8(a) rule, EPA could, among other things, generally require persons to report information to the agency when they intend to manufacture or process a listed chemical for a specific use or any use. However, for TCE, the use of TSCA section 8(a) rather than SNUR authority would have several limitations. First, if EPA were to require reporting under TSCA section 8(a) instead of TSCA section 5(a), EPA would not have the opportunity to review human and environmental hazards and exposures associated with the proposed significant new use and, if necessary, take immediate follow-up regulatory action under TSCA section 5(e) or 5(f) to prohibit or limit the activity before it begins. In addition, EPA may not receive important information from small businesses, because such firms generally are exempt from TSCA section 8(a) reporting requirements (see TSCA sections 8(a)(1)(A) and 8(a)(1)(B)). In view of the level of health concerns about TCE if used for the proposed significant new use, EPA believes that a

TSCA section 8(a) rule for this substance would not meet EPA's regulatory objectives.

## XI. Request for Comment

### A. Do you have comments or information about ongoing uses?

EPA welcomes comment on all aspects of this proposed rule. EPA based its understanding of the use profile of these chemicals on the published literature, the 2012 CDR submissions, market research, discussions with manufacturers, and review of SDSs. To confirm EPA's understanding, the Agency is requesting public comment on the EPA's understanding that cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants, and pepper spray contain TCE. The Agency is also requesting public comment if any of the listed uses that contain TCE are no longer available to consumers. EPA believes that other consumer products do not contain TCE, however, EPA is interested in information indicating that there are other ongoing uses of TCE in consumer products. In providing comments on an ongoing use of TCE in a consumer product, it would be helpful if you provide sufficient information for EPA to substantiate any assertions of use.

### B. What should I consider as I prepare my comments for EPA?

1. *Submitting CBI.* It is EPA's policy to include all comments received in the public docket without change or further notice to the commenter and to make the comments available on-line at [www.regulations.gov](http://www.regulations.gov), including any personal information provided, unless a comment includes information claimed to be CBI or other information whose disclosure is restricted by statute. Do not submit this information to EPA through [regulations.gov](http://regulations.gov) or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI information in a disk or CD ROM that you mail to EPA, mark the outside of the disk or CD ROM that you mail to EPA as CBI and then identify electronically within the disk or CD ROM the specific information that is claimed as CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2, subpart B.

2. *Tips for preparing your comments.* When submitting comments, remember to:

- i. Identify the document by docket ID number and other identifying information (subject heading, **Federal Register** date, and page number).
- ii. Follow directions. The agency may ask you to respond to specific questions or organize comments by referencing a CFR part or section number.
- iii. Explain why you agree or disagree; suggest alternatives and substitute language for your requested changes.
- iv. Describe any assumptions and provide any technical information and/or data that you used.
- v. If you estimate potential costs or burdens, explain how you arrived at your estimate in sufficient detail to allow for it to be reproduced.
- vi. Provide specific examples to illustrate your concerns and suggest alternatives.
- vii. Explain your views as clearly as possible, avoiding the use of profanity or personal threats.
- viii. Make sure to submit your comments by the comment period deadline identified.

## XII. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. U.S. EPA. Final Risk Assessment on Trichloroethylene (TCE). June 25, 2014.
2. U.S. EPA. Economic Analysis of the Significant New Use Rule for Trichloroethylene. February 19, 2015.
3. Letter from PLZ Aerospace Corporation. March 5, 2015.
4. U.S. EPA. (2011). Toxicological Review of Trichloroethylene (CAS No. 79-01-6). EPA/635/R-09/011F. Integrated Risk Information System, Washington, DC.
5. IARC (2014). *International Agency for Research on Cancer. Monographs on the Evaluation of Carcinogenic Risks to Humans: Cadmium, Trichloroethylene, Tetrachloroethylene, and Some Chlorinated Agents*, Volume 106. World Health Organization, Lyon, France.
6. U.S. EPA. (2014). TSCA Work Plan for Chemical Assessments: 2014 Update. Washington, DC.
7. U.S. EPA. Significant New Uses of Certain Chemical Substances. **Federal Register** of April 24, 1990, (55 FR 173776) (FRL-3658-5).

## XIII. Statutory and Executive Order Reviews

A. *Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review*

This proposed SNUR is not a "significant regulatory action" under the terms of the Executive Order 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under Executive Order 12866 and 13563, entitled "Improving Regulation and Regulatory Review" (76 FR 3821, January 21, 2011).

### B. Paperwork Reduction Act (PRA)

This action does not impose any new information collection burden under the PRA, 44 U.S.C. 3501 *et seq.* Burden is defined in 5 CFR 1320.3(b). The information collection activities associated with existing chemical SNURs are already approved by OMB under OMB control number 2070-0038 (EPA ICR No. 1188); and the information collection activities associated with export notifications are already approved by OMB under OMB control number 2070-0030 (EPA ICR No. 0795). If an entity were to submit a SNUN to the Agency, the annual burden is estimated to be less than 100 hours per response, and the estimated burden for export notifications is less than 1.5 hours per notification. In both cases, burden is estimated to be reduced for submitters who have already registered to use the electronic submission system.

An agency may not conduct or sponsor, and a person is not required to respond to a collection of information that requires OMB approval under the PRA, unless it has been approved by OMB and displays a currently valid OMB control number. The OMB control numbers for EPA's regulations in title 40 of the CFR, after appearing in the **Federal Register**, are listed in 40 CFR part 9, and included on the related collection instrument, or form, if applicable.

### C. Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the RFA, 5 U.S.C. 601 *et seq.*, I hereby certify that promulgation of this SNUR would not have a significant economic impact on a substantial number of small entities. The rationale supporting this conclusion is as follows.

A SNUR applies to any person (including small or large entities) who intends to engage in any activity described in the rule as a "significant new use." By definition of the word "new" and based on all information currently available to EPA, it appears



that no small or large entities presently engage in such activities. Since this SNUR will require a person who intends to engage in such activity in the future to first notify EPA by submitting a SNUN, no economic impact will occur unless someone files a SNUN to pursue a significant new use in the future or forgoes profits by avoiding or delaying the significant new use. Although some small entities may decide to conduct such activities in the future, EPA cannot presently determine how many, if any, there may be. However, EPA's experience to date is that, in response to the promulgation of SNURs covering over 1,000 chemical substances, the Agency receives only a handful of notices per year. During the six year period from 2005–2010, only three submitters self-identified as small in their SNUN submission (Ref. 2). EPA believes the cost of submitting a SNUN is relatively small compared to the cost of developing and marketing a chemical new to a firm or marketing a new use of the chemical and that the requirement to submit a SNUN generally does not have a significant economic impact.

Therefore, EPA believes that the potential economic impact of complying with this proposed SNUR is not expected to be significant or adversely impact a substantial number of small entities. In a SNUR that published as a final rule on August 8, 1997 (62 FR 42690) (FRL–5735–4), the Agency presented its general determination that proposed and final SNURs are not expected to have a significant economic impact on a substantial number of small entities, which was provided to the Chief Counsel for Advocacy of the Small Business Administration.

#### *D. Unfunded Mandates Reform Act (UMRA)*

Based on EPA's experience with proposing and finalizing SNURs, State, local, and Tribal governments have not been impacted by these rulemakings, and EPA does not have any reason to believe that any State, local, or Tribal government would be impacted by this rulemaking. As such, the requirements of sections 202, 203, 204, or 205 of UMRA, 2 U.S.C. 1531–1538, do not apply to this action.

#### *E. Executive Order 13132: Federalism*

This action will not have a substantial direct effect on 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, as specified in

Executive Order 13132 (64 FR 43255, August 10, 1999).

#### *F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments*

This proposed rule does not have Tribal implications because it is not expected to have any effect (*i.e.*, there will be no increase or decrease in authority or jurisdiction) on Tribal governments, on the relationship between the Federal government and the Indian tribes, or on the distribution of power and responsibilities between the Federal government and Indian tribes. Thus, Executive Order 13175 (65 FR 67249, November 9, 2000) does not apply to this action.

#### *G. Executive Order 13045: Protection of Children from Environmental Health Risks and Safety Risks*

This action is not subject to Executive Order 13045 (62 FR 19885, April 23, 1997), because this action is not intended to address environmental health or safety risks for children.

#### *H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*

This proposed rule is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not expected to affect energy supply, distribution, or use.

#### *I. National Technology Transfer and Advancement Act (NTTAA)*

Since this action does not involve any technical standards, section 12(d) of NTTAA, 15 U.S.C. 272 note, does not apply to this action.

#### *J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations*

This proposed rule does not invoke special consideration of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994), because EPA has determined that this action will not have disproportionately high and adverse human health or environmental effects on minority or low-income populations. This action does not affect the level of protection provided to human health or the environment.

#### **List of Subjects in 40 CFR Part 721**

Environmental protection, Chemicals, Hazardous substances, Reporting and recordkeeping requirements.

Dated: July 30, 2015.

**Wendy C. Hamnett,**

*Director, Office of Pollution Prevention and Toxics.*

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

#### **PART 721—[AMENDED]**

■ 1. The authority citation for part 721 continues to read as follows:

**Authority:** 15 U.S.C. 2604, 2607, and 2625(c).

■ 2. Add § 721.10851 to subpart E to read as follows:

#### **§ 721.10851 Trichloroethylene.**

(a) *Chemical substance and significant new uses subject to reporting.*

(1) The chemical substance trichloroethylene (CAS 79–01–6) is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section.

(2) Manufacture or processing for use in a consumer product except for use in cleaners and solvent degreasers, film cleaners, hoof polishes, lubricants, mirror edge sealants, and pepper spray.

(b) [Reserved]

[FR Doc. 2015–19348 Filed 8–6–15; 8:45 am]

**BILLING CODE 6560–50–P**

## **FEDERAL COMMUNICATIONS COMMISSION**

### **47 CFR Part 54**

[WC Docket Nos. 10–90 and 14–259; Report 3025]

#### **Petition for Reconsideration of Action in a Rulemaking Proceeding**

**AGENCY:** Federal Communications Commission.

**ACTION:** Petition for reconsideration.

**SUMMARY:** A Petition for Reconsideration (Petition) has been filed in the Commission's Rulemaking proceeding by Harold Mordkofsky, on behalf of Halstad Telephone Company.

**DATES:** Oppositions to the Petition must be filed on or before August 24, 2015. Replies to an opposition must be filed on or before September 1, 2015.

**ADDRESSES:** Federal Communications Commission, 445 12th Street SW., Washington, DC 20554.

**FOR FURTHER INFORMATION CONTACT:** Alexander Minard, Telecommunications Access Policy Division, Wireline Competition Bureau, (202) 418–7400, email: [Alexander.Minard@fcc.gov](mailto:Alexander.Minard@fcc.gov), TTY (202) 418–0484.

**SUPPLEMENTARY INFORMATION:** This is a summary of Commission's document,

Report No. 3025, released July 20, 2015. The full text of Report No. 3025 is available for viewing and copying in Room CY-B402, 445 12th Street SW., Washington, DC or may be accessed online via the Commission's Electronic Comment Filing System at <http://apps.fcc.gov/ecfs/>. The Commission will not send a copy of this *document*

pursuant to the Congressional Review Act, 5 U.S.C. 801(a)(1)(A), because this *document* does not have an impact on any rules of particular applicability.  
*Subjects:* Connect America Fund; Rural Broadband Experiments, released by the Commission on June 15, 2015, in WC Docket Nos. 10-90 and 14-259, and published pursuant to 47 CFR 1.429(e).

*See also* § 1.4(b)(1) of the Commission's rules.

*Number of Petitions Filed:* 1.

Federal Communications Commission.

**Marlene H. Dortch,**

*Secretary.*

[FR Doc. 2015-19374 Filed 8-6-15; 8:45 am]

**BILLING CODE 6712-01-P**

# Notices

Federal Register

Vol. 80, No. 152

Friday, August 7, 2015

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

### Submission for OMB Review; Comment Request

August 3, 2015.

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 regarding (a) 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; (b) the accuracy of the agency's estimate of burden including the validity of the methodology and assumptions used; (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 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 September 8, 2015 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), New Executive Office Building, 725 17th Street NW., Washington, DC 20502. Commenters are encouraged to submit their comments to OMB via email to: [OIRA\\_Submission@OMB.EOP.GOV](mailto: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.

### Farm Service Agency

*Title:* Request for Aerial Photography.

*OMB Control Number:* 0560-0176.

*Summary of Collection:* The Farm Service Agency (FSA) Aerial Photography Field Office (APFO) has the authority to coordinate aerial photography work in USDA, develop and carry out aerial photography and remote sensing programs and the Agency's aerial photography flying contract programs. The film APFO secures is public domain and reproductions are available at cost to any customer with a need. FSA will collect information using the following three forms FSA-441, Request for Aerial Imagery, FSA 441B, Customer Digital Print Form, and FSA 441C APFO Service Quality Survey.

*Need and Use of the Information:* FSA will collect the name, address, contact name, telephone, fax, email, customer code, agency code, purchase order number, credit card number/exp. date and amount remitted/PO amount. Customers have the option of placing orders by mail, fax, telephone, and walk-in. Furnishing this information requires the customer to research and prepare their request before submitting it to APFO. Information collected is used to process fiscal obligations, communicate with the customer, process the request, and ship the requested products.

*Description of Respondents:* Farms; Individuals or household; Business or other for-profit; Federal Government; State, Local or Tribal Government.

*Number of Respondents:* 12,120.

*Frequency of Responses:* Recordkeeping; Reporting; Annually; Other (when ordering).

*Total Burden Hours:* 3,770.

### Ruth Brown,

Departmental Information Collection Clearance Officer.

[FR Doc. 2015-19406 Filed 8-6-15; 8:45 am]

**BILLING CODE 3410-05-P**

## DEPARTMENT OF AGRICULTURE

### Forest Service

### Tuolumne and Mariposa Counties Resource Advisory Committee

**AGENCY:** Forest Service, USDA.

**ACTION:** Notice of meeting.

**SUMMARY:** The Tuolumne and Mariposa Counties Resource Advisory Committee (RAC) will meet in Sonora, California. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act. Additional RAC information, including the meeting agenda and the meeting summary/minutes can be found at the following Web site: <http://www.fs.usda.gov/main/pts/specialprojects/racweb>.

**DATES:** The meeting will be held September 10, 2015, from 12:00 p.m. to 3:00 p.m.

All RAC meetings are subject to cancellation. For status of meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

**ADDRESSES:** The meeting will be held at the City of Sonora Fire Department, 201 South Shephard Street, Sonora, California.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Stanislaus National Forest Supervisor's Office. Please call ahead to facilitate entry into the building.

**FOR FURTHER INFORMATION CONTACT:** Beth Martinez, RAC Coordinator, by phone at 209-532-3671, extension 321; or via email at [bethmartinez@fs.fed.us](mailto:bethmartinez@fs.fed.us).

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

**SUPPLEMENTARY INFORMATION:** The purpose of the meeting is:

1. To vote on project proposals; and
2. Make recommendations to the

Forest Service from the Tuolumne and Mariposa Counties RAC.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by at least a week in advance to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time for oral comments must be sent to Beth Martinez, RAC Coordinator, Stanislaus National Forest, 19777 Greenley Road, Sonora, California 95370; by email to [bethmartinez@fs.fed.us](mailto:bethmartinez@fs.fed.us), or via facsimile to ATTN: Beth Martinez at (209) 533-1890.

**Meeting Accommodations:** If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices or other reasonable accommodation for access to the facility or proceedings by contacting the person listed in the section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case by case basis.

Dated: August 3, 2015.

**Jeanne M. Higgins,**  
Forest Supervisor.

[FR Doc. 2015-19462 Filed 8-6-15; 8:45 am]

BILLING CODE 3410-11-P

## DEPARTMENT OF AGRICULTURE

### Forest Service

#### Tuolumne and Mariposa Counties Resource Advisory Committee

**AGENCY:** Forest Service, USDA.

**ACTION:** Notice of meeting.

**SUMMARY:** The Tuolumne and Mariposa Counties Resource Advisory Committee (RAC) will meet in Sonora, California. The committee is authorized under the Secure Rural Schools and Community Self-Determination Act (the Act) and operates in compliance with the Federal Advisory Committee Act. The purpose of the committee is to improve collaborative relationships and to provide advice and recommendations to the Forest Service concerning projects and funding consistent with Title II of the Act. Additional RAC information, including the meeting agenda and the

meeting summary/minutes can be found at the following Web site: <http://www.fs.usda.gov/main/pts/specialprojects/racweb>.

**DATES:** The meeting will be held August 31, 2015, from 12:00 p.m. to 3:00 p.m.

All RAC meetings are subject to cancellation. For status of meeting prior to attendance, please contact the person listed under **FOR FURTHER INFORMATION CONTACT**.

**ADDRESSES:** The meeting will be held at the City of Sonora Fire Department, 201 South Shephard Street, Sonora, California.

Written comments may be submitted as described under **SUPPLEMENTARY INFORMATION**. All comments, including names and addresses when provided, are placed in the record and are available for public inspection and copying. The public may inspect comments received at the Stanislaus National Forest Supervisor's Office. Please call ahead to facilitate entry into the building.

**FOR FURTHER INFORMATION CONTACT:** Beth Martinez, RAC Coordinator, by phone at 209-532-3671, extension 321; or via email at [bethmartinez@fs.fed.us](mailto:bethmartinez@fs.fed.us).

Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8:00 a.m. and 8:00 p.m., Eastern Standard Time, Monday through Friday.

**SUPPLEMENTARY INFORMATION:** The purpose of the meeting is for project proponents to make oral presentations about their projects.

The meeting is open to the public. The agenda will include time for people to make oral statements of three minutes or less. Individuals wishing to make an oral statement should request in writing by at least a week in advance to be scheduled on the agenda. Anyone who would like to bring related matters to the attention of the committee may file written statements with the committee staff before or after the meeting. Written comments and requests for time for oral comments must be sent to Beth Martinez, RAC Coordinator, Stanislaus National Forest, 19777 Greenley Road, Sonora, California 95370; by email to [bethmartinez@fs.fed.us](mailto:bethmartinez@fs.fed.us), or via facsimile to ATTN: Beth Martinez at 209-533-1890.

**Meeting Accommodations:** If you are a person requiring reasonable accommodation, please make requests in advance for sign language interpreting, assistive listening devices or other reasonable accommodation for access to the facility or proceedings by contacting the person listed in the

section titled **FOR FURTHER INFORMATION CONTACT**. All reasonable accommodation requests are managed on a case by case basis.

Dated: August 3, 2015.

**Jeanne M. Higgins**  
Forest Supervisor.

[FR Doc. 2015-19461 Filed 8-6-15; 8:45 am]

BILLING CODE 3411-15-P

## DEPARTMENT OF AGRICULTURE

### Rural Business-Cooperative Service

#### Inviting Rural Business Development Grant Program Applications for Grants To Provide Technical Assistance for Rural Transportation Systems

**AGENCY:** Rural Business—Cooperative Service, USDA.

**ACTION:** Initial Notice; Correction.

**SUMMARY:** This document corrects an error in the initial notice that appeared in the **Federal Register** on July 28, 2015, entitled "Inviting Rural Business Development Grant Program Applications for Grants to Provide Technical Assistance for Rural Transportation Systems." On page 44928, first column, the incorrect application deadline date was used and does not match with the date under the **DATES** section of the initial notice.

**DATES:** This document is effective August 7, 2015.

**FOR FURTHER INFORMATION CONTACT:** Specialty Programs Division, Business Programs, Rural Business-Cooperative Service, United States Department of Agriculture, 1400 Independence Avenue SW., MS 3226, Room 4204-South, Washington, DC 20250-3226, telephone (202) 720-1400.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2015-18391 of July 28, 2015 (80 FR 44925), make the following corrections:

1. On page 44928, in the first column, at the fifty-first line, remove "September 28" and add "August 27" in its place.

Dated: July 31, 2015.

**Lillian E. Salerno,**  
Administrator, Rural Business-Cooperative Service.

[FR Doc. 2015-19405 Filed 8-6-15; 8:45 am]

BILLING CODE 3410-XY-P

**DEPARTMENT OF AGRICULTURE****Rural Utilities Service****Energy Answers Arcibo, LLC: Notice of Availability of a Draft Environmental Impact Statement and Notice of a Public Meeting**

**AGENCY:** Rural Utilities Service, USDA.

**ACTION:** Notice of availability of a draft environmental impact statement.

**SUMMARY:** The Rural Utilities Service (RUS), an agency within the U.S. Department of Agriculture (USDA), has issued a Draft Environmental Impact Statement (EIS) for Energy Answers Arcibo, LLC's (Energy Answers) proposed Waste to Energy Project (Project) in Arcibo, Puerto Rico. RUS is issuing the Draft EIS to inform interested parties and the general public about the proposed Project and to invite the public to comment on the scope, proposed action, and other issues addressed in the Draft EIS. The Draft EIS addresses the construction, operation, and maintenance of Energy Answers' proposed Project, a waste-to-energy facility in the Cambalache Ward of Arcibo, Puerto Rico. RUS prepared the EIS in accordance with the National Environmental Policy Act (NEPA), as amended, the Council on Environmental Quality's Regulation for Implementing the Procedural Provisions of the NEPA (40 CFR parts 1500–1508), and RUS's Environmental Policies and Procedures (7 CFR part 1794). RUS will hold a public hearing to receive oral comments on the Draft EIS.

**DATES:** The public comment period on the Draft EIS will be announced in the U.S. Environmental Protection Agency's (USEPA) EIS receipt notice, which will be published in the **Federal Register**. RUS will consider all substantive written comments on the Draft EIS received or postmarked by that date. Agencies, interested parties, and the general public are invited to submit comments on the Draft EIS at any time during the public comment period. A public hearing also is scheduled for August 20, 2015 from 5 to 8 p.m. at the Arcibo Country Club in Arcibo, 00612, Puerto Rico. Oral comments submitted during the hearing will be restricted to a specified time frame to ensure that all interested parties have the opportunity to speak. Doors will open at 4:30 p.m. for registration; RUS will receive oral comments immediately following a short presentation at 5 p.m.

**ADDRESSES:** The public hearing will be held at the Arcibo Country Club in Arcibo, Puerto Rico, 00612. Copies of

the Draft EIS will be available for public viewing at the Arcibo Public Library (Nicolas Nabal Barreto), located at: 210 Santiago Iglesias Pantin Ave., Arcibo, Puerto Rico 00612. Parties wishing to be placed on the Project mailing list or those wishing to participate more directly with RUS as a "consulting party" in Section 106 review may submit a written request to: Ms. Lauren McGee Rayburn, Environmental Scientist, Rural Utilities Service, 84 Coxe Ave., Suite 1E, Ashville, North Carolina 28801, *telephone:* (202) 695–2540, *fax:* (202) 690–0649, or *email:* [Lauren.McGee@wdc.usda.gov](mailto:Lauren.McGee@wdc.usda.gov).

**FOR FURTHER INFORMATION CONTACT:** For information on the proposed Project and the Draft EIS process, please contact Ms. Lauren McGee Rayburn, Environmental Scientist, Rural Utilities Service, 84 Coxe Ave., Suite 1E, Ashville, North Carolina 28801, *telephone:* (202) 695–2540, *fax:* (202) 690–0649, or *email:* [Lauren.McGee@wdc.usda.gov](mailto:Lauren.McGee@wdc.usda.gov). Parties wishing to be placed on the Project mailing list for future information and to receive copies of the EIS should also contact Ms. Rayburn.

**SUPPLEMENTARY INFORMATION:** Energy Answers plans to request financial assistance for the proposed Project from RUS. Completing the EIS is one of RUS's requirements in processing Energy Answers' pending application, along with other technical and financial considerations. Energy Answers proposes to construct a waste to energy generation and resource recovery facility in the Cambalache Ward of Arcibo, Puerto Rico. The proposed facility would process approximately 2100 tons of municipal waste per day and generate a net capacity of 77 megawatts (MW). The Puerto Rico Electric Power Authority will purchase power generated from the facility. The preferred location of the facility is the site of a former paper mill and would cover approximately 79.6 acres of the 90-acre parcel. The proposal would include the following facility components: A municipal solid waste receiving and processing building; processed refuse fuel storage building; boiler and steam turbine; emission control system; ash processing and storage building; and other associated infrastructure and buildings. Two other connected actions, which would be constructed by other utilities, include installation of an approximately 2.0-mile raw water line and construction of a 38 kilovolt (kV) transmission line approximately 0.8 miles in length. The connected actions will be addressed in the proposed Project's EIS.

In accordance with 7 CFR 1794.74 and 40 CFR 1502.21, RUS incorporates by reference the environmental impact analyses and associated documentation prepared by the Puerto Rico Industrial Development Company (PRIDCO) and the USEPA where appropriate. PRIDCO served as a lead agency in preparing an EIS under the Puerto Rico Environmental Public Policy Act, Article 4(B)(3), Law No. 416 (September 22, 2004). The USEPA completed air quality analyses and issued a Prevention of Significant Deterioration (PSD) permit for the proposed Project on June 11, 2013. As applicable, the EIS will document changes in the affected environment and environmental consequences that may have changed since issuance of the PRIDCO-EIS and USEPA PSD permit.

Because the proposed Project may involve action in floodplains or wetlands, this Notice also serves as a notice of proposed floodplain or wetland action. The draft EIS will include a floodplain/wetland assessment and, if required, a floodplain/wetland statement of findings will be issued with the Final EIS.

RUS has determined that its action regarding the proposed Project would be an undertaking subject to review under Section 106 of the National Historic Preservation Act, 16 U.S.C. 470 and its implementing regulations, "Protection of Historic Properties" (36 CFR part 800). As part of its broad environmental review process, RUS must take into account the effect of the proposed Project on historic properties in accordance with Section 106. Pursuant to 36 CFR 800.2(d)(3), RUS is using its procedures for public involvement under NEPA to meet its responsibilities to solicit and consider the views of the public during Section 106 review. Accordingly, comments submitted in response to this Notice will inform RUS decision-making in its Section 106 review process. Any party wishing to participate more directly with RUS as a "consulting party" in Section 106 review may submit a written request to the RUS contact provided in this Notice.

The Draft EIS is available in both Spanish and English for review at the following Web site: <http://www.rd.usda.gov/publications/environmental-studies/impact-statements/arcibo-waste-energy-generation-and-resource>. The Draft EIS will be available for review and comment for 45 days after the USEPA's EIS receipt notice in the **Federal Register**. Following this review period, RUS may prepare a Final EIS. After a 30-day review period of the Final EIS,

RUS may publish a Record of Decision (ROD). Notices announcing the availability of the Final EIS and ROD will be published in the **Federal Register** and in local newspapers.

Any final action by RUS related to the proposed Project will be subject to, and contingent upon, compliance with all relevant presidential executive orders and federal, state, and local environmental laws and regulations in addition to the completion of the environmental review requirements as prescribed in RUS's Environmental Policies and Procedures, 7 CFR part 1794, as amended.

**Christopher A. Mclean,**

*Assistant Administrator—Electric Programs, Rural Utilities Service.*

[FR Doc. 2015-19455 Filed 8-6-15; 8:45 am]

**BILLING CODE P**

## COMMISSION ON CIVIL RIGHTS

### Notice of Public Meeting of the Arizona Advisory Committee To Receive Information From Police Agencies and Persons Involved in the Administration of Justice Regarding Police Community Relations

**AGENCY:** U.S. Commission on Civil Rights.

**ACTION:** Announcement of meeting.

**SUMMARY:** Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a meeting of the Arizona Advisory Committee (Committee) to the Commission will be held on Tuesday, August 25, 2015. The purpose of the meeting is for the Committee to hear from police agencies and persons involved in the administration of justice regarding police community relations. The meeting will be held at the Native American Connections, 4520 N. Central Avenue, Phoenix, AZ 85012. It is scheduled to begin at 1:30 p.m. and adjourn at approximately 5:00 p.m.

Members of the public are entitled to make comments in the open period at the end of the meeting. Members of the public may also submit written comments. The comments must be received in the Western Regional Office of the Commission by September 25, 2015. The address is Western Regional Office, U.S. Commission on Civil Rights, 300 N. Los Angeles Street, Suite 2010, Los Angeles, CA 90012. Persons wishing to email their comments may do so by sending them to Peter Minarik, Regional Director, Western Regional Office, at

*pminarik@usccr.gov*. Persons who desire additional information should contact the Western Regional Office, at (213) 894-3437, (or for hearing impaired TDD 913-551-1414), or by email to *pminarik@usccr.gov*. Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least ten (10) working days before the scheduled date of the meeting.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at <http://facadatabase.gov/committee/meetings.aspx?cid=235> and clicking on the "Meeting Details" and "Documents" links. Records generated from this meeting may also be inspected and reproduced at the Western Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's Web site, <http://www.usccr.gov>, or may contact the Western Regional Office at the above email or street address.

#### Agenda:

Presentations by local police agencies  
Presentations by persons and organizations involved in the administration of justice  
Open Comment  
Adjournment

**DATES:** Tuesday, August 25, 2015 from 1:30 p.m. to 5:00 p.m. PST.

**ADDRESSES:** Native American Connections, 4520 N. Central Avenue, Phoenix, AZ 85012.

**FOR FURTHER INFORMATION CONTACT:** Peter Minarik, DFO, at (213) 894-3437 or *pminarik@usccr.gov*.

Dated: August 3, 2015.

**David Mussatt,**

*Chief, Regional Programs Coordination Unit.*

[FR Doc. 2015-19403 Filed 8-6-15; 8:45 am]

**BILLING CODE 6335-0-1P**

## COMMISSION ON CIVIL RIGHTS

### Sunshine Act Meeting Notice

**AGENCY:** United States Commission on Civil Rights.

**ACTION:** Notice of Commission Business Meeting.

**DATES:** *Date and Time:* Friday, August 14, 2015; 10:00 a.m. EST.

**ADDRESSES:** *Place:* 1331 Pennsylvania Ave. NW., Suite 1150, Washington, DC.

**FOR FURTHER INFORMATION CONTACT:** Lenore Ostrowsky, Acting Chief, Public Affairs Unit (202) 376-8591.

Hearing-impaired persons who will attend the briefing and require the

services of a sign language interpreter should contact Pamela Dunston at (202) 376-8105 or at *signlanguage@usccr.gov* at least seven business days before the scheduled date of the meeting.

#### SUPPLEMENTARY INFORMATION:

#### Meeting Agenda

This meeting is open to the public.

- I. Approval of Agenda
- II. Program Planning
  - Budget Status
  - OCRE Contractor Update
  - Discussion and vote on 2015 Statutory Enforcement Report on The State of Civil Rights at Immigration Detention Facilities, Part A and B
  - Discussion and vote on part A of Peaceful Coexistence report
  - Discussion and vote on two topics for 2016 Commission reports
  - Discussion and vote on dates for Future Commission Business Meetings
- III. Management and Operations
  - Staff Director Report
  - Reports by SAC Chairs for Nevada and Illinois
- IV. State Advisory Committee (SAC) Appointments
  - Illinois
  - Maryland
  - South Dakota
  - Tennessee
  - Wisconsin
- V. Adjourn Meeting

Dated: August 4, 2015.

**David Mussatt,**

*Chief, Regional Programs Unit, U.S. Commission on Civil Rights.*

[FR Doc. 2015-19541 Filed 8-5-15; 11:15 am]

**BILLING CODE P**

## COMMISSION ON CIVIL RIGHTS

### Notice of Public Meeting of the Arizona Advisory Committee To Receive Opinion and Perspective From Members of the Community Regarding Crime Reduction, Police Training, and Police Community Relations

**AGENCY:** U.S. Commission on Civil Rights.

**ACTION:** Announcement of meeting.

**SUMMARY:** Notice is hereby given, pursuant to the provisions of the rules and regulations of the U.S. Commission on Civil Rights (Commission) and the Federal Advisory Committee Act (FACA) that a meeting of the Arizona Advisory Committee (Committee) to the Commission will be held on Wednesday, August 26, 2015. The purpose of the meeting is for the Committee to receive opinion and

perspective from members of the community regarding crime reduction, police training, and police community relations. The meeting will be held at the Cholla Public Library, 10050 Metro Parkway E., Phoenix, AZ 85051. It is scheduled to begin at 1:30 p.m. and adjourn at approximately 5:30 p.m.

Members of the public are entitled to make comments in the open period at the end of the meeting. Members of the public may also submit written comments. The comments must be received in the Western Regional Office of the Commission by September 30, 2015. The address is Western Regional Office, U.S. Commission on Civil Rights, 300 N. Los Angeles Street, Suite 2010, Los Angeles, CA 90012. Persons wishing to email their comments may do so by sending them to Peter Minarik, Regional Director, Western Regional Office, at [pminarik@usccr.gov](mailto:pminarik@usccr.gov). Persons who desire additional information should contact the Western Regional Office, at (213) 894-3437, (or for hearing impaired TDD 913-551-1414), or by email to [pminarik@usccr.gov](mailto:pminarik@usccr.gov). Hearing-impaired persons who will attend the meeting and require the services of a sign language interpreter should contact the Regional Office at least ten (10) working days before the scheduled date of the meeting.

Records and documents discussed during the meeting will be available for public viewing prior to and after the meeting at <http://facadatabase.gov/committee/meetings.aspx?cid=235> and clicking on the "Meeting Details" and "Documents" links. Records generated from this meeting may also be inspected and reproduced at the Western Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this Committee are directed to the Commission's Web site, <http://www.usccr.gov>, or may contact the Western Regional Office at the above email or street address.

#### Agenda:

- Session 1: 1:30 Invited panelists from the community
- Session 2: 2:30 Invited panelists from the community
- Session 3: 3:30 Invited panelists from the community
- 4:30 Open Comment
- Adjournment

**DATES:** Wednesday, August 26, 2015 from 1:30 p.m. to 5:30 p.m. PST.

**ADDRESSES:** Cholla Public Library, 10050 Metro Parkway E., Phoenix, AZ 85051

**FOR FURTHER INFORMATION CONTACT:** Peter Minarik, DFO, at (213) 894-3437 or [pminarik@usccr.gov](mailto:pminarik@usccr.gov).

Dated: August 3, 2015.

**David Mussatt,**

*Chief, Regional Programs Coordination Unit.*

[FR Doc. 2015-19404 Filed 8-6-15; 8:45 am]

**BILLING CODE 6335-01-P**

## DEPARTMENT OF COMMERCE

[Docket No. 150720624-5624-01]

### Privacy Act of 1974, New System of Records

**AGENCY:** U.S. Department of Commerce, National Oceanic and Atmospheric Administration.

**ACTION:** Notice of Privacy Act system of records; "COMMERCE/NOAA-23; Economic Data Collection Program for West Coast Groundfish Trawl Catch Share Program off the coast of Washington, Oregon, and California."

**SUMMARY:** This notice announces the Department of Commerce (Department) proposal for a new system of records under the Privacy Act. NOAA's National Marine Fisheries Service (NMFS), Northwest Fisheries Science Center (NWFSC), is creating a system of records for the mandatory collection of economic data in the West Coast Region consisting of the Economic Data Collection (EDC) for West Coast Groundfish Trawl Catch Share Program. Information will be collected from individuals under the authority of the Magnuson-Stevens Fishery Conservation and Management Act and the American Fisheries Act. This record system is necessary to evaluate information on costs of fishing and processing, revenues for harvesters and processors, and employment information.

**DATES:** To be considered, written comments must be submitted on or before September 8, 2015. Unless comments are received, the system of records will become effective as proposed on the date of publication of a subsequent notice in the **Federal Register**.

**ADDRESSES:** Comments may be mailed to Erin Steiner, NOAA Fisheries, Northwest Fisheries Science Center, FRAM Division, 2725 Montlake Boulevard East, Seattle, WA 98112.

**SUPPLEMENTARY INFORMATION:** This notice announces the Department of Commerce (Department) proposal for a new system of records under the Privacy Act. NMFS' NWFSC is creating a system of records for the EDC for the West Coast Groundfish Trawl Catch Share Program. This record system is necessary to evaluate information on

costs of fishing and processing, revenues for harvesters and processors, and employment information.

Under the EDC, information would be requested from individuals under the authority of the Magnuson-Stevens Fishery Conservation and Management Act and the 50 CFR 660.114. This collection would apply to all owners, lessees, and charterers of a catcher vessel registered to a limited entry trawl endorsed permit, a mothership vessel registered to a mothership permit, or a catcher-processor vessel registered to a catcher-processor endorsed limited entry trawl permit; owners of a first receiver site license; and owners and lessees of a shorebased processor that received round or headed and gutted individual fishing quota groundfish species or whiting from a first receiver are required to submit an EDC to the NWFSC Economics and Social Science Research Program (ESSR).

The collection of information is necessary to identify participants and their roles in these fisheries and to evaluate the programs in which they participate. NMFS would collect information from individuals in order to evaluate the economic effects of fisheries programs, specifically the effects on the harvesting and processing sectors, and to determine the economic efficiency and distributional effects of the programs.

#### COMMERCE/NOAA-23

##### SYSTEM NAME:

COMMERCE/NOAA-23, Economic Data Collection (EDC) Program for West Coast Groundfish Trawl Catch Share Program off the coast of Washington, Oregon, and California.

##### SECURITY CLASSIFICATION:

Moderate.

The EDC system is designed as follows: (1) Participants are required to submit an annual EDC to the NMFS Northwest Fisheries Science Center (NWFSC) Economics and Social Science Research Program (ESSR); (2) Upon request, the NWFSC will provide the EDC information with individual identifiers to NOAA Office for Enforcement and the U.S. Coast Guard; and (3) Upon request, NWFSC ESSR will provide the EDC information with individual identifiers to the Department of Justice (DOJ) and Federal Trade Commission (FTC) to assist in anti-trust analysis of the Program.

##### SYSTEM LOCATIONS:

NMFS Northwest Fisheries Science Center, 2725 Montlake Blvd. East, Seattle, WA 98112

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

*Data from 2009 and 2010:* All owners, lessees, and charterers of a catcher vessel registered to a limited entry trawl endorsed permit at any time in 2009 or 2010; all owners, lessees, and charterers of a mothership vessel that received whiting in 2009 or 2010 as recorded in NMFS' North Pacific (NORPAC) database; all owners, lessees, and charterers of a catcher processor vessel that harvested whiting in 2009 or 2010 as recorded in NMFS' NORPAC database; all owners and lessees of a shorebased processor and all buyers that received groundfish or whiting harvested with a limited entry trawl permit as listed in the Pacific Fisheries Information Network (PacFIN) database in 2009 or 2010.

*Data from 2011 and beyond:* All owners, lessees, and charterers of a catcher vessel registered to a limited entry trawl endorsed permit at any time in 2011 and beyond; all owners, lessees, and charterers of a mothership (MS) vessel registered to an MS permit at any time in 2011 and beyond; all owners, lessees, and charterers of a catcher processor vessel registered to a catcher-processor (C/P)-endorsed limited entry trawl permit at any time in 2011 and beyond; all owners of a first receiver site license in 2011 and beyond; all owners and lessees of a shorebased processor (as defined under "processor" at § 660.11, for purposes of EDC) that received round or headed-and-gutted individual fishing quota species groundfish or whiting from a first receiver in 2011 and beyond.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

System would include records for historical, annual, and current EDCs including financial information, harvest activity and cost, product and cost information, labor cost information for crew, and sales information. The EDCs request data on cost, revenue, ownership, and employment and will be used to study the economic impacts of the West Coast Trawl Groundfish Catch Share Program on affected harvesters, processors, and communities, as well as net benefits to the nation.

Each report would include the following: The name, title, telephone number, fax number, and email address of the person completing the EDC; name and address of the owner or lessee of the plant or vessel; Federal fisheries permit number; Federal processor permit number; Coast Guard vessel registration number or state vessel registration number, Federal license number, state buyer number, and an assigned internal individual identifier.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C. 1801 *et seq.* (Magnuson-Stevens Act), Section 313(j) of the Magnuson-Stevens Act, 16 U.S.C. 1853; 50 CFR 660.114.

**PURPOSE(S):**

This information will allow NMFS to evaluate the economic effects of the West Coast Trawl Groundfish Catch Share Program, specifically the harvesting and processing sectors; the determination of the economic efficiency and distributional effects of the Program.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS OF AND THE PURPOSES OF SUCH USES:**

In addition to those disclosures generally permitted under 5 U.S.C. 552a(b) of the Privacy Act, these records or information contained therein may specifically be disclosed outside the Department of Commerce (Department). The records or information contained therein may specifically be disclosed as a routine use as stated below. The Department will, when so authorized, make the determination as to the relevancy of a record prior to its decision to disclose a document.

1. In the event that a system of records maintained by the Department to carry out its functions indicates a violation or potential violation of law or contract, whether civil, criminal or regulatory in nature and whether arising by general statute or particular program statute or contract, rule, regulation, or order issued pursuant thereto, or the necessity to protect an interest of the Department, the relevant records in the system of records, may be referred to the appropriate agency, whether Federal, State, local, or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute or contract, rule, regulation, or order issued pursuant thereto, or protecting the interest of the Department.

2. A record from this system of records may be disclosed in the course of presenting evidence to a court, magistrate, hearing officer or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations, administrative appeals and hearings.

3. A record in this system of records may be disclosed to a Member of Congress submitting a request involving an individual when the individual has requested assistance from the Member

with respect to the subject matter of the record.

4. A record in this system of records may be disclosed to the Department of Justice in connection with determining whether the Freedom of Information Act (5 U.S.C. 552) requires disclosure thereof.

5. A record in this system will be disclosed to the Department of Treasury for the purpose of reporting and recouping delinquent debts owed the United States pursuant to the Debt Collection Improvement Act of 1996.

6. A record in this system of records may be disclosed to a contractor of the Department having need for the information in the performance of the contract but not operating a system of records within the meaning of 5 U.S.C. 552a(m).

7. A record in this system of records may be disclosed to the applicable Fishery Management Council (Council) staff and contractors tasked with the development of analyses to support Council decisions about Fishery Management Programs.

8. A record in this system of records may be disclosed to appropriate agencies, entities and persons when: (1) It is suspected or determined that the security or confidentiality of information in the system of records has been compromised; (2) the Department 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 whether systems or programs (whether maintained by the Department 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 Department's efforts to respond to the suspected or confirmed compromise and to prevent, minimize, or remedy such harm.

9. A record in this system of records may be disclosed to the Department of Justice and the Federal Trade Commission to assist in anti-trust analysis of the fisheries programs.

10. A record from this system of records may be disclosed, as a routine use, to a Federal, state or local agency maintaining civil, criminal or other relevant enforcement information or other pertinent information, such as current licenses, if necessary to obtain information relevant to a Department decision concerning the assignment, hiring or retention of an individual, the issuance of a security clearance, the



letting of a contract, or the issuance of a license, grant or other benefit.

11. A record from this system of records may be disclosed, as a routine use, to a Federal, state, local, or international agency, in response to its request, in connection with the assignment, hiring or retention of an individual, the issuance of a security clearance, the reporting of an investigation of an individual, the letting of a contract, or the issuance of a license, grant, or other benefit by the requesting agency, to the extent that the information is relevant and necessary to the requesting agency's decision on the matter.

12. A record in this system of records which contains medical information may be disclosed, as a routine use, to the medical advisor of any individual submitting a request for access to the record under the Act and 15 CFR part 4b if, in the sole judgment of the Department, disclosure could have an adverse effect upon the individual, under the provision of 5 U.S.C. 552a(f)(3) and implementing regulations at 15 CFR 4b.6.

13. A record in this system of records may be disclosed, as a routine use, to the Office of Management and Budget in connection with the review of private relief legislation as set forth in OMB Circular No. A-19 at any stage of the legislative coordination and clearance process as set forth in that Circular.

14. A record in this system may be transferred, as a routine use, to the Office of Personnel Management: for personnel research purposes; as a data source for management information; for the production of summary descriptive statistics and analytical studies in support of the function for which the records are collected and maintained; or for related manpower studies.

15. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services Administration (GSA), or his designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.* GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals

**DISCLOSURE TO CONSUMER REPORTING AGENCIES:**

Disclosure to consumer reporting agencies pursuant to 5 U.S.C.

552a(b)(12) may be made from this system to "consumer reporting agencies" as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) and the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)).

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Computerized data base; CDs; back-up files stored on tape; paper records in file folders in locked metal cabinets and/or locked rooms.

**RETRIEVABILITY:**

Records are organized and retrieved by NMFS internal identification number, name of owner or lessee, vessel permit number, buyer identification number, vessel name, or plant name. Records can be accessed by any file element or any combination thereof.

**SAFEGUARDS:**

The system of records is stored in a building with doors that are locked during and after business hours. Visitors to the facility must register and must be accompanied by Federal personnel at all times. Only those that have the need to know, to carry out the official duties of their job, have access to the information. Paper records are maintained in secured file cabinets in areas that are accessible only to authorized personnel of the Data Collection Agent. Electronic records containing Privacy Act information are protected by a user identification/password. The user identification/password is issued to individuals by authorized personnel.

NMFS, Northwest Fisheries Science Center, contractors, to whom access to this information is granted in accordance with this system of records routine uses provision, are instructed on the confidential nature of this information.

All electronic information disseminated by NOAA adheres to the standards set out in Appendix III, Security of Automated Information Resources, OMB Circular A-130; the Computer Security Act (15 U.S.C. 278g-3 and 278g-4); and the Government Information Security Reform Act, Public Law 106-398; and follows NIST SP 800-18, Guide for Developing Security Plans for Federal Information Systems; NIST SP 800-26, Security Self-Assessment Guide for Information Technology Systems; and NIST SP 800-53, Recommended Security Controls for Federal Information Systems.

**RETENTION AND DISPOSAL:**

All records are retained and disposed of in accordance with National Archives

and Records Administration regulations (36 CFR Subchapter XII, Chapter B—Records Management); Departmental directives and comprehensive records schedules; NOAA Administrative Order 205-01; and the NMFS Records Disposition Schedule, Chapter 1500.

**SYSTEM MANAGER(S) AND ADDRESS:**

Northwest Fisheries Science Center  
Economics Program Manager, NMFS  
Northwest Fisheries Science Center,  
2725 Montlake Blvd. East, Seattle, WA  
98112.

**NOTIFICATION PROCEDURE:**

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the national Privacy Act Officer: Privacy Act Officer, NOAA, 1315 East-West Highway, Room 10641, Silver Spring MD 20910. Written requests must be signed by the requesting individual. Requestor must make the request in writing and provide his/her name, address, and date of the request and record sought. All such requests must comply with the inquiry provisions of the Department's Privacy Act rules which appear at 15 CFR part 4, subpart B, Appendix A.

**RECORD ACCESS PROCEDURES:**

Requests for access to records maintained in this system of records should be addressed to the same address given in the Notification Procedure section above.

**CONTESTING RECORD PROCEDURES:**

The Department's rules for access, for contesting contents, and appealing initial determinations by the individual concerned are provided for in 15 CFR part 4, subpart B, Appendix A.

**RECORD SOURCE CATEGORIES:**

Information contained in this system will be collected from individuals participating in the EDC data collections.

**EXEMPTIONS CLAIMED FOR THE SYSTEM:**

None.

Dated: August 3, 2015.

**Michael J. Toland,**

*Department of Commerce, Acting Freedom of Information/Privacy Act Officer.*

[FR Doc. 2015-19452 Filed 8-6-15; 8:45 am]

**BILLING CODE 3510-DT-P**

**DEPARTMENT OF COMMERCE****[Docket No. 150720626–5626–01]****Privacy Act of 1974; Amended System of Records**

**AGENCY:** U.S. Department of Commerce, National Oceanic and Atmospheric Administration.

**ACTION:** Notice of Proposed Amendment to Privacy Act System of Records: COMMERCE/NOAA–19, Permits and Registrations for United States Federally Regulated Fisheries.

**SUMMARY:** This notice announces the Department of Commerce's (Department) proposal to amend the system of records entitled "COMMERCE/NOAA–19, Permits and Registrations for United States Federally Regulated Fisheries," under the Privacy Act of 1974, as amended. The National Oceanic and Atmospheric Administration's (NOAA) National Marine Fisheries Service (NMFS) is revising its system of records for permits and non-permit registrations for use with a variety of fisheries management programs. Information will be collected from individuals under the authority of the Magnuson-Stevens Fishery Conservation and Management Act, the High Seas Fishing Compliance Act, the American Fisheries Act, the Tuna Conventions Act of 1950, the Atlantic Coastal Fisheries Cooperative Management Act, the Atlantic Tunas Convention Authorization Act, the Northern Pacific Halibut Act, the Antarctic Marine Living Resources Convention Act, the Western and Central Pacific Fisheries Convention Implementation Act, international fisheries regulations regarding U.S. Vessels Fishing in Colombian Treaty Waters, and the Marine Mammal Protection Act. This revised record system is necessary to identify participants in the fisheries and to evaluate the qualifications of the applicants. We invite public comment on the amended system announced in this publication.

**DATES:** To be considered, written comments must be submitted on or before September 8, 2015. Unless comments are received, the new system of records will become effective as proposed on the date of publication of a subsequent notice in the **Federal Register**.

**ADDRESSES:** Comments may be mailed to Sarah Brabson, NOAA Office of the Chief Information Officer, Room 9856, 1315 East-West Highway, Silver Spring, MD 20910.

**FOR FURTHER INFORMATION CONTACT:** Sarah Brabson, NOAA Office of the Chief Information Officer, Room 9856, 1315 East-West Highway, Silver Spring, MD 20910.

**SUPPLEMENTARY INFORMATION:** NMFS is revising its system of records for permit and non-permit registrations for use with a variety of fisheries management programs. NMFS requires the use of permits or registrations by participants in U.S. Federally regulated fisheries. Information collections would be requested from individuals under the authority of the Magnuson-Stevens Fishery Conservation and Management Act, the High Seas Fishing Compliance Act, the American Fisheries Act, the Atlantic Coastal Fisheries Cooperative Management Act, the Tuna Conventions Act of 1950, the Atlantic Tunas Convention Authorization Act, the Northern Pacific Halibut Act, the Antarctic Marine Living Resources Convention Act, the Western and Central Pacific Fisheries Convention Implementation Act, International Fisheries Regulations regarding U.S. Vessels Fishing in Colombian Treaty Waters, the Marine Mammal Protection Act, the Endangered Species Act and the Fur Seal Act. The collection of information is necessary to identify participants in these fisheries and to evaluate the qualifications of the applicants. NMFS would collect information from individuals in order to issue, renew, or transfer fishing permits, or to make non-permit registrations. NMFS may use lists of permit holders, or registrants as sample frames for the conduct of surveys to collect information necessary to the administration of the statutes cited above. The authority for the mandatory collection of the Tax Identification Number (Employer Identification Number or Social Security Number) is 31 U.S.C. 7701.

**COMMERCE/NOAA–19****SYSTEM NAME:**

COMMERCE/NOAA–19, Permits and Registrations for United States Federally Regulated Fisheries.

**SECURITY CLASSIFICATION:**

None.

**SYSTEM LOCATION:**

a. NMFS Greater Atlantic Region, 55 Great Republic Dr., Gloucester, MA 01930 (includes Atlantic Highly Migratory Species (HMS) Tuna Dealer permits).

b. NMFS Southeast Region, 263 13th Avenue South, St. Petersburg FL 33701 (includes HMS International Trade

Permit, Shark and swordfish vessel permits, shark and swordfish dealer permits).

c. NMFS West Coast Region, Sustainable Fisheries Division, 7600 Sand Point Way NE., Bldg. #1, Seattle, WA 98115.

d. NMFS West Coast Region, 501 West Ocean Boulevard, Suite 4200, Long Beach, CA 90802.

e. NMFS Southwest Fisheries Science Center, 8604 La Jolla Shores Drive, La Jolla, CA 92037 (Pacific Highly Migratory Species database only).

f. NMFS Office of the Chief Information Officer, 1315 East-West Highway, Silver Spring, MD 20910 (National Permits System).

g. NMFS Pacific Islands Region, 1845 Wasp Boulevard, Building 176, Honolulu, HI 96818.

h. NMFS Alaska Region, 709 West Ninth Street, Juneau, AK 99801.

i. NMFS Office of Science and Technology, 1315 East-West Highway, Silver Spring, MD 20910 (National Saltwater Angler Registry).

j. NMFS Office of International Affairs, 1315 East-West Highway, Silver Spring, MD 20910 (High Seas Fishing Compliance Act and Antarctic Marine Living Resources harvesting and dealer permit data).

k. NMFS Office of Sustainable Fisheries, 3209 Frederic St., Pascagoula, MS 39567 (Antarctic Marine Living Resources preauthorization certification data).

l. NMFS Office of Sustainable Fisheries, 1315 East-West Highway, Room 13130, Silver Spring, MD 20910 (Atlantic HMS Tuna vessel permits, HMS Angling Permit, HMS Charter/headboat permits database).

**CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:**

Owners or holders of a permit or registration as recognized by NMFS, owner agents, vessel owners, and/or operators. Individuals, who apply for any permit, permit exception, permit exemption or regulation exemption, registration, dedicated access privilege or fishing quota share either initially, annually, or by transfer. Applicants seeking permission to fish in a manner that would otherwise be prohibited in order to conduct experimental fishing. Owners of processing facilities and/or fish dealers. Permit qualifiers (persons whose incomes are used for permit qualification). Allocation assignees under a Southeast Region individual fishing quota.

**CATEGORIES OF RECORDS IN THE SYSTEM:**

*This information is collected and/or maintained by all regions and divisions:*

For applicants and related entities referred to in regions/divisions: name, address, business telephone number and date of birth; Tax Identification Number (TIN), Employer Identification Number (EIN) or Social Security Number (SSN), required for all permits, under the authority 31 U.S.C. 7701. For purposes of administering the various NMFS fisheries permit and registration programs, a person shall be considered to be doing business with a Federal agency including, but not limited to, if the person is an applicant for, or recipient of, a Federal license, permit, right-of-way, grant, or benefit payment administered by the agency, or insurance administered by the agency pursuant to subsection (c)(2)(B) of 31 U.S.C 7701.

*Additional information is collected and/or maintained by individual regions and divisions:*

*Greater Atlantic Region*

For transferable permits: Current permit number, permit status information, type of application, name and type of applicant, cellular telephone number and/or fax number, hair and eye color, height and weight, ID-sized photograph, medical records for resolution of permit dispute, enforcement actions, court and legal documents, and permit sanction notice files by NOAA General Counsel, checking account numbers, cancelled checks, tax returns, internal permit number specific to each limited entry permit, baseline specifications on limited entry permit, country, captain's license, State and Federal Dealer Numbers (if applicable), name of incorporation, state and date of incorporation of business and articles of incorporation, coast on which dealer does business, processing sector, facilities where fish received, vessel landing receipts and records, dealer purchase receipts, bills of sale, type of vessel registration, NMFS unique vessel ID, year vessel built, hailing port, hailing port state, principal port, principal state, vessel operations type (catching and/or processing: for at-sea processing permit), fish hold capacity, passenger capacity, VMS status, crew size, fishery type, fishery management plan and category, maximum days at sea, quota allocation and shares, regional fishery management organization, species or species code, type of gear, gear code and rank, buoy and trap/pot color, number of tags assigned to vessel, number of traps, and dredge size and number.

*Southeast Region*

Fee payment information, applicant cellular telephone number and/or fax

number, email address, Web site, gender, hair and eye color, height and weight, ID-sized photograph, corporation name, Dunn and Bradstreet Corporation Number, state and date of incorporation; for all entities with a business relationship (officer, owner or shareholder) to a wreckfish certificate holder, or with a business relationship (officer, owner or shareholder) to a vessel owner or vessel lessee, position held in the business, percent ownership of the business, and citizenship status; NMFS internal identification number, county, country, marriage certificate, divorce decree, death certificate, trust documents, probated will, enforcement actions, court and legal documents, and permit sanction notices files by General Counsel, name of vessel permit applicant if not owner, and relationship to owner, type of vessel ownership, captain's license, original permit, permit payment information, name of permit transferor and number of permit before transfer, permit and vessel sale price (for permit transfers), date of permit transfer signature, notarized, sale and lease agreement with lease start and end dates if applicable, income or license qualifier for certain fisheries, Income Qualification Affidavit for income qualified fisheries, U.S. importer number, State and Federal dealer numbers (if applicable), plant name and operator, hull identification number, hailing port and hailing port state, year vessel built, location where vessel built, vessel function, vessel characteristics (length, breadth, external markings, hull/or superstructure color), gross and net tonnage, type of construction, fuel capacity and type, horsepower (engine, pump), type of product storage, fish hold capacity, live well capacity, radio call sign, vessel communication types and numbers, crew size, passenger capacity, fishery type, quota shares, vessel landing receipts and records, bills of sale, processing facility where fish are received, gear type, species/gear endorsements, buoy/trap color code, number of traps, trap tag number series, trap dimensions, trap mesh size, designated fishing zone, aquaculture reports: site description, material deposited and harvested, value of material, Highly Migratory Species workshop certificate, informational telephone calls recorded with member of public's knowledge, (or customer service evaluation and constituent statement records); U.S. Citizenship or permanent resident alien status, facility name, address, telephone information (for dealer permits), and permit or license numbers for other Federal or state permit/licenses issued.

*Atlantic Highly Migratory Species*

Current permit number, permit status information, type of application, name and type of applicant, business email address, cellular telephone and/or fax number, Web site, corporation name and state and date of incorporation, Dunn and Bradstreet Corporation Number, percent/rank of ownership interest, lease start/end date, income or license qualifier for certain fisheries, United States Coast Guard (USCG) Certificate of Documentation number or state vessel registration number, U.S. Importer Number (dealers), State and Federal Dealer Numbers (if applicable), processing facility where fish are received, name of vessel, type of vessel registration, hull identification number, vessel characteristics (length, breadth, external markings, hull/or superstructure color), gross and net tonnage, type of construction, fuel capacity and type, horsepower (engine, pump), type of product storage, passenger capacity; crew size, hailing port, hailing port state, principal port, principal port state, fish hold capacity, year vessel built, fishery type, species or species code, type of fishing gear, gear code; vessel monitoring system (VMS) activation certification, vessel name, and vessel function.

*West Coast Region*

Northwest Permits: NMFS internal identification number, permit/license number, applicant or new permit/license owner name, (current and new) permit/license or vessel owner name, email address, name of authorized representative and title, permit action requested, midseason sablefish tier landed amount, application fee payment information (check/money order date, check/money order number, bank account number or credit card last 4 digits, check amount), copies of checks, divorce decree, marriage certificate, death certificate, probated will, trust documents, medical records of permit owners seeking exemption from certain permit requirements, proof of citizenship, enforcement actions and settlement agreements, power of attorney documents, affidavits, court and legal documents, articles of incorporation, state and date of incorporation, permit sanction notices, period of permit lease, permit sale/lease price, sales/lease agreement, vessel name and registration number, vessel length overall, location of where vessel built, documentation of loss or destruction of vessel, vessel registration documentation (USCG or state), names of entities/individuals having a share(s) in a corporate/business entity, percent of ownership interest in corporate/

business entity, Small Business Act designation/certification, landing/delivery receipts/data and records, catch/delivery/processing history bill of lading, sales and contract agreements, amount of quota share for IFQ species associated with QS permit, mothership/catcher vessel endorsement and catch history identification number and amount of whiting catch history assignment, name of first receiver and landing facility contact, first receiver catch monitor plan, state scale inspection documentation, landing facility owner name, physical address of first receiving facility, mothership catcher vessels designation of whether it operate in coop or non-coop fishery and obligation to mothership permit (number), catcher processor designation of whether it will operate as mothership, mothership designation of whether it will operate solely as mothership, cooperative name, cooperative manager name, mutual exception agreements, mothership processing withdrawal certification, cooperative/membership agreement (list of members, permits, vessels, cooperative requirements, amendments), list of vessels participating in cooperative, list of permits and their obligation to a mothership permit. Southwest Permits: Permit status information, type of application, name of applicant and relationship to owner or owner manager if not owner or operator, and names of other individuals on application (vessel owner(s), owner's agent, dealer, corporation members), and position in company if applicable, corporation name, Dunn and Bradstreet Corporation Number, state and date of incorporation and articles of incorporation (if applicable), cellular telephone number and/or fax number, business email address, USCG Certificate of Documentation number or state vessel registration number, country, other federal, state and commercial licenses held by operator, name of permit transferor and number of permit before transfer, type of vessel (commercial fishing, charter), vessel photograph, hull identification number, hailing port, hailing port state, principal port, principal port state, year vessel built, where vessel built, maximum vessel speed, fish hold capacity, processing equipment, passenger capacity, crew size, international radio call sign, Vessel Monitoring System (VMS) status, dolphin safety gear on board, previous vessel flag, previous vessel name and effective dates, species/gear endorsements, fishery type, type of fishing gear, gear code, fishing status

(active or inactive), intent to make intentional purse seine sets on marine mammals, date, location, and provider of most recent tuna purse seine marine mammal skipper workshop.

#### *Pacific Islands Region*

Current permit number, permit status information, type of application, name of applicant and of other individuals on application (vessel owner(s), owner's agent, dealer, corporation members), and position in company if applicable, corporation name, state and date of incorporation, cellular telephone number and/or fax number, email address, photograph identification, verification of citizenship or nationality, owner of checking account from which application processing fees made, date and number of check, enforcement actions, court and legal documents, and permit sanction notices filed by General Counsel, name of permit transferor and transferee and number of permit before transfer, letters of authorization or power of attorney, compliance with protected species workshop, USCG Certificate of Documentation number or state vessel registration number, vessel name, permits registered to vessel, international radio call sign, year vessel built, location where vessel built, endorsements, vessel markings and photograph, vessel refrigeration and capacity, fish hold capacity, communication types and addresses, fishery type, percent of ownership interest, ownership and catch history as basis for permit qualification or renewal vessel landing receipts and records, dealer purchase receipts, and bills of sale.

#### *Alaska Region*

Current permit number, permit status information, type of application, name of applicant and of other individuals on application (vessel owner(s), owner's agent, dealer, corporation members), and position in company if applicable, corporation name, state and date of incorporation and articles of incorporation (if applicable), cellular and/or fax telephone number, business email address, country, citizenship, NMFS internal identification number, USCG Certificate of Documentation number or state vessel registration number, vessel name, reference names, owner beneficiary, death certificate, marriage certificate, divorce decree, trust documents, probated will, medical information for emergency transfer of certain permits only, enforcement actions, court and legal documents, and permit sanction notices files by General Counsel, bank account number, canceled checks, tax returns, name of Alaska Native tribe, community of

residence, fishery community organization, community governing body contact person, nonprofit name, community represented by nonprofit, cooperative representative, percent of ownership interest, permit restrictions, quota type, names of other quota holders if affiliated with any, cooperative member receiving quota against cap, names and relationship of permit transferor and transferee, transfer eligibility certificate, sector and region before transfer, reason for transfer, broker's name and fee, lien information (if applicable), quota transfer costs, permit financing source, permit fee, sale/lease agreement, period of lease, agreement to return shares (if applicable), and documentation of military service for certain quota leases; for crab rationalization: Affidavit that right of first refusal contracts were signed, number of units and pounds of fish transferred, applicable dealer license numbers, processing plant name and identification, operation type and operator, type of vessel registration, State of Alaska registration number, NMFS vessel identification number, hull identification number, hailing port and hailing port state, vessel breadth, gross tonnage, fuel capacity and horsepower, numbers of existing permits if applicable to current application, documentation of loss or destruction of a vessel, list of vessels in a vessel cooperative, vessel operations type in terms of catching and/or processing, species/gear endorsements for fisheries requiring vessel monitoring systems, fishery type, species or species code, fishery management plan, days at sea allocations, quota shares, type of fishing gear, gear code, vessel landing receipts and records, bills of sale, delivery receipts, dealer purchase receipts, and processing sector and facility where fish are received.

#### *High Seas Fishing Compliance Act*

Name of applicant and of other individuals on application (vessel owner(s), vessel operator(s), owner's agent, dealer, corporation members), citizenship, cellular telephone and/or fax number, email, positions of individuals in company if applicable, corporation name, State and date of incorporation (if applicable), current permit number, permit status information, type of application, internal identification number, percent/rank of ownership interest, hull identification number, vessel photograph, type of vessel registration, USCG Certificate of Documentation number or state vessel registration number, vessel name, year vessel built, where vessel built, fish hold capacity,

hailing port, hailing port state, crew size, international radio call sign, previous vessel flag, previous vessel name, fishery type, fishery management plan, regional fishery management organization, type of vessel, vessel code, and vessel refrigeration type.

*Antarctic Marine Living Resources*

Current permit number, permit status information, type of application, name of applicant and of other individuals on application (vessel owner(s), owner's agent, dealer, corporation members), and position in company if applicable, corporation name, state and date of incorporation and articles of incorporation (if applicable), nationality, cellular telephone and/or fax number, type of vessel (commercial fishing, charter), where vessel built, year vessel built, fish hold capacity, USCG Certificate of Documentation number or state vessel registration number, vessel name, International Maritime Organization number (if issued), vessel communication types and serial numbers, details of tamper-proof VMS elements, ice classification, processing equipment, international radio call sign, foreign vessel flag, previous vessel flag, previous vessel name, permit number of supporting foreign vessel, crew size, species code, type of fishing gear, information on the known and anticipated impacts of bottom trawling gear on vulnerable marine ecosystems, species and amount to be imported, and the products to be derived from an anticipated catch of krill.

*National Saltwater Angler Registry Program*

Email address, business telephone number, designation as owner-operator or for-hire vessel, vessel name and registration/documentation number, and a statement of the region(s) in which the registrant fishes.

**AUTHORITY FOR MAINTENANCE OF THE SYSTEM:**

Magnuson-Stevens Fishery Conservation and Management Act, 16 U.S.C. 1801 *et seq.* (Magnuson-Stevens Act); High Seas Fishing Compliance Act of 1995, 16 U.S.C. 5501 *et seq.*; International Fisheries Regulations: Vessels of the United States Fishing in Colombian Treaty Waters, 50 CFR 300.120; the American Fisheries Act, Title II, Public Law 105-277; the Atlantic Coastal Fisheries Cooperative Management Act of 1993, 16 U.S.C. 5101-5108, as amended 1996; the Tuna Conventions Act of 1950, 16 U.S.C. 951-961; the Atlantic Tunas Convention Authorization Act, 16 U.S.C., Chapter 16A; the Northern Pacific Halibut Act of 1982, 16 U.S.C. 773 *et seq.* (Halibut Act); the Antarctic Marine Living

Resources Convention Act of 1984, 16 U.S.C. 2431-2444; the Western and Central Pacific Fisheries Convention Implementation Act, 16 U.S.C. 6901 *et seq.* (WCPFCIA); the Marine Mammal Protection Act, 16 U.S.C. 1361; and Taxpayer Identifying Number, 31 U.S.C. 7701.

**PURPOSES:**

This information will allow NMFS to identify owners and holders of permits and non-permit registrations; identify vessel owners and operators; evaluate requests by applicants and current participants, or agency actions, related to the issuance, renewal, transfer, revocation, suspension or modification of a permit or registration.

**ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND PURPOSES OF SUCH USES:**

1. In the event that a system of records maintained by the Department to carry out its functions indicates a violation or potential violation of law or contract, whether civil, criminal or regulatory in nature and whether arising by general statute or particular program statute or contract, rule, regulation, or order issued pursuant thereto, or the necessity to protect an interest of the Department, the relevant records in the system of records may be referred to the appropriate agency, whether Federal, State, local, or foreign, charged with the responsibility of investigating or prosecuting such violation or charged with enforcing or implementing the statute or contract, rule, regulation, or order issued pursuant thereto, or protecting the interest of the Department.

2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate or administrative tribunal, including disclosures to opposing counsel representing the requester and/or subject of the records in the course of settlement negotiations.

3. A record in this system of records may be disclosed to a Member of Congress submitting a request involving an individual when the individual has requested assistance from the Member with respect to the subject matter of the record.

4. A record in this system of records may be disclosed, as a routine use, to the Department of Justice in connection with determining whether disclosure thereof is required by the Freedom of Information Act (5 U.S.C. 552).

5. A record in this system will be disclosed to the Department of Treasury for the purpose of reporting and

recouping delinquent debts owed the United States pursuant to the Debt Collection Improvement Act of 1996.

6. A record in this system may be disclosed to the Department of Homeland Security for the purposes of determining the admissibility of certain seafood imports into the United States.

7. A record in this system of records may be disclosed, as a routine use, to a contractor of the Department having need for the information in the performance of the contract, but not operating a system of records within the meaning of 5 U.S.C. 552a(m).

8. A record in this system of records may be disclosed to approved persons at the state or interstate level within the applicable Marine Fisheries Commission for the purpose of co-managing a fishery or for making determinations about eligibility for permits when state data are all or part of the basis for the permits.

9. A record in this system of records may be disclosed to the applicable Fishery Management Council (Council) staff and contractors tasked with the development of analyses to support Council decisions about Fishery Management Programs.

10. A record in this system of records may be disclosed to the applicable NMFS Observer Program for purposes of identifying current permit owners and vessels and making a random assignment of observers to vessels in a given fishing season.

11. A record in this system of records may be disclosed to the applicable regional or international fisheries management body for the purposes of identifying current permit owners and vessels pursuant to applicable statutes or regulations and/or conservation and management measures adopted by a regional or international fisheries management body, such as: The Food and Agriculture Organization of the United Nations, Commission for the Conservation of Antarctic Marine Living Resources, Inter-American Tropical Tuna Commission, International Pacific Halibut Commission, and International Commission for the Conservation of Atlantic Tunas.

12. A record in this system of records may be disclosed to appropriate agencies, entities, and persons when: (1) It is suspected or determined that the security or confidentiality of information in the system of records has been compromised; (2) the Department has determined that as a result of the suspected or confirmed compromise there is a risk of harm to economic or property interests, identify theft or fraud, or harm to the security or integrity of this system or other systems

or programs (whether maintained by the Department or another agency) 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 Department's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

**DISCLOSURE TO CONSUMER REPORTING AGENCIES:**

Disclosure to consumer reporting agencies pursuant to 5 U.S.C. 552a(b)(12) may be made from this system to "consumer reporting agencies" as defined in the Fair Credit Reporting Act (15 U.S.C. 1681a(f)) and the Federal Claims Collection Act of 1966 (31 U.S.C. 3701(a)(3)).

**POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:**

**STORAGE:**

Computerized database; CDs; back-up files stored on tape, paper records stored in file folders in locked metal cabinets and/or locked rooms.

**RETRIEVABILITY:**

Records are organized and retrieved by NMFS internal identification number, name of entity, permit number, vessel name or identification number, or processing plant name. Records can be accessed by any file element or any combination thereof.

**SAFEGUARDS:**

The system of records is stored in a building with doors that are locked during and after business hours. Visitors to the facility must register with security guards and must be accompanied by Federal personnel at all times. Records are stored in a locked room and/or a locked file cabinet. Electronic records containing Privacy Act information are protected by a user identification/password. The user identification/password is issued to individuals as authorized by authorized personnel.

All electronic information disseminated by NOAA adheres to the standards set out in Appendix III, Security of Automated Information Resources, OMB Circular A-130; the Computer Security Act (15 U.S.C. 278g-3 and 278g-4); and the Government Information Security Reform Act, Public Law 106-398; and follows NIST SP 800-18, Guide for Developing Security Plans for Federal Information Systems; NIST SP 800-26, Security Self-Assessment Guide for Information Technology Systems; and NIST SP 800-53, Recommended Security Controls for Federal Information Systems.

**RETENTION AND DISPOSAL:**

All records are retained and disposed of in accordance with National Archive and Records Administration regulations (36 CFR Chapter XII, Subchapter B—Records Management); Departmental directives and comprehensive records schedules; NOAA Administrative Order 205-01; and the NMFS Records Disposition Schedule, Chapter 1500.

**SYSTEM MANGER(S) AND ADDRESS:**

For records at location a.: Division Chief, Fisheries Statistics Office, NMFS Greater Atlantic Region, NMFS Greater Atlantic Region, 55 Great Republic Dr., Gloucester, MA 01930.

For records at location b.: Assistant Regional Administrator for Operations, Management, and Information Services, NMFS Southeast Region, 263 13th Avenue South, St. Petersburg, FL 33701.

For records at location c.: Permit Team Leader, NMFS West Coast Region, Sustainable Fisheries Division, 7600 Sand Point Way NE., Bldg. #1, Seattle, WA 98115.

For records at location d.: Permits Specialist, NMFS West Coast Region, 501 West Ocean Boulevard, Suite 4200, Long Beach, CA 90802.

For records at location e.: Supervisory IT Specialist, NMFS Southwest Fisheries Science Center, 8604 La Jolla Shores Drive, La Jolla, CA 92037 (Pacific Highly Migratory Species database only).

For records at location f.: Supervisory IT Specialist, NMFS Office of the Chief Information Officer, 1315 East-West Highway, Silver Spring, MD 20910 (National Permits System).

For records at location g.: Information/Permit Specialist, Sustainable Fisheries Division, NMFS Pacific Islands Region, 1845 Wasp Boulevard, Building 176, Honolulu, HI 96818.

For records at location h.: Information/Permit Specialist, Sustainable Fisheries Division, NMFS Alaska Region, 709 West Ninth Street, Juneau, AK 99801.

For records at location i.: Chief, Fisheries Statistics Division, NMFS Office of Science and Technology, 1315 East-West Highway, Silver Spring, MD 20910 (National Saltwater Angler Registry).

For records at location j.: Fishery Management Specialist, Office of International Affairs, 1315 East-West Highway, Silver Spring, MD 20910 (High Seas Fishing Compliance Act and Antarctic Marine Living Resources harvesting and dealer permit data).

For records at location k.: Fishery Biologist, NMFS Office of Sustainable Fisheries, 3209 Frederic St., Pascagoula,

MS 39567 (Antarctic Marine Living Resources preauthorization certification data).

For records at location l.: Division Chief, Highly Migratory Species Management (F/SF1), NMFS 1315 East-West Highway, Room 13458, Silver Spring, MD 20910 (Atlantic HMS Tuna vessel permits, HMS Angling Permit, HMS Charter/headboat permits database).

**NOTIFICATION PROCEDURE:**

Individuals seeking to determine whether information about themselves is contained in this system should address written inquiries to the national or regional Privacy Act Officer:

Privacy Act Officer, NOAA, 1315 East-West Highway, Room 10641, Silver Spring, MD 20910.

Privacy Act Officer, NMFS Greater Atlantic Region, 55 Great Republic Dr., Gloucester, MA 01930.

Privacy Act Officer, NMFS Southeast Region, 263 13th Avenue South, St. Petersburg, FL 33701.

Privacy Act Officer, NMFS West Coast Region, 7600 Sand Point Way NE., Bldg. #1, Seattle, WA 98115.

Privacy Act Officer, NMFS West Coast Region, 501 West Ocean Boulevard, Suite 4200, Long Beach, CA 90802.

Privacy Act Officer, NMFS Pacific Islands Region, 1845 Wasp Boulevard, Building 176, Honolulu, HI 96818.

Privacy Act Officer, NMFS Alaska Region, P.O. Box 21668, Juneau, Alaska 99802, or delivered to the Federal Building, 709 West 9th Street, Juneau, Alaska 99801.

Written requests must be signed by the requesting individual. Requestor must make the request in writing and provide his/her name, address, and date of the request and record sought. All such requests must comply with the inquiry provisions of the Department's Privacy Act rules which appear at 15 CFR part 4, Appendix A.

**RECORD ACCESS PROCEDURES:**

Requests for access to records maintained in this system of records should be addressed to the same address given in the Notification section above. **Note:** Complete records for jointly held permits are made accessible to each holder upon his/her request.

The Department's rules for access, for contesting contents, and appealing initial determinations by the individual concerned are provided for in 15 CFR part 4, Appendix A.

**RECORD SOURCE CATEGORIES:**

Information in this system will be collected from individuals applying for a permit or registration or from an entity

supplying related documentation regarding an application, permit, or registration.

**EXEMPTIONS CLAIMED FOR THE SYSTEM:**

None.

Dated: August 3, 2015.

**Michael J. Toland,**

*Department of Commerce, Acting Freedom of Information/Privacy Act Officer.*

[FR Doc. 2015-19451 Filed 8-6-15; 8:45 am]

**BILLING CODE 3510-22-P**

**DEPARTMENT OF COMMERCE**

**Foreign-Trade Zones Board**

[B-19-2015]

**Authorization of Production Activity; Foreign-Trade Subzone 167B; Polaris Industries, Inc. (Spark-Ignition Internal Combustion Engines); Osceola, Wisconsin**

On March 30, 2015, Polaris Industries, Inc., operator of Subzone 167B, submitted a notification of proposed production activity to the Foreign-Trade Zones (FTZ) Board for its facility located in Osceola, Wisconsin.

The notification was processed in accordance with the regulations of the FTZ Board (15 CFR part 400), including notice in the **Federal Register** inviting public comment (80 FR 19276, 4-10-2015). The FTZ Board has determined that no further review of the activity is warranted at this time. The production activity described in the notification is authorized, subject to the FTZ Act and the FTZ Board's regulations, including Section 400.14.

Dated: August 3, 2015.

**Andrew McGilvray,**

*Executive Secretary.*

[FR Doc. 2015-19485 Filed 8-6-15; 8:45 am]

**BILLING CODE 3510-DS-P**

**DEPARTMENT OF COMMERCE**

**International Trade Administration**

[C-533-839]

**Carbazole Violet Pigment 23 From India: Final Results of Expedited Second Sunset Review of the Countervailing Duty Order**

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** The Department of Commerce finds that revocation of the countervailing duty (CVD) order on carbazole violet pigment 23 (CVP-23) from India would be likely to lead to

continuation or recurrence of a countervailable subsidy at the levels indicated in the "Final Results of Sunset Review" section of this notice.

**DATES:** Effective Date: August 7, 2015.

**FOR FURTHER INFORMATION CONTACT:**

Jacqueline Arrowsmith, Office VII, AD/CVD Operations, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone (202) 482-5255.

**SUPPLEMENTARY INFORMATION:**

**Background**

On December 29, 2004, the Department of Commerce (the Department) published the CVD order on CVP-23 from India.<sup>1</sup> On April 1, 2015, the Department published a notice of initiation of the second sunset review of the *CVD Order* on CVP-23 from India pursuant to section 751(c) of the Tariff Act of 1930, as amended (the Act).<sup>2</sup> On April 13, 2015, Nation Ford Chemical Company (NFC) and Sun Chemical Corporation (Sun) filed a notice of intent to participate in the review.<sup>3</sup> NFC and Sun claimed interested party status under section 771(9)(C) of the Act, as domestic producers of the domestic like product.<sup>4</sup>

The Department received an adequate substantive response from the domestic industry within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i). The Department did not receive a response from the Government of India or any respondent interested party to the proceeding. As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(B)(2) and (C)(2), the Department conducted an expedited review of this *CVD Order* on CVP-23 from India.

**Scope of the Order**

The merchandise subject to this *CVD Order* is CVP-23. Imports of merchandise included within the scope of this order are currently classifiable under subheading 3204.17.9040 of the Harmonized Tariff Schedule of the United States. The Issues and Decision Memorandum, which is hereby adopted

<sup>1</sup> See: *Notice of Countervailing Duty Order: Carbazole Violet Pigment 23 From India*, 69 FR 77995 (December 29, 2004) (*CVD Order*).

<sup>2</sup> See *Initiation of Five Year ("Sunset") Review*, 79 FR 65186 (April 1, 2015).

<sup>3</sup> See Letter from NFC and Sun to the Department, "Carbazole Violet Pigment 23 from India/Notice of Intent to Participate in Second Sunset Review of Countervailing Duty Order," dated April 13, 2015.

<sup>4</sup> In its response, NFC and Sun claim to be domestic producers of CVP-23. *Id.* at 2.

by this notice, provides a full description of the scope of the order.<sup>5</sup>

The Issues and Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <http://access.trade.gov> and in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed at <http://enforcement.trade.gov/frn/>. The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

**Analysis of Comments Received**

All issues raised in this review are addressed in the Issues and Decision Memorandum. The issues discussed include the likelihood of continuation or recurrence of a countervailable subsidy and the net countervailable subsidy rate likely to prevail if the *CVD Order* were revoked.

**Final Results of Sunset Review**

Pursuant to sections 752(b)(1) and (3) of the Act, we determine that revocation of the *CVD Order* on CVP-23 from India would be likely to lead to continuation or recurrence of a net countervailable subsidy at the rates listed below:

Manufacturers exporters/ producers	Net countervailable subsidy (percent)
Alpanil Industries Ltd ....	14.93
Pidilite Industries Ltd ....	15.24
AMI Pigments Pvt. Ltd ..	33.61
All Others .....	18.66

**Notification Regarding Administrative Protective Order**

This notice also serves as the only reminder to parties subject to administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials or conversion to judicial protective orders is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

<sup>5</sup> See Department Memorandum, "Issues and Decision Memorandum for the Final Results of the Expedited Second Sunset Review of the Countervailing Duty Order on Carbazole Violet Pigment 23 from India," dated concurrently with, and hereby adopted by, this notice.

The Department is issuing and publishing these final results and this notice in accordance with sections 751(c), 752(b), and 777(i)(1) of the Act.

Dated: July 30, 2015.

**Ronald K. Lorentzen,**

*Acting Assistant Secretary for Enforcement and Compliance.*

[FR Doc. 2015-19354 Filed 8-6-15; 8:45 am]

BILLING CODE 3510-DS-P

## DEPARTMENT OF COMMERCE

### International Trade Administration

[A-520-803]

#### **Polyethylene Terephthalate Film, Sheet, and Strip From the United Arab Emirates: Negative Final Determination of Circumvention of the Antidumping Duty Order**

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** On May 7, 2015, the Department of Commerce (the Department) published the negative preliminary determination of circumvention of the antidumping duty order<sup>1</sup> on polyethylene terephthalate film, sheet, and strip (PET film) from the United Arab Emirates (UAE).<sup>2</sup> We continue to determine that imports of PET film produced by JBF Bahrain S.P.C. (JBF Bahrain) in the Kingdom of Bahrain (Bahrain) are not circumventing the *Order*, pursuant to section 781(b) of the Tariff Act of 1930, as amended (the Act) and 19 CFR 351.225(h).

**DATES:** Effective date: August 7, 2015.

**FOR FURTHER INFORMATION CONTACT:** Andrew Huston, AD/CVD Operations, Office VII, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482-4261.

#### **SUPPLEMENTARY INFORMATION:**

##### **Background**

On July 29, 2014, the Department initiated an anti-circumvention inquiry of the antidumping duty order on PET

film from the UAE, pursuant to section 781(b) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.225(h).<sup>3</sup> On May 7, 2015, the Department published the *Preliminary Determination* in the **Federal Register**. The Department invited interested parties to comment on the *Preliminary Determination*. On June 8, 2015, Polyplex USA LLC and FLEX USA, Inc. (Domestic Parties) and JBF Bahrain submitted timely case briefs. On June 10, 2015, the Department sent a letter to Domestic Parties, noting certain deficiencies in Domestic Parties' submission, and requesting that Domestic Parties resubmit their case brief. Domestic Parties timely resubmitted their case brief on June 11, 2015. On June 15, 2015, Domestic Parties, and DuPont Teijin Films, Mitsubishi Polyester Film Inc., and SKC, Inc. (collectively, Petitioners), filed timely rebuttal briefs. On June 18, 2015, JBF Bahrain submitted a timely rebuttal brief. On July 9, 2015, pursuant to 19 CFR 351.310, the Department held a public hearing, following a timely request by Domestic Parties.

##### **Scope of the Order**

The products covered by the order are all gauges of raw, pre-treated, or primed polyethylene terephthalate film, whether extruded or co-extruded. Excluded are metallized films and other finished films that have had at least one of their surfaces modified by the application of a performance-enhancing resinous or inorganic layer more than 0.00001 inches thick. Also excluded is roller transport cleaning film which has at least one of its surfaces modified by application of 0.5 micrometers of SBR latex. Tracing and drafting film is also excluded. Polyethylene terephthalate film is classifiable under subheading 3920.62.00.90 of the Harmonized Tariff Schedule of the United States (HTSUS). While HTSUS subheadings are provided for convenience and customs purposes, our written description of the scope of the order is dispositive.

##### **Scope of the Anti-Circumvention Inquiry**

This anti-circumvention inquiry covers PET film produced in Bahrain by JBF Bahrain from inputs (PET chips and silica chips) manufactured in the UAE, and that is subsequently exported from Bahrain to the United States.

<sup>3</sup> See *Polyethylene Terephthalate Film, Sheet, and Strip from the United Arab Emirates: Initiation of Anti-Circumvention Inquiry on Antidumping Duty Order*, 79 FR 44006 (July 29, 2014).

##### **Analysis of Comments Received**

All issues raised in the comments by parties in this proceeding are addressed in the Issues and Decision Memorandum.<sup>4</sup> A list of the issues which the parties raised, to which the Department has responded in the Issues and Decision Memorandum is attached to this notice as Appendix 1. The Issues and Decision Memorandum is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System ("ACCESS"). ACCESS is available to registered users at <http://access.trade.gov>, and it is available to all parties in the Central Records Unit in room B8024 of the main Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <http://enforcement.trade.gov/frn/>. The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

##### **Negative Final Determination of Circumvention**

In the *Preliminary Determination*, the Department preliminarily determined that the process of completion or assembly of PET film produced by JBF Bahrain in Bahrain is not minor or insignificant, within the meaning of section 781(b)(2) of the Act. After reviewing comments from interested parties, we continue to find that the process of completion or assembly is not minor or insignificant. Therefore the Department determines that PET film produced by JBF Bahrain, exported from Bahrain to the United States, is not circumventing the *Order*.

##### **Notification Regarding Administrative Protective Orders**

This notice is the only reminder to parties subject to the administrative protective order (APO) of their responsibility concerning the return or destruction of proprietary information disclosed under the APO in accordance with 19 CFR 351.305(a)(3), which continues to govern business proprietary information in this segment of the proceeding. Timely written notification of the return or destruction of APO materials, or conversion to

<sup>4</sup> See Memorandum to Ronald K. Lorentzen, Acting Assistant Secretary for Enforcement and Compliance, from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, "Polyethylene Terephthalate Film, Sheet, and Strip from the United Arab Emirates: Decision Memorandum for the Final Determination of Anti-Circumvention Inquiry of the Antidumping Duty Order" (Issues and Decision Memorandum), dated concurrently with this determination and hereby adopted by this notice.

<sup>1</sup> See *Polyethylene Terephthalate Film, Sheet, and Strip From Brazil, the People's Republic of China and the United Arab Emirates: Antidumping Duty Orders and Amended Final Determination of Sales at Less Than Fair Value for the United Arab Emirates*, 73 FR 66595 (November 10, 2008) (*Order*).

<sup>2</sup> See *Preliminary Negative Determination of Circumvention of the Antidumping Order on Polyethylene Terephthalate Film, Sheet, and Strip from the United Arab Emirates*, 80 FR 26229 (May 7, 2015) (*Preliminary Determination*), and the accompanying Preliminary Decision Memorandum.



judicial protective order, is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

This negative final circumvention determination is published in accordance with section 781(b) of the Act and 19 CFR 351.225.

Dated: July 31, 2015.

**Ronald K. Lorentzen**

*Acting Assistant Secretary for Enforcement and Compliance.*

## Appendix 1

### List of Issues Discussed in the Issues and Decision Memorandum

Comment 1: Whether JBF Bahrain has taken deliberate action to circumvent the *Order*

Comment 2: Whether JBF Bahrain's process of completion or assembly is substantial or significant under Section 781(b)(2) of the Act

Comment 3: Whether the value of the merchandise produced in the order country is a significant portion of the total value of the merchandise exported to the United States under Section 781(b)(1)(D) of the Act

Comment 4: Completion by JBF Bahrain from parts or components produced in the UAE under Section 781(b)(1)(B) of the Act

Comment 5: Whether record evidence shows that Domestic Parties are interested parties

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**BILLING CODE 3510-DS-P**

## DEPARTMENT OF COMMERCE

### International Trade Administration

[A-570-985]

#### Xanthan Gum From the People's Republic of China: Preliminary Results of Antidumping Duty Administrative Review and Preliminary Determination of No Shipments; 2013-2014

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** The Department of Commerce ("the Department") is conducting an administrative review of the antidumping duty order on xanthan gum from the People's Republic of China ("PRC"). The period of review ("POR") is July 19, 2013, through June 30, 2014.<sup>1</sup> The Department initiated this

<sup>1</sup> The POR for this administrative review begins on July 19, 2013, the date the International Trade Commission ("ITC") published its final determination of threat of material injury in the underlying investigation and the date from which merchandise subject to the antidumping duty order on xanthan gum from the PRC remains suspended from liquidation pursuant to the underlying investigation. The ITC's finding was not accompanied by a finding that injury would have

review with respect to eight companies, two of which have been collapsed with a mandatory respondent. The two collapsed mandatory respondents are: Deosen Biochemical Ltd./Deosen Biochemical (Ordos) Ltd. ("Deosen") and Neimenggu Fufeng Biotechnologies Co., Ltd. (aka Inner Mongolia Fufeng Biotechnologies Co., Ltd.)/Shandong Fufeng Fermentation Co., Ltd./Xinjiang Fufeng Biotechnologies Co., Ltd. ("Fufeng"). The Department preliminarily finds that the mandatory respondent Deosen sold subject merchandise in the United States at prices below normal value ("NV") during the POR, but that Fufeng did not. Interested parties are invited to comment on these preliminary results.

**DATES:** Effective date: August 7, 2015.

#### FOR FURTHER INFORMATION CONTACT:

Brandon Farlander or Erin Kearney, AD/CVD Operations, Office IV, Enforcement & Compliance, International Trade Administration, Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482-0182 or (202) 482-0167, respectively.

#### SUPPLEMENTARY INFORMATION:

##### Scope of the Order

The scope of the order covers dry xanthan gum, whether or not coated or blended with other products. Further, xanthan gum is included in this order regardless of physical form, including, but not limited to, solutions, slurries, dry powders of any particle size, or unground fiber. Merchandise covered by the scope of this order is classified in the Harmonized Tariff Schedule of the United States at subheading 3913.90.20. This tariff classification is provided for convenience and customs purposes; however, the written description of the scope is dispositive.<sup>2</sup>

##### Preliminary Determination of No Shipments

Based on an analysis of U.S. Customs and Border Protection ("CBP")

resulted but for the imposition of suspension of liquidation. See *Xanthan Gum From Austria and China*, 78 FR 43226 (July 19, 2013). Accordingly, merchandise subject to the investigation remains suspended from liquidation beginning on July 19, 2013, the date the ITC published its final determination, see *Xanthan Gum From the People's Republic of China: Amended Final Determination of Sales at Less Than Fair Value and Antidumping Duty Order*, 78 FR 43143, 43144 (July 19, 2013), and this date serves as the first day of the POR for this administrative review.

<sup>2</sup> For a complete description of the Scope of the Order, see "Decision Memorandum for the Preliminary Results of the Antidumping Duty Administrative Review of Xanthan Gum from the People's Republic of China," ("Preliminary Decision Memorandum"), dated concurrently with this notice.

information, and questionnaire responses provided by A.H.A. International Co., Ltd. ("AHA") and Deosen, the Department preliminarily determines that AHA did not have any reviewable transactions during the POR. For additional information regarding this determination, see the Preliminary Decision Memorandum.

Consistent with an announced refinement to its assessment practice in non-market economy ("NME") cases, the Department is not rescinding this review for AHA, but intends to complete the review and issue appropriate instructions to CBP based on the final results of the review.<sup>3</sup>

##### Preliminary Affiliation and Single Entity Determination

Based on record evidence, the Department preliminarily finds that Deosen Biochemical Ltd. and Deosen Biochemical (Ordos) Ltd. are affiliated pursuant to section 771(33)(G) of the Tariff Act of 1930, as amended (the "Act") and should be treated as a single entity for AD purposes pursuant to 19 CFR 351.401(f). Furthermore, based on record evidence, the Department preliminarily finds that Neimenggu Fufeng Biotechnologies Co., Ltd. (aka Inner Mongolia Fufeng Biotechnologies Co., Ltd.), Shandong Fufeng Fermentation Co. Ltd., and Xinjiang Fufeng Biotechnologies Co., Ltd. are affiliated pursuant to section 771(33)(F) of the Act and should be treated as a single entity for AD purposes pursuant to 19 CFR 351.401(f). For additional information, see the Preliminary Decision Memorandum.

##### Separate Rates

The Department preliminarily determines that information placed on the record by the mandatory respondents Deosen and Fufeng, as well as by the separate rate applicants CP Kelco (Shandong) Biological Company Limited and Shanghai Smart Chemicals Co. Ltd., demonstrates that these companies are entitled to separate rate status. Hebei Xinhe Biochemical Co. Ltd., which did not claim that it made no shipments of subject merchandise during the POR, failed to submit a separate rate application or separate rate certification. Therefore, this company is not eligible for separate rate status.<sup>4</sup>

<sup>3</sup> See *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties*, 76 FR 65694, 65694-95 (October 24, 2011) and the "Assessment Rates" section, below.

<sup>4</sup> See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 79 FR 51548, 51549 (August 29, 2014) ("All firms listed below that wish to qualify for separate rate status in the administrative reviews involving NME

Accordingly, the Department preliminarily finds that the PRC-wide entity includes this company. For additional information, see the Preliminary Decision Memorandum.

**PRC-Wide Entity**

The Department’s change in policy regarding conditional review of the PRC-wide entity applies to this administrative review.<sup>5</sup> Under this policy, the PRC-wide entity will not be under review unless a party specifically requests, or the Department self-initiates, a review of the entity. Because no party requested a review of the PRC-wide entity in this review, the entity is not under review and the entity’s rate is not subject to change (*i.e.*, 154.07 percent).<sup>6</sup>

**Rate for Separate-Rate Companies Not Individually Examined**

The statute and the Department’s regulations do not address the establishment of a rate to be applied to respondents not selected for individual examination when the Department limits its examination of companies subject to the administrative review pursuant to section 777A(c)(2)(B) of the Act. Generally, the Department looks to section 735(c)(5) of the Act, which provides instructions for calculating the all-others rate in an investigation, for

guidance when calculating the rate for respondents not individually examined in an administrative review. Section 735(c)(5)(A) of the Act articulates a preference for not calculating an all-others rate using rates which are zero, *de minimis* or based entirely on facts available. Accordingly, the Department’s usual practice has been to determine the dumping margin for companies not individually examined by averaging the weighted-average dumping margins for the individually examined respondents, excluding rates that are zero, *de minimis*, or based entirely on facts available.<sup>7</sup> Consistent with this practice, because we preliminarily determine that the weighted-average dumping margin calculated for Fufeng is zero, the Department assigned to the companies not individually examined, but which demonstrated their eligibility for a separate rate, a margin equal to the weighted-average dumping margin calculated for Deosen.

**Methodology**

The Department is conducting this review in accordance with section 751(a)(1)(B) of the Act. The Department calculated export prices and constructed export prices in accordance with section 772 of the Act. Given that the PRC is a

NME country, within the meaning of section 771(18) of the Act, the Department calculated NV in accordance with section 773(c) of the Act.

For a full description of the methodology underlying the preliminary results of this review, see the Preliminary Decision Memorandum.<sup>8</sup> The Preliminary Decision Memorandum is a public document and is made available to the public *via* Enforcement and Compliance’s Antidumping and Countervailing Duty Centralized Electronic Service System (“ACCESS”). ACCESS is available to registered users at <http://access.trade.gov>, and is available to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be found at <http://enforcement.trade.gov/frn/>. The signed and the electronic versions of the Preliminary Decision Memorandum are identical in content.

**Preliminary Results of Review**

The Department preliminarily determines that the following weighted-average dumping margins exist for the POR:

Exporter	Weighted-average dumping margin (percent)
Neimenggu Fufeng Biotechnologies Co., Ltd. (aka Inner Mongolia Fufeng Biotechnologies Co., Ltd.)/Shandong Fufeng Fermentation Co., Ltd./Xinjiang Fufeng Biotechnologies Co., Ltd	0.00
Deosen Biochemical Ltd./Deosen Biochemical (Ordos) Ltd	5.14
CP Kelco (Shandong) Biological Company Limited	5.14
Shanghai Smart Chemicals Co. Ltd	5.14

**Disclosure and Public Comment**

The Department intends to disclose to parties the calculations performed for these preliminary results of review not later than ten days after the date of the public announcement of, or, if there is no public announcement, within five days after the date of publication of, the preliminary results of review in accordance with 19 CFR 351.224(b). Interested parties may submit case briefs no later than 30 days after the date of

publication of these preliminary results of review.<sup>9</sup> Rebuttal briefs may be filed no later than five days after case briefs are due and may respond only to arguments raised in the case briefs.<sup>10</sup> A table of contents, list of authorities used, and an executive summary of issues should accompany any briefs submitted to the Department.<sup>11</sup> The summary should be limited to five pages total, including footnotes.

Interested parties who wish to request a hearing must submit a written request

to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, within 30 days after the date of publication of this notice.<sup>12</sup> Requests should contain the party’s name, address, and telephone number, the number of participants, and a list of the issues to be discussed. Oral argument presentations will be limited to issues raised in the briefs. If a request for a hearing is made, the Department intends to hold the hearing at the U.S.

countries must complete, as appropriate, either a separate rate application or certification . . .”).

<sup>5</sup> See *Antidumping Proceedings: Announcement of Change in Department Practice for Respondent Selection in Antidumping Duty Proceedings and Conditional Review of the Nonmarket Economy Entity in NME Antidumping Duty Proceedings*, 78 FR 65963 (November 4, 2013).

<sup>6</sup> See *Steel Wire Garment Hangers From the People’s Republic of China: Final Results of Antidumping Duty Administrative Review, 2012–2013*, 80 FR 13332 (March 13, 2015), and accompanying Issues and Decision Memorandum.

<sup>7</sup> See *Ball Bearings and Parts Thereof From France, Germany, Italy, Japan, and the United Kingdom: Final Results of Antidumping Duty Administrative Reviews and Rescission of Reviews in Part*, 73 FR 52823, 52824 (September 11, 2008),

and accompanying Issues and Decision Memorandum at Comment 16.

<sup>8</sup> A list of topics discussed in the Preliminary Decision Memorandum is provided in the Appendix to this notice.

<sup>9</sup> See 19 CFR 351.309(c)(1)(ii).

<sup>10</sup> See 19 CFR 351.309(d).

<sup>11</sup> See 19 CFR 351.309(c)(2), (d)(2).

<sup>12</sup> See 19 CFR 351.310(c).

Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, at a date and time to be determined.<sup>13</sup> Parties should confirm by telephone the date, time, and location of the hearing two days before the scheduled date.

All submissions, with limited exceptions, must be filed electronically using ACCESS.<sup>14</sup> An electronically filed document must be received successfully in its entirety by the Department's electronic records system, ACCESS, by 5 p.m. Eastern Time ("ET") on the due date. Documents excepted from the electronic submission requirements must be filed manually (*i.e.*, in paper form) with the APO/Dockets Unit in Room 18022 and stamped with the date and time of receipt by 5 p.m. ET on the due date.<sup>15</sup>

Unless otherwise extended, the Department intends to issue the final results of this administrative review, which will include the results of its analysis of issues raised in any briefs, within 120 days of publication of these preliminary results, pursuant to section 751(a)(3)(A) of the Act.

#### Assessment Rates

Upon issuance of the final results of this review, the Department will determine, and CBP shall assess, antidumping duties on all appropriate entries covered by this review.<sup>16</sup> The Department intends to issue assessment instructions to CBP 15 days after the publication date of the final results of this review. For each individually examined respondent in this review whose weighted-average dumping margin in the final results of review is above *de minimis* (*i.e.*, greater than or equal to 0.5 percent), the Department intends to calculate importer- (or customer) specific assessment rates, in accordance with 19 CFR 351.212(b)(1).<sup>17</sup> Where the respondent reported reliable entered values, the Department intends to calculate importer- (or customer) specific *ad valorem* rates by aggregating the dumping margins calculated for all U.S. sales to the importer (or customer) and dividing this amount by the total entered value of the sales to the importer (or customer).<sup>18</sup> Where the

Department calculates an importer- (or customer) specific weighted-average dumping margin by dividing the total amount of dumping for reviewed sales to the importer (or customer) by the total sales quantity associated with those transactions, the Department will direct CBP to assess importer- (or customer) specific assessment rates based on the resulting per-unit rates.<sup>19</sup> We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer-specific assessment rate is above *de minimis*. Where either the respondent's weighted average dumping margin is zero or *de minimis*, or an importer (or customer-) specific *ad valorem* or per-unit rate is zero or *de minimis*, the Department will instruct CBP to liquidate appropriate entries without regard to antidumping duties.<sup>20</sup>

On October 24, 2011, the Department announced a refinement to its assessment practice in NME antidumping duty cases.<sup>21</sup> Pursuant to this refinement in practice, for entries that were not reported in the U.S. sales database submitted by an exporter individually examined during this review, the Department will instruct CBP to liquidate such entries at the PRC-wide rate. Additionally, pursuant to this refinement, if the Department determines that an exporter under review had no shipments of the subject merchandise, any suspended entries that entered under that exporter's case number will be liquidated at the PRC-wide rate.

In accordance with section 751(a)(2)(C) of the Act, the final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review and for future deposits of estimated duties, where applicable.

#### Cash Deposit Requirements

The Department will instruct CBP to require a cash deposit equal to the weighted-average amount by which the normal value exceeds U.S. price. The following cash deposit requirements will be effective upon publication of the final results of this administrative review for shipments of the subject merchandise from the PRC entered, or withdrawn from warehouse, for consumption on or after the publication date, as provided by section 751(a)(2)(C) of the Act: (1) For the exporters listed

above, the cash deposit rate will be equal to the weighted-average dumping margin established in the final results of this review (except, if the rate is zero or *de minimis*, then the cash deposit rate will be zero for that exporter); (2) for previously investigated PRC and non-PRC exporters not listed above that have separate rates, the cash deposit rate will continue to be the exporter-specific rate published for the most recently completed segment of this proceeding; (3) for all PRC exporters of subject merchandise which have not been found to be entitled to a separate rate, the cash deposit rate will be the PRC-wide rate of 154.07 percent (4) for all non-PRC exporters of subject merchandise that have not received their own rate, the cash deposit rate will be the rate applicable to the PRC exporter that supplied that non-PRC exporter. These deposit requirements, when imposed, shall remain in effect until further notice.

#### Notification to Importers

This notice also serves as a preliminary reminder to importers of their responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this POR. Failure to comply with this requirement could result in the Department's presumption that reimbursement of antidumping duties occurred and the subsequent assessment of double antidumping duties.

We are issuing and publishing these results in accordance with sections 751(a)(1) and 777(i)(1) of the Act and 19 CFR 351.213.

Dated: July 31, 2015.

**Ronald K. Lorentzen,**

*Acting Assistant Secretary for Enforcement and Compliance.*

#### Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

1. Summary
2. Background
3. Scope of the Order
4. Selection of Respondents
5. Preliminary Determination of No Shipments
6. Single Entity Treatment
7. Discussion of the Methodology
  - a. Non-Market Economy Country
  - b. Separate Rate
  - c. Surrogate Country
  - d. Date of Sale
  - e. Comparisons to Normal Value
  - f. U.S. Price
  - g. Normal Value
  - h. Currency Conversion
8. Conclusion

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<sup>13</sup> See 19 CFR 351.310(d).

<sup>14</sup> See generally 19 CFR 351.303.

<sup>15</sup> See *Antidumping and Countervailing Duty Proceedings: Electronic Filing Procedures; Administrative Protective Order Procedures*, 76 FR 39263 (July 6, 2011).

<sup>16</sup> See 19 CFR 351.212(b)(1).

<sup>17</sup> See *Antidumping Proceedings: Calculation of the Weighted Average Dumping Margin and Assessment Rate in Certain Antidumping Proceedings: Final Modification*, 77 FR 8101 (February 14, 2012) ("*Final Modification*").

<sup>18</sup> See 19 CFR 351.212(b)(1).

<sup>19</sup> *Id.*

<sup>20</sup> See *Final Modification* at 8103.

<sup>21</sup> See *Non-Market Economy Antidumping Proceedings: Assessment of Antidumping Duties*, 76 FR 65694 (October 24, 2011), for a full discussion of this practice.

**DEPARTMENT OF COMMERCE****International Trade Administration**

[A-570-002]

**Chloropicrin From the People's Republic of China: Final Results of the Expedited Sunset Review of the Antidumping Duty Order**

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** On April 1, 2015, the Department of Commerce ("the Department") initiated a sunset review of the antidumping duty order on chloropicrin from the People's Republic of China ("PRC")<sup>1</sup> pursuant to section 751(c) of the Tariff Act of 1930, as amended ("the Act"). Based on the notice of intent to participate and adequate response filed by the domestic interested parties, and the lack of response from any respondent interested party, the Department conducted an expedited sunset review of the *Order* pursuant. As a result of this sunset review, the Department finds that revocation of the *Order* would likely lead to continuation or recurrence of dumping, at the levels indicated in the "Final Results of Sunset Review"<sup>2</sup> section of this notice.

**DATES:** *Effective date:* August 7, 2015.

**FOR FURTHER INFORMATION CONTACT:** Howard Smith, AD/CVD Operations, Office IV, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482-5193.

**SUPPLEMENTARY INFORMATION:****Background**

On April 1, 2015, the Department initiated a sunset review of the order on chloropicrin from the PRC pursuant to section 751(c) of the Act.<sup>2</sup> On April 15, 2015, the Department received a timely notice of intent to participate in the sunset review from Ashta Chemicals, Inc. ("Ashta"), Niklor Chemical Company, Inc. ("Niklor"), and Trinity Manufacturing, Inc. ("Trinity"), domestic interested parties, pursuant to 19 CFR 351.218(d)(1)(i). On May 1, 2015, Ashta, Niklor, and Trinity filed a timely substantive response with the Department pursuant to 19 CFR 351.218(d)(3)(i). The Department did not receive a substantive response from

any respondent interested party. As a result, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2), the Department conducted an expedited sunset review of the *Order*.

**Scope of the Order**

The merchandise subject to the antidumping duty order is chloropicrin, also known as trichloronitromethane. A major use of the product is as a pre-plant soil fumigant (pesticide). Such merchandise is currently classifiable under Harmonized Tariff Schedule ("HTS") item number 2904.90.50.05.<sup>3</sup> The HTS item number is provided for convenience and customs purposes. The written description remains dispositive.

**Analysis of Comments Received**

All issues raised in this sunset review are addressed in the "Issues and Decision Memorandum for the Expedited Sunset Review of the Antidumping Duty Order on Chloropicrin from the People's Republic of China" from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, dated concurrently with, and hereby adopted by, this notice ("Decision Memorandum"). The issues discussed in the Decision Memorandum include the likelihood of continuation or recurrence of dumping and the magnitude of the margins likely to prevail if the *Order* were to be revoked. Parties may find a complete discussion of all issues raised in the review and the corresponding recommendations in this public memorandum which is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Services System ("ACCESS"). ACCESS is available to registered users at <http://access.trade.gov> and is available to all parties in the Central Records Unit, Room B8024 of the main Department of Commerce building. In addition, a complete version of the Decision Memorandum is available directly on the Web at <http://enforcement.trade.gov/frn/index.html>. The signed Decision Memorandum and the electronic versions of the Decision Memorandum are identical in content.

**Final Results of Sunset Review**

Pursuant to Section 752(c)(3) of the Act, the Department determines that revocation of the *Order* would be likely

to lead to continuation or recurrence of dumping at weighted average margins up to 58.00 percent.

**Notification Regarding Administrative Protective Orders**

This notice also serves as the only reminder to parties subject to administrative protective order ("APO") of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

We are issuing and publishing these results and notice in accordance with sections 751(c), 752, and 777(i)(1) of the Act and 19 CFR 351.218.

Dated: July 29, 2015.

**Paul Piquado,**

*Assistant Secretary for Enforcement and Compliance.*

[FR Doc. 2015-19480 Filed 8-6-15; 8:45 am]

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**DEPARTMENT OF COMMERCE****International Trade Administration**

[A-475-818]

**Certain Pasta From Italy: Preliminary Results of Antidumping Duty Administrative Review; 2013-2014**

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** In response to requests from interested parties, the Department of Commerce (the Department) is conducting an administrative review of the antidumping duty order on certain pasta (pasta) from Italy,<sup>1</sup> covering the period July 1, 2013, through June 30, 2014. The initiation of the instant review<sup>2</sup> covered six companies, and we have partially rescinded the review with respect to two companies, as discussed below.<sup>3</sup> Thus, this review covers four companies: The mandatory respondents, La Molisana S.p.A. (La Molisana) and

<sup>1</sup> See *Notice of Antidumping Duty Order and Amended Final Determination of Sales at Less Than Fair Value: Certain Pasta from Italy*, 61 FR 38547 (July 24, 1996).

<sup>2</sup> See *Initiation of Antidumping and Countervailing Duty Administrative Reviews*, 79 FR 51548 (August 29, 2014) (*Initiation Notice*).

<sup>3</sup> See *Certain Pasta from Italy: Notice of Partial Rescission of Antidumping Duty Administrative Review*, 80 FR 4541 (January 28, 2015) (*Partial Rescission*).

<sup>1</sup> See *Antidumping Duty Order; Chloropicrin from the People's Republic of China*, 49 FR 10691 (March 22, 1984) ("Order").

<sup>2</sup> See *Initiation of Five-year ("Sunset") Review*, 80 FR 17388 (April 1, 2015).

<sup>3</sup> In 2004, a new HTS category was developed and identified specifically for imports of chloropicrin, i.e., 2904.90.50.05. Previously, the HTS category that included chloropicrin was 2904.90.50.

Rummo S.p.A. Molino e Pastificio (the Rummo Group),<sup>4</sup> and Pastificio Andalini S.p.A. (Andalini) and Delverde Industrie Alimentari S.p.A. (Delverde), which were not selected for individual examination. We preliminarily determine that La Molisana and the Rummo Group made sales of subject merchandise at less than normal value during the period of review (POR). Interested parties are invited to comment on these preliminary results.

**DATES:** *Effective date:* August 7, 2015.  
**FOR FURTHER INFORMATION CONTACT:** Joy Zhang or George McMahon, AD/CVD Operations, Office III, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482-1168 or (202) 482-1167, respectively.

*Scope of the Order*

Imports covered by the order are shipments of certain non-egg dry pasta. The merchandise subject to review is currently classifiable under items 1901.90.90.95 and 1902.19.20 of the Harmonized Tariff Schedule of the United States (HTSUS). Although the

HTSUS subheadings are provided for convenience and customs purposes, the written description of the merchandise subject to the order is dispositive.<sup>5</sup>

*Partial Rescission of the 2013-2014 Administrative Review*

On October 10, 2014, and November 25, 2014, respectively, Dalla Costa Alimentare srl (Dalla Costa) and Pasta Lensi S.r.l. (Pasta Lensi) timely withdrew their requests for an administrative review.<sup>6</sup> In accordance with 19 CFR 351.213(d)(1),<sup>7</sup> and consistent with our practice,<sup>8</sup> we rescinded this review, in part, with respect to Dalla Costa and Pasta Lensi.<sup>9</sup>

**SUPPLEMENTARY INFORMATION:**

**Methodology**

The Department conducted this review in accordance with section 751(a)(2) of the Tariff Act of 1930, as amended (the Act). Constructed export price or export price is calculated in accordance with section 772 of the Act. Normal value is calculated in accordance with section 773 of the Act. For a full description of the methodology underlying our preliminary results, see Preliminary

Decision Memorandum dated concurrently with this notice and hereby adopted by this notice. The Preliminary Decision Memorandum is a public document and is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). ACCESS is available to registered users at <http://access.trade.gov> and is available to all parties in the Central Records Unit, room B8024 of the main Department of Commerce building. In addition, a complete version of the Preliminary Decision Memorandum can be accessed directly on the Internet at <http://enforcement.trade.gov/frn/index.html>. The signed Preliminary Decision Memorandum and the electronic version of the Preliminary Decision Memorandum are identical in content.

**Preliminary Results of the Review**

As a result of this review, we preliminarily determine the following weighted-average dumping margins<sup>10</sup> for the period July 1, 2013, through June 30, 2014:

Producer and/or exporter	Weighted-average dumping margin (percent)
La Molisana S.p.A. (La Molisana) .....	12.90
Rummo S.p.A., Lenta Lavorazione, Pasta Castiglioni, and Rummo S.p.A. Molino e Pastificio (collectively, the Rummo Group) .....	1.18
Pastificio Andalini S.p.A. (Andalini) .....	8.91
Delverde Industrie Alimentari S.p.A. (Delverde) .....	8.91

**Assessment Rate**

Upon issuance of the final results, the Department shall determine, and U.S. Customs and Border Protection (CBP) shall assess, antidumping duties on all appropriate entries covered by this review. If the weighted-average

dumping margin for La Molisana or the Rummo Group is not zero or *de minimis* (i.e., less than 0.5 percent), we will calculate importer-specific *ad valorem* antidumping duty assessment rates based on the ratio of the total amount of dumping calculated for the importer's

examined sales to the total entered value of those same sales in accordance with 19 CFR 351.212(b)(1). We will instruct CBP to assess antidumping duties on all appropriate entries covered by this review when the importer-specific assessment rate calculated in

<sup>4</sup> The Rummo Group consists of Rummo S.p.A., Lenta Lavorazione, Pasta Castiglioni, and Rummo S.p.A. Molino e Pastificio. In this review, we found that the facts have not changed with respect to Rummo and its affiliates and therefore, we followed the same methodology as we did in the most recent completed review (AR 17) by collapsing the affiliated companies as the Rummo Group. See *Certain Pasta From Italy: Notice of Final Results of 17th Antidumping Duty Administrative Review; 2012-2013*, 80 FR 8604 (February 18, 2015) (AR 17 Final Results).

<sup>5</sup> For a full description of the scope of the order, see the "Decision Memorandum for the Preliminary Results of Antidumping Duty Administrative Review and Partial Rescission: Certain Pasta from Italy; 2013-2014" from Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and

Compliance, dated concurrently with this notice (Preliminary Decision Memorandum).

<sup>6</sup> See Letter from Dalla Costa to the Department, "Antidumping Duty Administrative Review of Certain Pasta from Italy: Withdrawal of Review Request for Administrative Review of Dalla Costa Alimentare SRL," dated October 10, 2014; Letter from Pasta Lensi to the Department, "Pasta from Italy: Withdrawal of Request for Administrative Review," dated November 25, 2014.

<sup>7</sup> Under 19 CFR 351.213(d)(1), the Department will rescind an administrative review "if a party that requested the review withdraws the request within 90 days of the date of publication of notice of initiation of the requested review." The instant review was initiated on August 29, 2014. Therefore, the deadline to withdraw review requests was November 27, 2014. Thus, the Dalla Costa and Pasta Lensi withdrawal requests are timely.

<sup>8</sup> See, e.g., *Brass Sheet and Strip from Germany: Notice of Rescission of Antidumping Duty*

*Administrative Review*, 73 FR 49170 (August 20, 2008); see also *Certain Lined Paper Products from India: Notice of Partial Rescission of Antidumping Duty Administrative Review and Extension of Time Limit for the Preliminary Results of Antidumping Duty Administrative Review*, 74 FR 21781 (May 11, 2009).

<sup>9</sup> See *Partial Rescission*.

<sup>10</sup> The rate applied to the non-selected companies is a weighted-average percentage margin calculated based on the publicly-ranged U.S. volumes of the two reviewed companies with an affirmative dumping margin, for the period July 1, 2013, through June 30, 2014. See Memorandum to the File, titled, "Certain Pasta from Italy: Margin for Respondents Not Selected for Individual Examination," from Joy Zhang and George McMahon, Case Analysts, through Eric B. Greynolds, Program Manager, dated concurrently with this notice.

the final results of this review is not zero or *de minimis*. Where either the respondent's weighted-average dumping margin is zero or *de minimis*, or an importer-specific assessment rate is zero or *de minimis*, we will instruct CBP to liquidate the appropriate entries without regard to antidumping duties. The final results of this review shall be the basis for the assessment of antidumping duties on entries of merchandise covered by the final results of this review where applicable.

In accordance with the Department's "automatic assessment" practice, for entries of subject merchandise during the POR produced by each respondent for which they did not know that their merchandise was destined for the United States, we will instruct CBP to liquidate unreviewed entries at the all-others rate if there is no rate for the intermediate company(ies) involved in the transaction. For a full discussion of this clarification, see *Antidumping and Countervailing Duty Proceedings: Assessment of Antidumping Duties*, 68 FR 23954 (May 6, 2003).

We intend to issue instructions to CBP 15 days after publication of the final results of this review.

#### Cash Deposit Requirements

The following cash deposit requirements will be effective upon publication of the notice of final results of administrative review for all shipments of subject merchandise entered, or withdrawn from warehouse, for consumption on or after the publication of the final results of this administrative review, as provided by section 751(a)(2) of the Act: (1) The cash deposit rate for respondents noted above will be the rate established in the final results of this administrative review; (2) for merchandise exported by manufacturers or exporters not covered in this administrative review but covered in a prior segment of the proceeding, the cash deposit rate will continue to be the company-specific rate published for the most recently completed segment of this proceeding; (3) if the exporter is not a firm covered in this review, a prior review, or the original investigation, but the manufacturer is, the cash deposit rate will be the rate established for the most recently completed segment of this proceeding for the manufacturer of the subject merchandise; and (4) the cash deposit rate for all other manufacturers or exporters will continue to be 15.45 percent, the all-others rate established in the antidumping investigation as modified by the section 129

determination.<sup>11</sup> These cash deposit requirements, when imposed, shall remain in effect until further notice.

#### Disclosure and Public Comment

The Department will disclose to parties to this proceeding the calculations performed in reaching the preliminary results within five days of the date of publication of these preliminary results.<sup>12</sup> Pursuant to 19 CFR 351.309(c), interested parties may submit cases briefs not later than 30 days after the date of publication of this notice. Rebuttal briefs, limited to issues raised in the case briefs, may be filed not later than five days after the date for filing case briefs.<sup>13</sup> Parties who submit comments are requested to submit: (1) A statement of the issue; (2) a brief summary of the argument; and (3) a table of authorities. All briefs must be filed electronically using ACCESS. An electronically filed document must be received successfully in its entirety by the Department's electronic records system, ACCESS.

Interested parties who wish to request a hearing must submit a written request to the Assistant Secretary for Enforcement and Compliance, U.S. Department of Commerce, using Enforcement and Compliance's ACCESS system within 30 days of publication of this notice.<sup>14</sup> Requests should contain the party's name, address, and telephone number, the number of participants, and a list of the issues to be discussed. If a request for a hearing is made, we will inform parties of the scheduled date for the hearing which will be held at the U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230, at a time and location to be determined.<sup>15</sup> Parties should confirm by telephone the date, time, and location of the hearing.

Unless the deadline is extended pursuant to section 751(a)(2)(B)(iv) of the Act, the Department will issue the final results of this administrative review, including the results of our analysis of the issues raised by the parties in their case briefs, within 120 days after issuance of these preliminary results.

#### Notification to Importers

This notice serves as a preliminary reminder to importers of their

<sup>11</sup> See *Implementation of the Findings of the WTO Panel in US—Zeroing (EC): Notice of Determinations Under Section 129 of the Uruguay Round Agreements Act and Revocations and Partial Revocations of Certain Antidumping Duty Orders*, 72 FR 25261 (May 4, 2007).

<sup>12</sup> See 19 CFR 351.224(b).

<sup>13</sup> See 19 CFR 351.309(d).

<sup>14</sup> See 19 CFR 351.310(c).

<sup>15</sup> See 19 CFR 351.310.

responsibility under 19 CFR 351.402(f)(2) to file a certificate regarding the reimbursement of antidumping duties prior to liquidation of the relevant entries during this review period. Failure to comply with this requirement could result in the Secretary's presumption that reimbursement of antidumping duties occurred and increase the subsequent assessment of the antidumping duties by the amount of antidumping duties reimbursed.

These preliminary results of review are issued and published in accordance with sections 751(a)(1) and 777(i)(1) of the Act.

Dated: July 31, 2015.

**Ronald K. Lorentzen,**

*Acting Assistant Secretary for Enforcement and Compliance.*

#### Appendix—List of Topics Discussed in the Preliminary Decision Memorandum

1. Summary
2. Background
3. Scope of the Order
4. Discussion of Methodology
  - Date of Sale
  - Comparisons to Normal Value
  - Product Comparisons
  - Determination of Comparison Method
  - Results of the Differential Pricing (DP) Analysis
  - Export Price
  - Constructed Export Price
  - Normal Value
    - A. Home Market Viability
    - B. Level of Trade
    - C. Cost of Production
    - D. Calculation of Cost of Production
    - E. Test of Home Market Prices
    - F. Results of the COP Test
  - Margins for Companies Not Selected for Individual Examination
  - Currency Conversion
5. Recommendation

[FR Doc. 2015-19481 Filed 8-6-15; 8:45 am]

BILLING CODE 3510-DS-P

#### DEPARTMENT OF COMMERCE

##### International Trade Administration

[A-570-827]

#### Cased Pencils From the People's Republic of China: Initiation of Antidumping Duty New Shipper Review

**AGENCY:** Enforcement and Compliance, International Trade Administration, Department of Commerce.

**SUMMARY:** On May 29, 2015, the Department of Commerce (the Department) received a timely request for a new shipper review (NSR) from

Wah Yuen Stationery Co. Ltd. (Wah Yuen), in accordance with section 751(a)(2)(B)(i) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.214(c).<sup>1</sup> On June 22, 2015, the Department issued a letter to Wah Yuen requesting that it correct certain deficiencies in its initial request.<sup>2</sup> On June 29, 2015, Wah Yuen submitted a timely response to the Department's request.<sup>3</sup> The Department has determined that the request for a new shipper review of the antidumping duty order on cased pencils from the People's Republic of China (PRC) meets the statutory and regulatory requirements for initiation. Thus, we are initiating a new shipper review.

**DATES:** *Effective date:* August 7, 2015.

**FOR FURTHER INFORMATION CONTACT:**

Mary Kolberg, AD/CVD Operations Office I, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; Telephone: (202) 482-1785.

**SUPPLEMENTARY INFORMATION:**

**Background**

The antidumping duty order on cased pencils from the PRC published in the *Federal Register* on December 28, 1994.<sup>4</sup> Pursuant to section 751(a)(2)(B)(i) of the Act, we received a timely request for a new shipper review of the *Order* from Wah Yuen.<sup>5</sup> Wah Yuen certified that it is both the producer and exporter of the subject merchandise upon which its request was based.<sup>6</sup>

Pursuant to section 751(a)(2)(B)(i)(I) of the Act and 19 CFR 351.214(b)(2)(i), Wah Yuen certified that it did not export subject merchandise to the United States during the period of investigation (POI).<sup>7</sup> In addition, pursuant to section 751(a)(2)(B)(i)(II) of the Act and 19 CFR 351.214(b)(2)(iii)(A), Wah Yuen certified that, since the initiation of the investigation, it has

<sup>1</sup> See Letter from Wah Yuen, "Certain Cased Pencils from the People's Republic of China: Request for New Shipper Review and Notice of Appearance" dated May 29, 2015 (Wah Yuen NSR request).

<sup>2</sup> See Letter from Dana S. Mermelstein, regarding the opportunity to correct deficiencies, dated June 22, 2015.

<sup>3</sup> See Letter from Wah Yuen, "Certain Cased Pencils from the People's Republic of China: Supplemental Request for New Shipper Review" dated June 29, 2015 (Wah Yuen supplemental NSR request).

<sup>4</sup> See *Antidumping Duty Order: Certain Cased Pencils from the People's Republic of China*, 59 FR 66909 (December 28, 1994) (*Order*).

<sup>5</sup> See Wah Yuen NSR request.

<sup>6</sup> *Id.* at page 1.

<sup>7</sup> *Id.* at Exhibit 2.

never been affiliated with any exporter or producer who exported subject merchandise to the United States during the POI, including those respondents not individually examined during the POI.<sup>8</sup> As required by 19 CFR 351.214(b)(2)(iii)(B), Wah Yuen also certified that its export activities are not controlled by the government of the PRC.<sup>9</sup>

In addition to the certifications described above, pursuant to 19 CFR 351.214(b)(2), Wah Yuen submitted documentation establishing the following: (1) The date on which it first shipped subject merchandise for export to the United States; (2) the volume of its first shipment; and (3) the date of its first sale to an unaffiliated customer in the United States.<sup>10</sup>

**Period of Review**

In accordance with 19 CFR 351.214(g)(1)(B), the period of review (POR) for new shipper reviews initiated in the month immediately following the semiannual anniversary month will be the six-month period immediately preceding the semiannual anniversary month. Therefore, based on the *Order*, the POR for this NSR is December 1, 2014, through May 31, 2015.

**Initiation of New Shipper Reviews**

Pursuant to section 751(a)(2)(B) of the Act and 19 CFR 351.214(d)(1), the Department finds that the request from Wah Yuen meets threshold requirements for the initiation of a new shipper review of shipments of cased pencils from the PRC produced and exported by Wah Yuen.<sup>11</sup>

The Department intends to issue the preliminary results of this new shipper review no later than 180 days from the date of initiation and the final results of the review no later than 90 days after the date the preliminary results are issued.<sup>12</sup> It is the Department's usual practice, in cases involving non-market economy countries, to require that a company seeking to establish eligibility for an antidumping duty rate separate from the country-wide rate provide evidence of *de jure* and *de facto* absence of government control over the

<sup>8</sup> See Wah Yuen supplemental NSR request at Exhibit 5.

<sup>9</sup> See Wah Yuen NSR request at Exhibit 4.

<sup>10</sup> *Id.* at Exhibit 1 and Wah Yuen supplemental NSR request at Exhibit 6.

<sup>11</sup> See the memorandum to the file entitled "Cased Pencils from the People's Republic of China: Initiation Checklist for Antidumping Duty New Shipper Review of Wah Yuen Stationery Co., Ltd." dated concurrently with this notice.

<sup>12</sup> See section 751(a)(2)(B)(iv) of the Act and 19 CFR 351.214(i).

company's export activities.<sup>13</sup> Accordingly, we will issue a questionnaire to Wah Yuen that will include a section requesting information concerning its eligibility for a separate rate. The new shipper review of Wah Yuen will be rescinded if the Department determines that the new shipper applicant has not demonstrated that it is eligible for a separate rate.

We will instruct CBP to allow, at the option of the importer, the posting, until the completion of the review, of a bond or security in lieu of a cash deposit for the entry of the subject merchandise from Wah Yuen, in accordance with section 751(a)(2)(B)(iii) of the Act and 19 CFR 351.214(e). Specifically, the bonding privilege will apply only to entries of subject merchandise exported and produced by Wah Yuen, the sales of which are the basis for this NSR request.

Interested parties requiring access to proprietary information in the new shipper review should submit applications for disclosure under administrative protective order, in accordance with 19 CFR 351.305 and 351.306.

This initiation and notice are published in accordance with section 751(a)(2)(B) of the Act and 19 CFR 351.214 and 351.221(c)(1)(i).

Dated: July 31, 2015.

**Christian Marsh,**

*Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.*

[FR Doc. 2015-19484 Filed 8-6-15; 8:45 am]

**BILLING CODE 3510-DS-P**

**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

**RIN 0648-XE013**

**Caribbean Fishery Management Council (CFMC); Public Meeting**

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

**ACTION:** Notice of a public meeting.

**SUMMARY:** The Caribbean Fishery Management Council's (Council) Outreach and Education Advisory Panel (OEAP) will meet.

**DATES:** The meeting will be held on August 25, 2015, from 9 a.m. to 5 p.m.

<sup>13</sup> See *Freshwater Crawfish Tail Meat From the People's Republic of China: Initiation of Antidumping Duty New Shipper Reviews*, 79 FR 64749 (October 31, 2014).

**ADDRESSES:** The meeting will be held at CFMC Office, 270 Munoz Rivera Avenue, Suite 401, San Juan, Puerto Rico 00918.

**FOR FURTHER INFORMATION CONTACT:** Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico 00918, telephone: (787) 766-5926.

**SUPPLEMENTARY INFORMATION:** The OEAP will meet to discuss the items contained in the following agenda:

9 a.m.–5 p.m.

- Call to Order
- Adoption of Agenda
- OEAP Chairperson's Report:
- OEAP Members
- Outreach priorities for 2015–20
- Conduct 2 MREP training sessions in USVI and PR (Eastern coast)
- Initiate campaign for Sustainable Seafood Campaign partnering with TNC and UPRSG
- Calendars
- Produce Fact Sheets/Infographics/small posters on:
- New lobster traps
- Octopus life cycle
- Forage fish
- Handling Fresh Tuna fish
- Essential Fish Habitats
- Status of:
- Island-based FMPs
- Newsletter
- Web site
- 2016 Calendar
- CFMC Brochure
- USVI activities
- PR Commercial Fisheries Project (PEPCO)—Helena Antoun
- MREP-Caribbean: Helena Antoun
- Other Business

The OEAP meeting will convene on August 25, 2015, from 9 a.m. until 5 p.m.

The meeting is open to the public, and will be conducted in English. Fishers and other interested persons are invited to attend and participate with oral or written statements regarding agenda issues.

#### Special Accommodations

This meeting is physically accessible to people with disabilities. For more information or request for sign language interpretation and/or other auxiliary aids, please contact Mr. Miguel A. Rolón, Executive Director, Caribbean Fishery Management Council, 270 Muñoz Rivera Avenue, Suite 401, San Juan, Puerto Rico 00918, telephone (787) 766-5926, at least 5 days prior to the meeting date.

Dated: August 3, 2015.

**Tracey L. Thompson,**

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

[FR Doc. 2015-19395 Filed 8-6-15; 8:45 am]

**BILLING CODE 3510-22-P**

## DEPARTMENT OF COMMERCE

### National Oceanic and Atmospheric Administration

**RIN 0648-XE065**

#### Marine Mammals; File No. 18903

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

**ACTION:** Notice; receipt of application.

**SUMMARY:** Notice is hereby given that Peter Tyack, Ph.D., Senior Scientist Emeritus, Woods Hole Oceanographic Institution, 86 Water Street, Woods Hole, Massachusetts 02543, has applied in due form for a permit to conduct research on several species of cetaceans worldwide.

**DATES:** Written, telefaxed, or email comments must be received on or before September 8, 2015.

**ADDRESSES:** The application and related documents are available for review by selecting “Records Open for Public Comment” from the “Features” box on the Applications and Permits for Protected Species (APPS) home page, <https://apps.nmfs.noaa.gov>, and then selecting File No. 18903 from the list of available applications.

These documents are also available upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427-8401; fax (301) 713-0376.

Written comments on this application should be submitted to the Chief, Permits and Conservation Division, at the address listed above. Comments may also be submitted by facsimile to (301) 713-0376, or by email to [NMFS.Pr1Comments@noaa.gov](mailto:NMFS.Pr1Comments@noaa.gov). Please include the File No. in the subject line of the email comment.

Those individuals requesting a public hearing should submit a written request to the Chief, Permits and Conservation Division at the address listed above. The request should set forth the specific reasons why a hearing on this application would be appropriate.

**FOR FURTHER INFORMATION CONTACT:** Courtney Smith or Amy Sloan, (301) 427-8401.

**SUPPLEMENTARY INFORMATION:** The subject permit is requested under the authority of the Marine Mammal Protection Act of 1972, as amended (MMPA; 16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216).

The applicant requests a permit to take multiple cetacean species during research activities focused on cetacean behavior, sound production and responses to sound in U.S. waters of the North Atlantic and North Pacific Ocean and international waters near the Mediterranean Sea and the Bahamas. See tables in the permit application for annual numbers of takes by species, stock and activity. Researchers would take animals by harassment during close approaches with vessels for behavioral observations and photo-identification; attachment of suction-cup or implantable tags and marking with zinc oxide; biopsy sampling; and playbacks of natural and simulated sound. Playback takes involve conducting sound playback experiments where subjects whose responses are being measured will be exposed to specific sounds in a carefully controlled manner using a source level <197.4 dB re 1 microPa at 1 m. Incidental harassment of other species in the area may occur during playbacks and vessel surveys. Skin samples would be imported from foreign field sites to the United States for genetic analyses. The requested permit would be valid for five years from issuance.

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), an initial determination has been made that the activity proposed is categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

Concurrent with the publication of this notice in the **Federal Register**, NMFS is forwarding copies of the application to the Marine Mammal Commission and its Committee of Scientific Advisors.

Dated: August 4, 2015.

**Julia Harrison,**

*Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 2015-19446 Filed 8-6-15; 8:45 am]

**BILLING CODE 3510-22-P**



**DEPARTMENT OF COMMERCE****National Oceanic and Atmospheric Administration****Notice of Fee Calculations for Special Use Permits**

**AGENCY:** Office of National Marine Sanctuaries (ONMS), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA).

**ACTION:** Notice; request for public comments.

**SUMMARY:** In accordance with a requirement of Public Law 106–513 (16 U.S.C. 1441(b)), NOAA hereby gives public notice of the methods, formulas and rationale for the calculations it will use in order to assess fees associated with special use permits (SUPs).

**DATES:** Comments must be received on or before October 6, 2015.

**ADDRESSES:** You may submit comments on this document, identified by NOAA–NOS–2015–0066, by any of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to [www.regulations.gov](http://www.regulations.gov)#!/docketDetail;D=NOAA-NOS-2015-0066, click the “Comment Now!” icon, complete the required fields, and enter or attach your comments.

- *Mail:* Submit all written comments to Matt Nichols, Office of National Marine Sanctuaries, 1305 East West Highway (N/NMS2), 11th Floor, Silver Spring, MD 20910.

*Instructions:* Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by ONMS. All comments received are a part of the public record and will generally be posted for public viewing on [www.regulations.gov](http://www.regulations.gov) without change. All personal identifying information (e.g., name, address, etc.), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. ONMS will accept anonymous comments (enter “N/A” in the required fields if you wish to remain anonymous).

**FOR FURTHER INFORMATION CONTACT:** Matt Nichols, Office of National Marine Sanctuaries, 1305 East West Highway (N/NMS2), Silver Spring, MD 20910, telephone (301) 713–7262, email [Matt.Nichols@noaa.gov](mailto:Matt.Nichols@noaa.gov).

**SUPPLEMENTARY INFORMATION:** This Federal Register document is also accessible via the Internet at: <http://www.access.gpo.gov/>.

**I. Background**

Congress first granted NOAA the authority to issue SUPs for conducting specific activities in national marine sanctuaries in the 1988 Amendments to the National Marine Sanctuaries Act (“NMSA”) (16 U.S.C. 1431 *et seq.*) (Pub. L. 100–627). The NMSA allows NOAA to establish categories of activities that may be subject to an SUP. The list of applicable categories of activities was last updated in 2013 (78 FR 25957). SUPs may be issued for the placement and recovery of objects on the seabed related to public or private events, or commercial filming; the continued presence of commercial submarine cables; the disposal of cremated human remains; recreational diving near the *USS Monitor*; the deployment of fireworks displays; or the operation of aircraft below the minimum altitude in restricted zones of national marine sanctuaries. Congress also gave NOAA the discretion to assess an SUP fee and laid out the basic components of an SUP fee (16 U.S.C. 1441(d)). The NMSA states:

(d) Fees—

(1) Assessment and Collection—The Secretary may assess and collect fees for the conduct of any activity under a permit issued under this section.

(2) Amount—The amount of the fee under this subsection shall be the equal to the sum of—

(A) Costs incurred, or expected to be incurred, by the Secretary in issuing the permit;

(B) Costs incurred, or expected to be incurred, by the Secretary as a direct result of the conduct of the activity for which the permit is issued, including costs of monitoring the conduct of the activity; and

(C) An amount which represents the fair market value of the use of the sanctuary resource.

(3) Use of Fees—Amounts collected by the Secretary in the form of fees under this section may be used by the Secretary—

(A) For issuing and administering permits under this section; and

(B) For expenses of managing national marine sanctuaries.

(4) Waiver or Reduction of Fees—The Secretary may accept in-kind contributions in lieu of a fee under paragraph (2)(C), or waive or reduce any fee assessed under this subsection for any activity that does not derive profit from the access to or use of sanctuary resources.

The purpose of this notice is to propose standard procedures for assessing fee components associated with the application for and issuance of an SUP. SUPs are generally a small portion of the total number of permits issued by ONMS. However, with the addition of new SUP categories in 2013 and the current and potential expansion

of the National Marine Sanctuary System, ONMS may see a rise in the number of applications submitted annually as well as an increase in the complexity of the proposed projects. Due to this, NOAA is asking for public comment on a set of proposed standard procedures for assessing SUP fees.

**II. Summary of Fee Calculations**

When an SUP is applied for by an interested party, and ultimately issued by ONMS, the total fee assessed to the applicant will be the sum of the three categories of fees provided for in section 310(d)(2) of the NMSA: administrative costs, implementation and monitoring costs, and fair market value.

**A. Administrative Costs per 16 U.S.C. 1441(d)(2)(A)**

NOAA proposes to assess a non-refundable \$50 application fee for each SUP application submitted. Administrative costs spent reviewing the permit for sufficiency and suitability would be calculated by multiplying a regional labor rate, derived from the pay rates of ONMS permitting staff and averaged across ONMS regions, by the time spent by staff reviewing each permit application. NOAA will update the rate every year to account for staff changes as well as inflation. Such administrative costs could also include, but are not necessarily limited to, any environmental analyses and consultations associated with evaluating the permit application and issuing the permit; and equipment used in permit review and issuance (e.g., vessels, dive equipment, vehicles, and general overhead). Equipment includes but is not limited to autonomous underwater vehicles, remotely operated underwater vehicles, and sampling equipment. If equipment is acquired specifically to monitor the permit, the actual cost of the acquisition will be included.

**B. Implementation and Monitoring Costs per 16 U.S.C. 1441(d)(2)(B)**

NOAA may also charge a fee for costs associated with the implementation and monitoring of a permitted activity. Such costs would include staff time (calculated similarly to the labor rate described above), equipment use (including vessels or aircraft to oversee permit implementation), the expenses of monitoring the impacts of a permitted activity, and compliance with the terms and conditions of the permit.

**C. Fair Market Value per 16 U.S.C. 1441(d)(2)(C)**

To date, NOAA ONMS has assessed fair market value (FMV) fees assessed for an SUP on a case-by-case basis. The

SUP category for continued operation and maintenance of submarine cables is the only category that has an established protocol for determining FMV (Aug. 28, 2002; 67 FR 55201). Conducting in-depth economic valuation studies for each SUP application are normally overly burdensome for NOAA and the permit applicant relative to the scope and effects of proposed SUP projects. In proposing standard FMV fees for the other six SUP categories, NOAA has examined the fees assessed for past

SUPs as well as comparable fees assessed by other federal, state, and local agencies for similar activities. NOAA is proposing to adopt a standard FMV fee structure for the remaining SUP categories, and is requesting public comment on the following set of FMV fees:

1. The placement and recovery of objects associated with public or private events on non-living substrate of the submerged lands of any national marine sanctuary. The FMV for this activity would be \$200 per event, based on fee

values historically applied at national marine sanctuaries for this activity.

2. The placement and recovery of objects related to commercial filming. With this notice, NOAA would adopt the fee structure below from the National Park Service (NPS), which shares a similar mandate with ONMS to protect natural spaces of national importance. ONMS has determined NPS's broad evaluation methods to be sound and within the intent of ONMS SUPs for commercial filming.

**FMV FEE TABLE FOR PLACEMENT AND RECOVERY OF OBJECTS ASSOCIATED WITH COMMERCIAL FILMING EVENTS**

Number of people	Motion pictures/videos	Number of people	Still photography
1–10 .....	\$150/day .....	1–10 .....	\$50/day.
11–30 .....	250/day .....	11–30 .....	150/day.
31–49 .....	500/day .....	Over 30 .....	250/day.
Over 50 .....	750/day .....	.....	.....

The number of people refers to the cast and/or crew on location within the sanctuary for the commercial filming event, including pre- and post-production.

3. The continued presence of commercial submarine cables on or within the submerged lands of any national marine sanctuary. NOAA assesses FMV for submarine cables in national marine sanctuaries based on the findings of its 2002 study entitled "Fair Market Value Analysis for a Fiber Optic Cable Permit in National Marine Sanctuaries"(67 FR 55201). FMV for cables is assessed annually and adjusted according to the consumer price index. NOAA would continue using this methodology for assessing FMV fees for the continued presence of commercial submarine cables.

4. The disposal of cremated human remains ("cremains") within or into any national marine sanctuary. NOAA would waive all fees, including the FMV fee, for private individuals disposing of cremains, but NOAA would assess a \$50 per disposal FMV fee for commercial operators. This value is based on similar practices of state governments, such as the State of Washington, which assesses a \$70 flat fee for a Cremated Human Remains Disposition Permit for disposal of cremains by airplane, boat, or other disposal methods for businesses.

5. Recreational diving near the USS Monitor. NOAA would waive the FMV fee for any SUP issued for recreational diving within Monitor National Marine Sanctuary, given that 1) individual recreational divers do not derive profits from their use of the sanctuary; and 2) permits for commercial recreational

divers further the sanctuary's objectives by educating the public about the sanctuary and the historical significance of the *U.S.S. Monitor*.

6. Fireworks displays. The FMV for fireworks would be a tiered structure based on the number of fireworks events conducted per calendar year. The fee schedule would be as follows: 1 event per calendar year—\$100; 2–5 events per calendar year—\$300; 6–10 events per calendar year—\$500; 11–20 events per calendar year—\$700.

7. The operation of aircraft below the minimum altitude in restricted zones of national marine sanctuaries. The FMV would be \$500 per site/per day. This is an existing value that has been applied historically at national marine sanctuaries for this activity.

**III. Waiver or Reduction of Fees**

NoAA may accept in-kind contributions in lieu of a fee, or waive or reduce any fee assessed for any activity that does not derive profit from the access to or use of sanctuary resources. NOAA may consider the benefits of the activity to support the goals and objectives of the sanctuary as an in-kind contribution in lieu of a fee.

**IV. Request for Comments**

NoAA is requesting comments on the proposed methods for assessment of SUP fees.

**V. Classification**

*A. National Environmental Policy Act*

NoAA has concluded that this action will not have a significant effect, individually or cumulatively, on the human environment. This action is categorically excluded from the

requirement to prepare an environmental assessment or environmental impact statement in accordance with Section 6.03c3(i) of NOAA Administrative Order 216–6. Specifically, this action is a notice of an administrative and legal nature. Furthermore, individual permit actions by NOAA will be subject to additional case-by-case analysis, as required under NEPA, which will be completed as new permit applications are submitted for specific projects and activities.

NoAA also expects that many of these individual actions will also meet the criteria of one or more of the categorical exclusions described in NOAA Administrative Order 216–6 because SUPs cannot be issued for activities that are expected to result in any destruction of, injury to, or loss of any sanctuary resource. However, the SUP authority may at times be used to allow activities that may meet the Council on Environmental Quality's definition of the term "significant" despite the lack of apparent environmental impacts. In addition, NOAA may, in certain circumstances, combine its SUP authority with other regulatory authorities to allow activities not described above that may result in environmental impacts and thus require the preparation of an environmental assessment or environmental impact statement. In these situations NOAA will ensure that the appropriate NEPA documentation is prepared prior to taking final action on a permit or making any irretrievable or irreversible commitment of agency resources.

**B. Paperwork Reduction Act**

Notwithstanding any other provisions of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, unless that collection of information displays a currently valid Office of Management and Budget (OMB) control number. Applications for the SUPs discussed in this notice involve a collection-of information requirement subject to the requirements of the PRA. OMB has approved this collection-of-information requirement under OMB control number 0648–0141.

Dated: July 20, 2015.

**John Armor,**

*Acting Director, Office of National Marine Sanctuaries.*

[FR Doc. 2015–19121 Filed 8–6–15; 8:45 am]

**BILLING CODE 3510–NK–P**

**DEPARTMENT OF COMMERCE****National Oceanic and Atmospheric Administration**

**RIN 0648–XA629**

**Marine Mammals; File No. 15471–02**

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

**ACTION:** Notice; issuance of permit amendment.

**SUMMARY:** Notice is hereby given that to Michael Adkesson, D.V.M., Chicago Zoological Society, 3300 Golf Rd., Brookfield, IL 60527 has been issued a minor amendment to Scientific Research Permit No. 15471–01.

**ADDRESSES:** The amendment and related documents are available for review upon written request or by appointment in the Permits and Conservation Division, Office of Protected Resources, NMFS, 1315 East-West Highway, Room 13705, Silver Spring, MD 20910; phone (301) 427–8401; fax (301) 713–0376.

**FOR FURTHER INFORMATION CONTACT:** Jennifer Skidmore, (301) 427–8401.

**SUPPLEMENTARY INFORMATION:** The requested permit amendment has been issued under the authority of the Marine Mammal Protection Act of 1972, as amended (16 U.S.C. 1361 *et seq.*) and the regulations governing the taking and importing of marine mammals (50 CFR part 216).

The original permit (No. 15741), issued on August 23, 2010 (75 FR 52721), and subsequent amendment

(No. 15741–01; 76 FR 60808) authorizes the importation of biological samples from South American fur seals (*Arctocephalus australis*) and South American sea lions (*Otaria flavescens*) for scientific research. These samples are part of ongoing health assessment studies of these species in Punta San Juan, Peru. The minor amendment (No. 15741–02) extends the duration of the permit for an additional year (August 31, 2016), but does not change any other terms or conditions of the permit.

Dated: August 4, 2015.

**Julia Harrison,**

*Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 2015–19431 Filed 8–6–15; 8:45 am]

**BILLING CODE 3510–22–P**

**COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED****Procurement List; Additions**

**AGENCY:** Committee for Purchase From People Who Are Blind or Severely Disabled.

**ACTION:** Additions to the Procurement List.

**SUMMARY:** This action adds products and a service to the Procurement List that will be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

**DATES:** Effective date September 7, 2015.

**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](mailto:CMTEFedReg@AbilityOne.gov).

**SUPPLEMENTARY INFORMATION:****Additions**

On 6/12/2015 (80 FR 33485–33489) and 6/26/2015 (80 FR 36773–36774), the Committee for Purchase From People Who Are Blind or Severely Disabled published notices of proposed additions to the Procurement List.

After consideration of the material presented to it concerning capability of qualified nonprofit agencies to furnish the products and service and impact of the additions on the current or most recent contractors, the Committee has determined that the products and service listed below are 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 any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products and service to the Government.

2. The action will result in authorizing small entities to furnish the products and service 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 and service proposed for addition to the Procurement List.

**End of Certification**

Accordingly, the following products and service are added to the Procurement List:

**Products**

NSN(s)—Product Name(s):

7510–00–272–9805—Envelope, Transparent, Large, 10"x13"

7510–00–NIB–9955—Envelope, Transparent, Large, 10"x13"

Mandatory Source of Supply: Georgia Industries for the Blind, Bainbridge, GA  
Mandatory Purchase For: Total Government Requirement

Contracting Activity: General Services Administration, New York, NY

Distribution: A-List

NSN(s)—Product Name(s):

6135–01–447–0949—Non-rechargeable, 9V alkaline battery

Mandatory Source of Supply: Eastern Carolina Vocational Center, Inc., Greenville, NC  
Mandatory Purchase For: Total Government Requirement

Contracting Activity: Defense Logistics Agency Land and Maritime, Columbus, OH

Distribution: A-List

**Service:**

Service Type: Janitorial Service  
Service is Mandatory For: USDA Forest Service

White Mountain National Forest Headquarters, 71 White Mountain Drive, Campton, NH

Mandatory Source of Supply: Community Workshops, Inc., Boston, MA

Contracting Activity: Forest Service, Allegheny National Forest, Warren, PA

**Barry S. Lineback,**

*Director, Business Operations.*

[FR Doc. 2015–19440 Filed 8–6–15; 8:45 am]

**BILLING CODE 6353–01–P**

## COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

### Procurement List Proposed Deletion

**AGENCY:** Committee for Purchase from People Who Are Blind or Severely Disabled.

**ACTION:** Proposed Deletion from the Procurement List.

**SUMMARY:** The Committee is proposing to delete a service from the Procurement List previously provided by the nonprofit agency employing persons who are blind or have other severe disabilities.

*Comments Must be Received on or Before:* 9/7/2015.

**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](mailto: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 action.

### Deletion

The following service is proposed for deletion from the Procurement List:

*Service:*

Service Type: Rebuilding Auto Components Service.

Mandatory For: Unknown.

Mandatory Source of Supply:

Federation Employment and Guidance Service, Inc., New York, NY (deleted).

Contracting Activity: General Services Administration, FPDS Agency Coordinator, Washington, DC.

**Barry S. Lineback,**

*Director, Business Operations.*

[FR Doc. 2015-19439 Filed 8-6-15; 8:45 am]

**BILLING CODE 6353-01-P**

## COMMODITY FUTURES TRADING COMMISSION

### Agency Information Collection

#### Activities: Proposed Collection, Comment Request, Foreign Board of Trade Registration

**AGENCY:** Commodity Futures Trading Commission.

**ACTION:** Notice.

**SUMMARY:** The Commodity Futures Trading Commission (“CFTC” or “Commission”) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (“PRA”), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment. The Commission adopted on December 5, 2011, a final rule, as authorized by the Wall Street Reform and Consumer Protection Act (“Dodd-Frank Act”), requiring foreign boards of trade (“FBOT”) that wish to provide their identified members or other participants located in the United States with direct access to their electronic trading and order matching systems to register with the Commission. This notice solicits comments on the reporting requirements applicable to FBOTs that apply for registration and to the reporting requirements applicable to registered FBOTs as identified in the final rule.

**DATES:** Comments must be submitted on or before October 6, 2015.

**ADDRESSES:** You may submit comments, identified by “FBOT Registration” or PRA collection 3038-0101 by any of the following methods:

- The Agency’s Web site, at <http://comments.cftc.gov/>. Follow the instructions for submitting comments through the Web site.
- *Mail:* Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.
- *Hand Delivery/Courier:* Same as mail above.
- *Federal eRulemaking Portal:* <http://www.regulations.gov/>. Follow the instructions for submitting comments through the Portal.

Please submit your comments using only one method.

### FOR FURTHER INFORMATION CONTACT:

Duane C. Andresen, Associate Director, Division of Market Oversight, Commodity Futures Trading Commission, (202) 418-5492; email: [dandresen@cftc.gov](mailto:dandresen@cftc.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA, 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 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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, the CFTC is publishing notice of the proposed collection of information listed below.

*Title:* Information Management Requirements for Registration of Foreign Boards of Trade (OMB Control No. 3038-0101). This is a request for extension of a currently approved information collection.

*Abstract:* Section 738 of the Dodd-Frank Act amended section 4(b) of the Commodity Exchange Act to provide that the Commission may adopt rules and regulations requiring FBOTs that wish to provide their members or other participants located in the United States with direct access to the FBOT’s electronic trading and order matching system to register with the Commission. Pursuant to this authorization, the CFTC adopted a final rule requiring FBOTs that wish to permit trading by direct access to provide certain information to the Commission in applications for registration and, once registered, to provide certain information to meet quarterly and annual reporting requirements.

With respect to the collection of information, the CFTC invites comments on:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have a practical use;
- The accuracy of the Commission’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Ways to enhance the quality, usefulness, and clarity of the information to be collected; and
- Ways to minimize the burden of 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.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to <http://www.cftc.gov>. You should submit only information that you wish to make available publicly. If you wish the Commission to consider information

that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations.<sup>1</sup> The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from <http://www.cftc.gov> that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the Information Collection Request will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

**Burden Statement:** The respondent burden for this collection is estimated to range from 1000 hours for the submission of a new registration application to two to eight hours per response for submission of required reports. These estimates include the time to locate, compile, validate, and verify and disclose and to ensure such information is maintained.

**Respondents/Affected Entities:** Foreign Boards of Trade.

**Estimated number of respondents:** 271.

**Estimated total annual burden on respondents:** 11,756 hours.

**Frequency of collection:** Once for new applications, quarterly and annually for required reports.

(Authority: 44 U.S.C. 3501 *et seq.*)

Dated: August 3, 2015.

**Robert N. Sidman,**

*Deputy Secretary of the Commission.*

[FR Doc. 2015-19394 Filed 8-6-15; 8:45 am]

**BILLING CODE 6351-01-P**

## COMMODITY FUTURES TRADING COMMISSION

### Agency Information Collection Activities: Notice of Intent To Renew Collection 3038-0085, Rule 50.50 End-User Notification of Non-Cleared Swaps

**AGENCY:** Commodity Futures Trading Commission.

**ACTION:** Notice.

**SUMMARY:** The Commodity Futures Trading Commission ("Commission") is announcing an opportunity for public comment on the proposed collection of certain information by the agency.

Under the Paperwork Reduction Act ("PRA"), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment. This notice solicits comments on reporting requirements relating to financial resource requirements for derivatives clearing organizations.

**DATES:** Comments must be submitted on or before October 6, 2015.

**ADDRESSES:** You may submit comments, identified by "Rule 50.50 End-User Notification of Non-Cleared Swaps," by any of the following methods:

- The Agency's Web site, at <http://comments.cftc.gov/>. Follow the instructions for submitting comments through the Web site.
- **Mail:** Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.
- **Hand Delivery/Courier:** Same as Mail above.
- **Federal eRulemaking Portal:** <http://www.regulations.gov/>. Follow the instructions for submitting comments through the Portal.

Please submit your comments using only one method.

**FOR FURTHER INFORMATION CONTACT:**

Peter A. Kals, Division of Clearing and Risk, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581, (202) 418-5466; email: [pkals@cftc.gov](mailto:pkals@cftc.gov) and refer to OMB Control No. 3038-0085.

**SUPPLEMENTARY INFORMATION:** Under the PRA, 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 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 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 Commission is publishing notice of the proposed extension of the collection of information listed below.

**Title:** Rule 50.50 End-User Notification of Non-Cleared Swap (OMB Control No. 3038-0085). This is a request for extension of a currently approved information collection.

**Abstract:** Rule 50.50 specifies requirements for non-financial end-users who elect the exception from the Commission's swap clearing requirement set forth in section 2(h)(7) of the Commodity Exchange Act. Among the requirements of Rule 50.50 is reporting certain information to a swap data repository registered with the Commission.

With respect to the collection of information, the Commission invites comments on:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have a practical use;
- The accuracy of the Commission's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Ways to enhance the quality, usefulness, and clarity of the information to be collected; and
- Ways to minimize the burden of 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.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to <http://www.cftc.gov>. You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission's regulations.<sup>1</sup>

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from <http://www.cftc.gov> that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the Information Collection Request will be retained in the public comment file and will be considered as required under the Administrative

<sup>1</sup> 17 CFR 145.9.

<sup>1</sup> 17 CFR 145.9.

Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

*Burden Statement:* The respondent burden for this collection is estimated to require between 10 minutes and one hour per response.

*Respondents/Affected Entities:* Non-financial end-users.

*Estimated number of respondents:* 1,092.

*Estimated total average annual burden on respondents:* 633 hours.

*Frequency of collection:* On occasion; annually.

(Authority: 44 U.S.C. 3501 *et seq.*)

Dated: August 3, 2015.

**Robert N. Sidman,**

*Deputy Secretary of the Commission.*

[FR Doc. 2015-19401 Filed 8-6-15; 8:45 am]

BILLING CODE 6351-01-P

## COMMODITY FUTURES TRADING COMMISSION

### Agency Information Collection Activities: Notice of Intent To Renew Collection 3038-0096, Swap Data Recordkeeping and Reporting Requirements

**AGENCY:** Commodity Futures Trading Commission.

**ACTION:** Notice.

**SUMMARY:** The Commodity Futures Trading Commission (“CFTC” or “Commission”) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (“PRA”), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information and to allow 60 days for public comment. This notice solicits comments on the swap data recordkeeping and reporting requirements codified in 17 CFR part 45. This part imposes recordkeeping and reporting requirements on the following entities: Swap Data Repositories (“SDRs”), Swap Execution Facilities (“SEFs”), Designated Contract Markets (“DCMs”), Derivatives Clearing Organizations (“DCOs”), Swap Dealers (“SDs”), Major Swap Participants (“MSPs”), and swap counterparties that are neither swap dealers nor major swap participants (“non-SD/MSP counterparties”).

**DATES:** Comments must be submitted on or before October 6, 2015.

**ADDRESSES:** You may submit comments, identified by “Renewal of Collection Pertaining to Swap Data Recordkeeping

and Reporting Requirements,” or Renewal 3038-0096, by any of the following methods:

- The Agency’s Web site, at <http://comments.cftc.gov/>. Follow the instructions for submitting comments through the Web site.
- Mail: Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.
- Hand Delivery/Courier: Same as Mail above.
- Federal eRulemaking Portal: <http://www.regulations.gov/>. Follow the instructions for submitting comments through the Portal.

Please submit your comments using only one method.

**FOR FURTHER INFORMATION CONTACT:**

Thomas Guerin, Division of Market Oversight, Commodity Futures Trading Commission, 1155 21st Street NW., (202) 734-4194; email: [tguerin@cftc.gov](mailto:tguerin@cftc.gov), and refer to OMB Control No. 3038-0096.

**SUPPLEMENTARY INFORMATION:** Under the PRA, 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 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 provide a 60-day notice in the **Federal Register** concerning each proposed collection of information before submitting the collection to OMB for approval. To comply with this requirement, the CFTC is publishing notice of the proposed collection of information listed below.

*Title:* Swap Data Recordkeeping and Reporting Requirements (OMB Control No. 3038-0096). This is a request for extension of a currently approved information collection.

*Abstract:* The collection of information is needed to ensure that the CFTC and other regulators have access to complete data concerning swaps, as required by the Commodity Exchange Act as amended by the Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111-203, 124 Stat. 1376 (2010). The data would be reported to and maintained in SDRs, where it would not be disclosed publicly, but would be available to the CFTC and other financial regulators for fulfillment of various regulatory mandates. The

information is for use by government entities to provide oversight and supervision and to ensure compliance with statutes and regulations relating to swaps.

With respect to the collection of information, the CFTC invites comments on:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have a practical use;
- The accuracy of the Commission’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Ways to enhance the quality, usefulness, and clarity of the information to be collected; and
- Ways to minimize the burden of 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.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to <http://www.cftc.gov>. You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission’s regulations.<sup>1</sup>

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from <http://www.cftc.gov> that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the Information Collection Request will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

*Burden Statement:* The total annual time burden for this collection is estimated to be 445,910 hours. This estimate includes the time to comply with swap data recordkeeping and reporting requirements codified in 17 CFR part 45. Provisions of CFTC

<sup>1</sup> 17 CFR 145.9.

Regulations 45.2, 45.3, 45.4, 45.5, 45.6, 45.7, and 45.14 result in information collection requirements within the meaning of the PRA. To the extent that the recordkeeping and reporting requirements codified in 17 CFR part 45 overlap with the requirements of other rulemakings for which the CFTC prepared and submitted an information collection burden estimate to OMB, the burden associated with the requirements are not being accounted for in the burden estimate for information collections under 17 CFR part 45 to avoid unnecessary duplication of information collection burdens.

*Respondents/Affected Entities:* SDRs, SEFs, DCMS, DCOs, SDs, MSPs, and non-SD/MSP counterparties.

*Estimated number of respondents:* 30,210.

*Estimated total annual burden on respondents:* 445,910 hours.

*Frequency of collection:* Ongoing.

*Authority:* 44 U.S.C. 3501 *et seq.*

Dated: August 3, 2015.

**Robert N. Sidman,**

*Deputy Secretary of the Commission.*

[FR Doc. 2015-19402 Filed 8-6-15; 8:45 am]

BILLING CODE 6351-01-P

## COMMODITY FUTURES TRADING COMMISSION

### Agency Information Collection Activities: Notice of Intent to Renew Collection Number 3038-0079, Conflict of Interest Policies and Procedures by Swap Dealers and Major Swap Participants

**AGENCY:** Commodity Futures Trading Commission.

**ACTION:** Notice.

**SUMMARY:** The Commodity Futures Trading Commission (“CFTC” or “Commission”) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act (“PRA”), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment. This notice solicits comments on the collections of information mandated by Commission regulation 23.605 (Conflicts of interest policies and procedures).

**DATES:** Comments must be submitted on or before October 6, 2015.

**ADDRESSES:** You may submit comments, identified by “Conflict of Interest Policies and Procedures by Swap Dealers and Major Swap Participants,” and Collection Number 3038-0079 by any of the following methods:

- The Agency’s Web site, at <http://comments.cftc.gov/>. Follow the instructions for submitting comments through the Web site.
- Mail: Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581.
- Hand Delivery/Courier: Same as Mail above.
- Federal eRulemaking Portal: <http://www.regulations.gov/>. Follow the instructions for submitting comments through the Portal. Please submit your comments using only one method.

All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to [www.cftc.gov](http://www.cftc.gov).

**FOR FURTHER INFORMATION CONTACT:**

Jacob Chachkin, Special Counsel, Division of Swap Dealer and Intermediary Oversight, Commodity Futures Trading Commission, (202) 418-5496; email: [jchachkin@cftc.gov](mailto:jchachkin@cftc.gov).

**SUPPLEMENTARY INFORMATION:** Under the PRA, 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 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 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 CFTC is publishing notice of the proposed collection of information listed below.

*Title:* Conflict of Interest Policies and Procedures by Swap Dealers and Major Swap Participants (OMB Control No. 3038-0079). This is a request for an extension of a currently approved information collection.

*Abstract:* On April 3, 2012 the Commission adopted Commission regulation 23.605 (Conflicts of interest policies and procedures)<sup>1</sup> under section

4s(j)(5)<sup>2</sup> of the Commodity Exchange Act (“CEA”). Commission regulation 23.605 requires, among other things, that swap dealers (“SD”)<sup>3</sup> and major swap participants (“MSP”)<sup>4</sup> adopt and implement conflicts of interest procedures and disclosures, establish written policies and procedures reasonably designed to ensure compliance with the conflicts of interest and disclosure obligations within the regulations, and maintain specified records related to those requirements.<sup>5</sup> The Commission believes that the information collection obligations imposed by Commission regulation 23.605 are essential (i) to ensuring that SDs and MSPs develop and maintain the conflicts of interest systems, procedures and disclosures required by the CEA, and Commission regulations, and (ii) to the effective evaluation of these registrants’ actual compliance with the CEA and Commission regulations.

With respect to the collection of information, the CFTC invites comments on:

- Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have a practical use;
- The accuracy of the Commission’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Ways to enhance the quality, usefulness, and clarity of the information to be collected; and
- Ways to minimize the burden of 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.

You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that you believe is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures established in § 145.9 of the Commission’s regulations.<sup>6</sup>

<sup>2</sup> 7 U.S.C. 6s(j)(5).

<sup>3</sup> For the definition of SD, *see* section 1a(49) of the CEA and Commission regulation 1.3(ggg). 7 U.S.C. 1a(49) and 17 CFR 1.3(ggg).

<sup>4</sup> For the definitions of MSP, *see* section 1a(33) of the CEA and Commission regulation 1.3(hhh). 7 U.S.C. a(33) and 17 CFR 1.3(hhh).

<sup>5</sup> *See* 17 CFR 23.605.

<sup>6</sup> 17 CFR 145.9.

<sup>1</sup> 17 CFR 23.605.

The Commission reserves the right, but shall have no obligation, to review, pre-screen, filter, redact, refuse or remove any or all of your submission from <http://www.cftc.gov> that it may deem to be inappropriate for publication, such as obscene language. All submissions that have been redacted or removed that contain comments on the merits of the information collection request will be retained in the public comment file and will be considered as required under the Administrative Procedure Act and other applicable laws, and may be accessible under the Freedom of Information Act.

**Burden Statement:** The respondent burden for this collection is estimated to be as follows:

**Number of Registrants:** 125.

**Estimated Average Burden Hours Per Registrant:** 44.5.

**Estimated Aggregate Burden Hours:** 5,562.5.

**Frequency of Recordkeeping:** As applicable.

**Authority:** 44 U.S.C. 3501 *et seq.*

Dated: August 3, 2015.

**Robert N. Sidman,**

*Deputy Secretary of the Commission.*

[FR Doc. 2015-19387 Filed 8-6-15; 8:45 am]

**BILLING CODE 6351-01-P**

## COMMODITY FUTURES TRADING COMMISSION

### Agency Information Collection Activities Under OMB Review

**AGENCY:** Commodity Futures Trading Commission.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995 (“PRA”), this notice announces that the Information Collection Request (“ICR”) abstracted below has been forwarded to the Office of Management and Budget (“OMB”) for review and comment. The ICR describes the nature of the information collection and its expected costs and burden.

**DATES:** Comments must be submitted on or before September 8, 2015.

**ADDRESSES:** Comments regarding the burden estimated or any other aspect of the information collection, including suggestions for reducing the burden, may be submitted directly to the Office of Information and Regulatory Affairs (“OIRA”) in OMB, within 30 days of the notice’s publication, by email at [OIRASubmissions@omb.eop.gov](mailto:OIRASubmissions@omb.eop.gov). Please identify the comments by OMB Control No. 3038-0092. Please provide the Commission with a copy of all

submitted comments at the address listed below. Please refer to OMB Reference No. 3038-0092, found on <http://reginfo.gov>. Comments may also be mailed to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for the Commodity Futures Trading Commission, 725 17th Street NW., Washington, DC 20503, or through the Agency’s Web site at <http://comments.cftc.gov>. Follow the instructions for submitting comments through the Web site.

Comments may also be mailed to: Christopher Kirkpatrick, Secretary of the Commission, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street NW., Washington, DC 20581 or by Hand Deliver/Courier at the same address.

A copy of the supporting statements for the collection of information discussed above may be obtained by visiting [RegInfo.gov](http://RegInfo.gov). All comments must be submitted in English, or if not, accompanied by an English translation. Comments will be posted as received to [www.cftc.gov](http://www.cftc.gov). You should submit only information that you wish to make available publicly. If you wish the Commission to consider information that is exempt from disclosure under the Freedom of Information Act, a petition for confidential treatment of the exempt information may be submitted according to the procedures set forth in section 145.9 of the Commission’s regulations.

**FOR FURTHER INFORMATION CONTACT:** Christopher Hower, Special Counsel, Division of Clearing and Risk, Commodity Futures Trading Commission, (202) 418-6703; email: [chower@cftc.gov](mailto:chower@cftc.gov), and refer to OMB Control No. 3038-0092.

#### SUPPLEMENTARY INFORMATION:

**Title:** Customer Clearing Documentation and Timing of Acceptance for Clearing (OMB Control No. 3038-0092). This is a request for extension of a currently approved information collection.

**Abstract:** Section 4d(c) of the Commodity Exchange Act (“CEA” or “Act”), as amended by the Dodd-Frank Act, directs the Commission to require futures commission merchants (“FCMs”) to implement conflict of interest procedures that address such issues the Commission determines to be appropriate. Similarly, section 4s(j)(5), as added by the Dodd-Frank Act, requires swap dealers (“SDs”) and major swap participants (“MSPs”) to implement conflict of interest procedures that address such issues the Commission determines to be appropriate. Section 4s(j)(5) also

requires SDs and MSPs to ensure that any persons providing clearing activities or making determinations as to accepting clearing customers are separated by appropriate informational partitions from persons whose involvement in pricing, trading, or clearing activities might bias their judgment or contravene the core principle of open access. Section 4s(j)(6) of the CEA prohibits a swap dealer and major swap participant from adopting any process or taking any action that results in any unreasonable restraint on trade or imposes any material anticompetitive burden on trading or clearing, unless necessary or appropriate to achieve the purposes of the Act. Section 2(h)(1)(B)(ii) of the CEA requires that derivatives clearing organization (“DCO”) rules provide for the non-discriminatory clearing of swaps executed bilaterally or through an unaffiliated designated contract market or swap execution facility.

Pursuant to these provisions, the Commission adopted § 1.71(d)(1) relating to FCMs and § 23.605(d)(1) relating to swap dealers and major swap participants. These regulations prohibit swap dealers and major swap participants from interfering or attempting to influence the decisions of affiliated FCMs with regard to the provision of clearing services and activities and prohibit FCMs from permitting them to do so. The Commission also adopted § 23.607 to prohibit swap dealers and major swap participants from adopting any process or taking any action that results in any unreasonable restraint on trade or imposes any material anticompetitive burden on trading or clearing, unless necessary or appropriate to achieve the purposes of the Act. The Commission adopted § 39.12(b)(2) requiring that derivatives clearing organization rules provide for the non-discriminatory clearing of swaps executed bilaterally or through an unaffiliated designated contract market or swap execution facility.

As discussed further below, the additional information collection burden arising from the proposed regulations primarily is restricted to the costs associated with the affected registrants’ obligation to maintain records related to clearing documentation between the customer and the customer’s clearing member.

The information collection obligations imposed by the regulations are necessary to implement certain provisions of the CEA, including ensuring that registrants exercise effective risk management and for the



efficient operation of trading venues among SDs, MSPs, FCMs, and DCOs.

**Burden Statement:** The respondent burden for this collection is estimated to average 16 hours for FCMs and SDs and MSPs, and 40 hours for DCOs per response. This estimate includes the total time, effort, or financial resources expended by persons to generate, maintain, retain, disclose, or provide information to or for a Federal agency. The total annual cost burden per respondent is estimated to be \$736 for FCMs, SDs, and MSPs and \$1,840 for DCOs. The Commission based its calculation on an hourly wage rate of \$46 for a financial manager to maintain the data.

**Respondents/Affected Entities:** Swap dealers, Major Swap Participants, Futures Commission Merchants, and Derivatives Clearing Organizations.

**Estimated Number of Respondents:** 239 Swap Dealers, Major Swap Participants and Futures Commission Merchants, and 14 Derivatives Clearing Organizations.

**Estimated Total Annual Burden on Respondents:** 3,824 for FCMs, SDs, and MSPs, and 560 hours for DCOs.

**Frequency of Collection:** As needed.

**Authority:** 44 U.S.C. 3501 *et seq.*

Dated: August 4, 2015.

**Robert N. Sidman,**

*Deputy Secretary of the Commission.*

[FR Doc. 2015-19448 Filed 8-6-15; 8:45 am]

**BILLING CODE 6351-01-P**

## CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

### Information Collection; Submission for OMB Review, Comment Request

**AGENCY:** Corporation for National and Community Service.

**ACTION:** Notice.

**SUMMARY:** The Corporation for National and Community Service (CNCS) has submitted a public information collection request (ICR) entitled AmeriCorps Child Care Program Information Collection for review and approval in accordance with the Paperwork Reduction Act of 1995, Public Law 104-13, (44 U.S.C. Chapter 35). Copies of this ICR, with applicable supporting documentation, may be obtained by calling the Corporation for National and Community Service, Jennifer Veazey, at 202-606-6770 or email to [jveazey@cns.gov](mailto:jveazey@cns.gov). Individuals who use a telecommunications device for the deaf (TTY-TDD) may call 1-800-833-3722 between 8:00 a.m. and 8:00 p.m. Eastern Time, Monday through Friday.

**DATES:** Comments may be submitted, identified by the title of the information collection activity, within September 8, 2015.

**ADDRESSES:** Comments may be submitted, identified by the title of the information collection activity, to the Office of Information and Regulatory Affairs, Attn: Ms. Sharon Mar, OMB Desk Officer for the Corporation for National and Community Service, by any of the following two methods within 30 days from the date of publication in the **Federal Register**:

(1) By fax to: 202-395-6974, Attention: Ms. Sharon Mar, OMB Desk Officer for the Corporation for National and Community Service; or

(2) By email to: [smar@omb.eop.gov](mailto:smar@omb.eop.gov).

**SUPPLEMENTARY INFORMATION:** The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of CNCS, 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;
- Propose ways to enhance the quality, utility, and clarity of the information to be collected; and
- Propose 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

A 60-day Notice requesting public comment was published in the **Federal Register** on April 15, 2015 at Volume 80, No. 72 FR 20200. This comment period ended June 15, 2015. No public comments were received from this Notice.

### Description

The information collection is requested of AmeriCorps Members who are applying for the AmeriCorps Child Care benefit (or in some cases, member of their households); information collected is used to determine a member's eligibility based upon statutory, regulatory, and program eligibility requirements. In addition, the information collection is requested of the child care providers to determine a child care provider's eligibility to provide the child care service.

Information is collected via hardcopy and electronically through an online application system.

CNCS seeks to renew the current AmeriCorps Child Care Application and add four new instruments: the AmeriCorps Member Application, Attendance Sheet, Member Update Form, and Statement of Work Activities.

The information collection will otherwise be used in the same manner as the existing application.

**Type of Review:** Renewal.

**Agency:** Corporation for National and Community Service.

**Title:** AmeriCorps Child Care Program Forms.

**OMB Number:** 3045-0142.

**Agency Number:** None.

**Affected Public:** AmeriCorps Members and Child Care Providers.

**Total Respondents:** 1400 total: 700 AmeriCorps Members and 700 Child Care Providers.

**Frequency:** Annual.

### Average Time Per Response

**AmeriCorps Member Application:** 60 minutes.

**Member Update Form:** 5 minutes.

**Statement of Work Activities Form (completed by Member):** 10 minutes.

**AmeriCorps Child Care Provider Application:** 40 minutes.

**Attendance Sheet (completed by Provider and signed by Member):** 20 minutes.

**Estimated Total Burden Hours:** 1,575 hours.

**Total Burden Cost (capital/startup):** None.

**Total Burden Cost (operating/maintenance):** None.

Dated: August 3, 2015.

**Erin Dahlin,**

*Deputy Chief of Program Operations.*

[FR Doc. 2015-19371 Filed 8-6-15; 8:45 am]

**BILLING CODE 6050-28-P**

## DEPARTMENT OF DEFENSE

### Office of the Secretary

[Docket ID: DoD-2015-OS-0028]

### Submission for OMB Review; Comment Request

**ACTION:** Notice.

**SUMMARY:** The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

**DATES:** Consideration will be given to all comments received by September 8, 2015.

**FOR FURTHER INFORMATION CONTACT:** Fred Licari, 571-372-0493.

**SUPPLEMENTARY INFORMATION:**

*Title, Associated Form and OMB Number:* Personnel Security System Access Request (PSSAR) Form; DD Form 2962; OMB Control Number 0704-XXXX.

*Type of Request:* New.

*Number of Respondents:* 44,000.

*Responses per Respondent:* 1.

*Annual Responses:* 44,000.

*Average Burden per Response:* 10 minutes.

*Annual Burden Hours:* 7,333.

*Needs and Uses:* JPAS requires personal data collection to facilitate the initiation, investigation and adjudication of information relevant to DoD security clearances and employment suitability determinations for military, civilian employees and contractors seeking such credentials. Security Managers working in private companies that contract with DoD and require access to JPAS to update security-related information about their company's employees must complete DD Form 2962 to access JPAS. Completion of the form assures users have met the requirements for access to the system of record.

*Affected Public:* Business or other for-profit.

*Frequency:* On occasion.

*Respondent's Obligation:* Voluntary.

*OMB Desk Officer:* Ms. Jasmeet Seehra.

Written comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at [Oira\\_submission@omb.eop.gov](mailto:Oira_submission@omb.eop.gov). Please identify the proposed information collection by DoD Desk Officer and the Docket ID number and title of the information collection.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

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

*Instructions:* All submissions received must include the agency name, Docket ID 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.

*DOD Clearance Officer:* Mr. Frederick Licari.

Written requests for copies of the information collection proposal should be sent to Mr. Licari at WHS/ESD Directives Division, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350-3100.

Dated: August 3, 2015.

**Aaron Siegel,**

*Alternate OSD Federal Register Liaison Officer, Department of Defense.*

[FR Doc. 2015-19376 Filed 8-6-15; 8:45 am]

**BILLING CODE 5001-06-P**

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## DEPARTMENT OF EDUCATION

### International Resource Information System (IRIS); Title; OMB Number; Correction

**AGENCY:** Department of Education.

**ACTION:** Correction Notice.

**SUMMARY:** On August 4, 2015 the U.S. Department of Education published a 30-day comment period notice in the **Federal Register** Page 46253 Column 3; Page 46254, Column 1 seeking public comment for an information collection Docket ID Number ED-2014-ICCD-0154 entitled, "Evaluation of the Pell Grant Experiments under the Experimental Sites Initiative". ED is requesting a correction to the Title and OMB Number. The correct title is International Resource Information System (IRIS), and the correct OMB Number is 1840-0759.

The Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management, hereby issues a correction notice as required by the Paperwork Reduction Act of 1995.

Dated: August 4, 2015.

**Kate Mullan,**

*Acting Director, Information Collection Clearance Division, Privacy, Information and Records Management Services, Office of Management.*

[FR Doc. 2015-19442 Filed 8-6-15; 8:45 am]

**BILLING CODE 4000-01-P**

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## DEPARTMENT OF EDUCATION

[Docket No.: ED-2015-ICCD-0099]

### Agency Information Collection Activities; Comment Request; Student Assistance General Provisions—Student Right-to-Know (SRK)

**AGENCY:** Federal Student Aid (FSA), 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 an extension of an existing information collection.

**DATES:** Interested persons are invited to submit comments on or before October 6, 2015.

**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-2015-ICCD-0099. 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 2E103, Washington, DC 20202-4537.

**FOR FURTHER INFORMATION CONTACT:** For specific questions related to collection activities, please contact Beth Grebeldinger, 202-377-4018.

**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:* Student Assistance General Provisions—Student Right-to-Know (SRK).

*OMB Control Number:* 1845–0004.

*Type of Review:* An extension of an existing information collection.

*Respondents/Affected Public:* Private Sector, State, Local and Tribal Governments.

*Total Estimated Number of Annual Responses:* 30,022.

*Total Estimated Number of Annual Burden Hours:* 18,670.

*Abstract:* Eligible participating institutions are required to provide this SRK information to all enrolled students, prospective students prior to their enrolling or entering into a financial obligation with the school as well as to institution's employees. The regulations in 34 CFR 668.41 relate to the required annual notices an institution must provide to current and prospective students and current and prospective employees as well as information that must be made available to any party who requests it, including the methods that the information may be disclosed. The regulations in 34 CFR 668.45 relate to the required calculation and availability of an institution's completion or graduation rates of its certificate or degree seeking, first-time, full-time undergraduate students using the Department's Integrated Postsecondary Education Data System (IPEDS) Web site.

Dated: August 4, 2015.

**Kate Mullan,**

*Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.*

[FR Doc. 2015–19443 Filed 8–6–15; 8:45 am]

**BILLING CODE 4000–01–P**

## DEPARTMENT OF EDUCATION

[Docket No.: ED–2015–ICCD–0067]

### Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and Approval; Comment Request; Assessing the Role of Noncognitive and School Environmental Factors in Students' Transitions to High School in New Mexico

**AGENCY:** Department of Education (ED), Institute of Education Sciences (IES).

**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 September 8, 2015.

**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–2015–ICCD–0067 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 2E105, Washington, DC 20202–4537.

**FOR FURTHER INFORMATION CONTACT:** For specific questions related to collection activities, please contact Christopher Boccanfuso, 202–219–1674.

**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:* Assessing the Role of Noncognitive and School

Environmental Factors in Students' Transitions to High School in New Mexico.

*OMB Control Number:* 1850—NEW.

*Type of Review:* A new information collection.

*Respondents/Affected Public:* State, Local and Tribal Governments.

*Total Estimated Number of Annual Responses:* 2,591.

*Total Estimated Number of Annual Burden Hours:* 773.

*Abstract:* The study will examine relationships between non-cognitive factors (e.g., growth mindset, learning strategies, and self-efficacy) and school environment and contextual factors (e.g., perceptions of school safety, supportive teachers and counselors, usefulness of academic work) and three measures of successful 9th grade transitions—overall freshman GPA, number of 9th grade course failures, and freshman year attendance for three districts in New Mexico. It will also examine whether non-cognitive and school environment factors contribute to the prediction of successful 9th grade transitions after academic factors have been taken into account. The study will use data that will be collected via a survey that was created with assistance from members of the New Mexico Achievement Gap Alliance. The survey data will be used in combination with extant student-level academic and demographic data that will be obtained from the New Mexico Public Education Department. This study will also include comparisons between Hispanic, Native American and white students.

Dated: August 4, 2015.

**Stephanie Valentine,**

*Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.*

[FR Doc. 2015–19468 Filed 8–6–15; 8:45 am]

**BILLING CODE 4000–01–P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. ER15–2367–000]

### Nittany Energy, LLC; Supplemental Notice That Initial Market-Based Rate Filing Includes Request for Blanket Section 204 Authorization

This is a supplemental notice in the above-referenced proceeding of Nittany Energy, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR

part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is August 24, 2015.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at <http://www.ferc.gov>. To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic 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](mailto:FERCOnlineSupport@ferc.gov) or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: August 3, 2015.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2015-19421 Filed 8-6-15; 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 exempt wholesale generator filings:

*Docket Numbers:* EG15-107-000.

*Applicants:* Cedar Bluff Wind, LLC.

*Description:* Notice of self-certification of Exempt Wholesale Generator Status of Cedar Bluff Wind, LLC.

*Filed Date:* 7/31/15.

*Accession Number:* 20150731-5302.

*Comments Due:* 5 p.m. ET 8/21/15.

Take notice that the Commission received the following electric rate filings:

*Docket Numbers:* ER11-3417-009; ER10-2895-013; ER14-1964-004; ER13-2143-006; ER10-3167-005; ER13-203-005; ER11-2292-013; ER11-3942-012; ER11-2293-013; ER10-2917-013; ER11-2294-012; ER12-2447-011; ER13-1613-006; ER10-2918-014; ER10-2920-013; ER11-3941-011; ER10-2921-013; ER10-2922-013; ER13-1346-005; ER10-2966-013; ER11-2383-008; ER10-3178-006.

*Applicants:* Alta Wind VIII, LLC, Bear Swamp Power Company LLC, BIF II Safe Harbor Holdings, LLC, Black Bear Development Holdings, LLC, Black Bear Hydro Partners, LLC, Black Bear SO, LLC, Brookfield Energy Marketing Inc., Brookfield Energy Marketing LP, Brookfield Energy Marketing US LLC, Brookfield Power Piney & Deep Creek LLC, Brookfield Renewable Energy Marketing US LLC, Brookfield Smoky Mountain Hydropower LLC, Brookfield White Pine Hydro LLC, Carr Street Generating Station, L.P., Erie Boulevard Hydropower, L.P., Granite Reliable Power, LLC, Great Lakes Hydro America, LLC, Hawks Nest Hydro LLC, Mesa Wind Power Corporation, Rumford Falls Hydro LLC, Safe Harbor Water Power Corporation, Windstar Energy, LLC.

*Description:* Notice of Non-Material Change in Status of the Brookfield Companies.

*Filed Date:* 7/31/15.

*Accession Number:* 20150731-5305.

*Comments Due:* 5 p.m. ET 8/21/15.

*Docket Numbers:* ER13-1943-003.

*Applicants:* Midcontinent Independent System Operator, Inc.

*Description:* Compliance filing: 2015-07-31\_MISO-PJM Order 1000 Interregional Compliance to be effective 1/1/2014.

*Filed Date:* 7/31/15.

*Accession Number:* 20150731-5236.

*Comments Due:* 5 p.m. ET 8/21/15.

*Docket Numbers:* ER13-1944-002.

*Applicants:* PJM Interconnection, L.L.C.

*Description:* Compliance filing: Compliance Filing per 12/18/14 Order in Docket No. ER13-1944-000 to be effective 1/1/2014.

*Filed Date:* 7/31/15.

*Accession Number:* 20150731-5205.

*Comments Due:* 5 p.m. ET 8/21/15.

*Docket Numbers:* ER15-1682-001.

*Applicants:* TransCanyon DCR, LLC.

*Description:* Compliance filing: TO Tariff CWIP Compliance Filing to be effective N/A.

*Filed Date:* 7/31/15.

*Accession Number:* 20150731-5246.

*Comments Due:* 5 p.m. ET 8/21/15.

*Docket Numbers:* ER15-2129-000.

*Applicants:* Slate Creek Wind Project, LLC.

*Description:* Supplement to July 8, 2015 Slate Creek Wind Project, LLC tariff filing.

*Filed Date:* 7/31/15.

*Accession Number:* 20150731-5298.

*Comments Due:* 5 p.m. ET 8/21/15.

*Docket Numbers:* ER15-2130-000.

*Applicants:* Roosevelt Wind Project, LLC.

*Description:* Supplement to July 8, 2015 Roosevelt Wind Project, LLC tariff filing.

*Filed Date:* 7/31/15.

*Accession Number:* 20150731-5297.

*Comments Due:* 5 p.m. ET 8/21/15.

*Docket Numbers:* ER15-2131-000.

*Applicants:* Milo Wind Project, LLC.

*Description:* Supplement to July 8, 2015 Milo Wind Project, LLC tariff filing.

*Filed Date:* 7/31/15.

*Accession Number:* 20150731-5296.

*Comments Due:* 5 p.m. ET 8/21/15.

*Docket Numbers:* ER15-2358-000.

*Applicants:* Pacific Gas and Electric Company.

*Description:* § 205(d) Rate Filing: Revisions to CDWR's Load Interconnection Agreement reflecting Amendment No. 1 to be effective 7/1/2015.

*Filed Date:* 7/31/15.

*Accession Number:* 20150731-5219.

*Comments Due:* 5 p.m. ET 8/21/15.

*Docket Numbers:* ER15-2359-000.

*Applicants:* Nevada Power Company.

*Description:* § 205(d) Rate Filing: OATT Attachment P Revisions to be effective 9/30/2015.

*Filed Date:* 7/31/15.

*Accession Number:* 20150731-5241.

*Comments Due:* 5 p.m. ET 8/21/15.

*Docket Numbers:* ER15-2360-000.

*Applicants:* Southwest Power Pool, Inc.

*Description:* § 205(d) Rate Filing: Basin Electric Power Cooperative Contract Services Agreement to be effective 10/1/2015.

*Filed Date:* 7/31/15.

*Accession Number:* 20150731-5245.

*Comments Due:* 5 p.m. ET 8/21/15.

*Docket Numbers:* ER15-2361-000.

*Applicants:* Southwest Power Pool, Inc.

*Description:* § 205(d) Rate Filing: 3065 Montana-Dakota Utilities Co. Market Participant Agr to be effective 10/1/2015.

*Filed Date:* 7/31/15.

*Accession Number:* 20150731-5247.

*Comments Due:* 5 p.m. ET 8/21/15.

*Docket Numbers:* ER15-2362-000.

*Applicants:* PJM Interconnection, L.L.C.

*Description:* § 205(d) Rate Filing: Original Service Agreements Nos. 4225 & 4226; Queue Nos. V1-011 & V1-012 to be effective 10/3/2014.

*Filed Date:* 7/31/15.

*Accession Number:* 20150731-5248.

*Comments Due:* 5 p.m. ET 8/21/15.

*Docket Numbers:* ER15-2363-000.

*Applicants:* Southwest Power Pool, Inc.

*Description:* § 205(d) Rate Filing: 3070 WAPA-UGP Market Participant Service Agreement to be effective 10/1/2015.

*Filed Date:* 7/31/15.

*Accession Number:* 20150731-5251.

*Comments Due:* 5 p.m. ET 8/21/15.

*Docket Numbers:* ER15-2364-000.

*Applicants:* Midcontinent Independent System Operator, Inc.

*Description:* § 205(d) Rate Filing: 2015-07-31\_Prairie Power Attachment O Filing to be effective 10/1/2015.

*Filed Date:* 7/31/15.

*Accession Number:* 20150731-5253.

*Comments Due:* 5 p.m. ET 8/21/15.

*Docket Numbers:* ER15-2365-000.

*Applicants:* PacifiCorp.

*Description:* § 205(d) Rate Filing: OATT EIM—Rev to Enhance Operation to be effective 9/30/2015.

*Filed Date:* 7/31/15.

*Accession Number:* 20150731-5255.

*Comments Due:* 5 p.m. ET 8/21/15.

*Docket Numbers:* ER15-2366-000.

*Applicants:* Black Hills Power, Inc.

*Description:* § 205(d) Rate Filing: Revised Black Hills Power, Inc. JOATT Schedule 2 to be effective 9/29/2015.

*Filed Date:* 7/31/15.

*Accession Number:* 20150731-5257.

*Comments Due:* 5 p.m. ET 8/21/15.

*Docket Numbers:* ER15-2367-000.

*Applicants:* Nittany Energy, LLC.

*Description:* Baseline eTariff Filing: Nittany Energy LLC Market Based Rate Tariff to be effective 9/30/2015.

*Filed Date:* 8/3/15.

*Accession Number:* 20150803-5001.

*Comments Due:* 5 p.m. ET 8/24/15.

*Docket Numbers:* ER15-2368-000.

*Applicants:* RC Cape May Holdings, LLC.

*Description:* Request for Waiver of RC Cape May Holdings, LLC.

*Filed Date:* 8/3/15.

*Accession Number:* 20150803-5069.

*Comments Due:* 5 p.m. ET 8/24/15.

*Docket Numbers:* ER15-2369-000.

*Applicants:* Midcontinent Independent System Operator, Inc.

*Description:* § 205(d) Rate Filing: 2015-08-03\_SA 2824 ATC-Marshfield Facilities Construction Agreement to be effective 10/2/2015.

*Filed Date:* 8/3/15.

*Accession Number:* 20150803-5095.

*Comments Due:* 5 p.m. ET 8/24/15.

*Docket Numbers:* ER15-2370-000.

*Applicants:* PJM Interconnection, L.L.C.

*Description:* § 205(d) Rate Filing: Request for Limited Waiver of Must Offer Exception Pre-Notification Date to be effective 8/25/2015.

*Filed Date:* 8/3/15.

*Accession Number:* 20150803-5113.

*Comments Due:* 5 p.m. ET 8/24/15.

Take notice that the Commission received the following electric securities filings:

*Docket Numbers:* ES15-40-000; ES15-42-000; ES15-43-000; ES15-44-000; ES15-45-000; ES15-46-000; ES15-47-000; ES15-48-000.

*Applicants:* Jersey Central Power & Light Co., Pennsylvania Power Company, Pennsylvania Electric Company, Metropolitan Edison Company, West Penn Power Company, Monongahela Power Company, The Potomac Edison Company, Trans-Allegheny Interstate Line Company.

*Description:* Application of Jersey Central Power & Light Company, *et al.* for Authorization under Section 204(a) of the Federal Power Act to Issue Short-Term Debt Securities.

*Filed Date:* 7/31/15.

*Accession Number:* 20150731-5287.

*Comments Due:* 5 p.m. ET 8/21/15.

*Docket Numbers:* ES15-41-000.

*Applicants:* Old Dominion Electric Cooperative, Inc.

*Description:* Application for Authorization to Issue Short- and Long-term Debt, to Guaranty Obligations, and for Waivers of Old Dominion Electric Cooperative.

*Filed Date:* 7/31/15.

*Accession Number:* 20150731-5289.

*Comments Due:* 5 p.m. ET 8/21/15.

Take notice that the Commission received the following land acquisition reports:

*Docket Numbers:* LA15-2-000.

*Applicants:* Virginia Electric and Power Company, Dominion Energy Marketing, Inc. Dominion Nuclear Connecticut, Inc. Dominion Energy Manchester Street, Inc. Dominion Retail, Inc. Fairless Energy, LLC, NedPower Mt. Storm, LLC, Fowler Ridge Wind Farm, LLC, Dominion Bridgeport Fuel Cell, LLC, RE Columbia Two LLC, RE Camelot LLC, Selmer Farm, LLC, Mulberry Farm, LLC, CID Solar, LLC, Cottonwood Solar, LLC, Pavant Solar LLC.

*Description:* Quarterly Land Acquisition Report of Dominion Resources Services, Inc.

*Filed Date:* 7/31/15.

*Accession Number:* 20150731-5288.

*Comments Due:* 5 p.m. ET 8/21/15.

*Docket Numbers:* LA15-2-000.

*Applicants:* Adelanto Solar, LLC, Adelanto Solar II, LLC, Ashtabula Wind, LLC, Ashtabula Wind II, LLC, Ashtabula Wind III, LLC, Backbone Mountain Windpower, LLC, Baldwin Wind, LLC, Bayswater Peaking Facility, LLC, Blackwell Wind, LLC, Butler Ridge Wind Energy Center, LLC, Cimarron Wind Energy, LLC, Crystal Lake Wind, LLC, Crystal Lake Wind II, LLC, Crystal Lake Wind III, LLC, Day County Wind, LLC, Desert Sunlight 250, LLC, Desert Sunlight 300, LLC, Diablo Winds, LLC, Elk City Wind, LLC, Elk City II Wind, LLC, Energy Storage Holdings, LLC, Ensign Wind, LLC, ESI Vansycle Partners, L.P., Florida Power & Light Company, FPL Energy Burleigh County Wind, LLC, FPL Energy Cabazon Wind, LLC, FPL Energy Cape, LLC, FPL Energy Cowboy Wind, LLC, FPL Energy Green Power Wind, LLC, FPL Energy Hancock County Wind, LLC, FPL Energy Illinois Wind, LLC, FPL Energy Marcus Hook, L.P., FPL Energy MH50, L.P., FPL Energy Montezuma Wind, LLC, FPL Energy Mower County, LLC, FPL Energy New Mexico Wind, LLC, FPL Energy North Dakota Wind, LLC, FPL Energy North Dakota Wind II, LLC, FPL Energy Oklahoma Wind, LLC, FPL Energy Oliver Wind I, LLC, FPL Energy Oliver Wind II, LLC, FPL Energy Sooner Wind, LLC, FPL Energy South Dakota Wind, LLC, FPL Energy Stateline II, Inc. FPL Energy Vansycle, LLC, FPL Energy Wyman, LLC, FPL Energy Wyman IV, LLC, Garden Wind, LLC, Genesis Solar, LLC, Gray County Wind Energy, LLC, Hatch Solar Energy Center I, LLC, Hawkeye Power Partners, LLC, High Majestic Wind Energy Center, LLC, High Majestic Wind II, LLC, High Winds, LLC, Jamaica Bay Peaking Facility, LLC, Lake Benton Power Partners II, LLC, Langdon Wind, LLC, Limon Wind, LLC, Limon Wind II, LLC, Limon Wind III,

LLC, Logan Wind Energy LLC, Mammoth Plains Wind Project, LLC, Mantua Creek Solar, LLC, McCoy Solar, LLC, Meyersdale Windpower LLC, Mill Run Windpower, LLC, Minco Wind, LLC, Minco Wind II, LLC, Minco Wind III, LLC, Minco Wind Interconnection Services, LLC, Mountain View Solar, LLC, NEPM II, LLC, NextEra Energy Duane Arnold, LLC, NextEra Energy Montezuma II Wind, LLC, NextEra Energy Point Beach, LLC, NextEra Energy Power Marketing, LLC, NextEra Energy Seabrook, LLC, NextEra Energy Services Massachusetts, LLC, Northeast Energy Associates, LP, North Jersey Energy Associates, A Limited Partnership, North Sky River Energy, LLC, Northern Colorado Wind Energy, LLC, Osceola Windpower, LLC, Osceola Windpower II, LLC, Palo Duro Wind Energy, LLC, Palo Duro Wind Interconnection Services, LLC, Paradise Solar Urban Renewal, L.L.C., Peetz Table Wind Energy, LLC, Pennsylvania Windfarms, LLC, Perrin Ranch Wind, LLC, Pheasant Run Wind, LLC, Red Mesa Wind, LLC, Seiling Wind, LLC, Seiling Wind II, LLC, Seiling Wind Interconnection Services, LLC, Shafter Solar, LLC, Sky River LLC, Somerset Windpower, LLC, Steele Flats Wind Project, LLC, Story Wind, LLC, Tuscola Bay Wind, LLC, Tuscola Wind II, LLC, Vasco Winds, LLC, Waymart Wind Farm, L.P., Wessington Wind Energy Center, LLC, White Oak Energy LLC, Wilton Wind II, LLC, Windpower Partners 1993, LLC.

*Description:* Quarterly Land Acquisition Report of the NextEra Companies.

*Filed Date:* 7/31/15.

*Accession Number:* 20150731-5301.

*Comments Due:* 5 p.m. ET 8/21/15.

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: August 3, 2015.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2015-19419 Filed 8-6-15; 8:45 am]

**BILLING CODE 6717-01-P**

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Project No. 2114-209]

#### Public Utility District No. 2 of Grant County; Notice of Application and Soliciting Comments, Motions To Intervene, and Protests

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Recreation resources management plan amendment pertaining to recreation facilities and amenities at Crescent Bar.

b. *Project No:* 2114-209.

c. *Date Filed:* May 26, 2015 and supplemented July 29, 2015.

d. *Applicant:* Public Utility District No. 2 of Grant County.

e. *Name of Project:* Priest Rapids Hydroelectric Project.

f. *Location:* The Priest Rapids Hydroelectric Project is located on the mid-Columbia River in portions of Grant, Yakima, Kittitas, Douglas, Benton, and Chelan counties, Washington.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791a-825r.

h. *Applicant Contact:* Ms. Shannon Lowry, Land and Recreation Manager, Grant PUD, P.O. Box 878, Ephrata, WA 98823-0878, or at (509) 754-5088 ext. 2191, or email: [Slowry@gcpud.org](mailto:Slowry@gcpud.org).

i. *FERC Contact:* Mary Karwoski at (202) 502-6543, or email: [mary.karwoski@ferc.gov](mailto:mary.karwoski@ferc.gov).

j. *Deadline for filing comments, motions to intervene, and protests:* September 2, 2015.

The Commission strongly encourages electronic filing. Please file motions to intervene, protests, and comments using the Commission's eFiling system at <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov), (866) 208-3676 (toll free), or (202) 502-8659 (TTY). In lieu of electronic filing, please

send a paper copy to: Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. The first page of any filing should include docket number P-2114-209.

The Commission's Rules of Practice and Procedure require all intervenors filing documents with the Commission to serve a copy of that document on each person whose name appears on the official service list for the project. Further, if an intervenor files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency.

k. *Description of Request:* The licensee requests Commission approval to modify the recreation resources management plan, pursuant to Article 418. The licensee proposes to relocate the existing off-island overnight camping facility and redevelop the existing 6.2 acre site into an enhanced day-use area, including: additional picnic furnishing and sites, shade structures, restroom with outdoor beach shower, site signage, an expanded and clearly defined swim area, and redeveloped on-site parking. A new 55-site overnight camping facility will be constructed on Crescent Bar Island and integrated with the existing 9-hole golf course. The golf course will remain with some modifications. A conceptual plan of the layout of the proposed 55-site campground is provided in the licensee's application.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street, NE., Room 2A, Washington, DC 20426, or by calling (202) 502-8371. This filing may also be viewed on the Commission's Web site 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. You may also register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, call 1-866-208-3676 or email [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov), for TTY, call (202) 502-8659. A copy is also available for inspection and reproduction at the address in item (h) above. Agencies may obtain copies of the application directly from the applicant.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. Comments, Protests, or Motions to Intervene: Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214, respectively. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. Filing and Service of Documents: Any filing must (1) bear in all capital letters the title "COMMENTS", "PROTEST", or "MOTION TO INTERVENE" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person commenting, protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or protests must set forth their evidentiary basis. Any filing made by an intervenor must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 385.2010.

Dated: August 3, 2015.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2015-19422 Filed 8-6-15; 8:45 am]

BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Project No. 8296-060]

#### **Malacha Hydro Limited Partnership and Juniper Ridge Ranches, Inc.; Notice of Application Accepted for Filing and Soliciting Comments, Motions To Intervene, and Protests**

Take notice that the following hydroelectric application has been filed with the Commission and is available for public inspection:

a. *Application Type:* Request to stay requirements of article 409 of project license.

b. *Project No.:* 8296-060.

c. *Date Filed:* January 6, 2015.

d. *Applicants:* Malacha Hydro Limited Partnership and Juniper Ridge Ranches, Inc.

e. *Name of Project:* Muck Valley Hydroelectric Project.

f. *Location:* The project is located on the Pit River in Lassen County, California.

g. *Filed Pursuant to:* Federal Power Act, 16 U.S.C. 791(a)-825(r).

h. *Applicant Contact:* Maria Litos, Director of Asset Management, Pacific Operations, Brookfield Renewable Energy Group, 601 S. Figueroa, Suite 2200, Los Angeles, CA 90017, telephone: 213-995-9905.

i. *FERC Contact:* Jon Cofrancesco, telephone: (202) 502-8951, and email address: [jon.cofrancesco@ferc.gov](mailto:jon.cofrancesco@ferc.gov).

j. *Deadline for filing comments, motions to intervene, and protests:* September 1, 2015.

All documents may be filed electronically via the Internet. See 18 CFR 385.2001(a)(1)(iii) and the instructions on the Commission's Web site at <http://www.ferc.gov/docs-filing/efiling.asp>. Commenters can submit brief comments up to 6,000 characters, without prior registration, using the eComment system at <http://www.ferc.gov/docs-filing/ecomment.asp>. You must include your name and contact information at the end of your comments. For assistance, please contact FERC Online Support at [FERCOnlineSupport@ferc.gov](mailto:FERCOnlineSupport@ferc.gov) or toll free at 1-866-208-3676, or for TTY, (202) 502-8659. Although the Commission strongly encourages electronic filing, documents may also be paper-filed. To paper-file, mail a copy to: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426. Please include the project number (P-8296-060) on any comments or motions filed.

k. *Description of Request:* Article 409 requires Malacha Hydro Limited Partnership and Juniper Ridge Ranches, Inc. (licensees) to upgrade existing access to adjacent public lands managed by the U.S. Bureau of Land Management (BLM), including the construction of trail-head parking facilities, within five years from license issuance. The project license was issued on December 2, 1986. Since license issuance, the licensees have been unable to fulfill this license condition due to an on-going land exchange matter between the BLM and a private landowner, whose land is necessary to provide access to the trailhead parking facilities. The BLM land to be exchanged for the landowner's property is located within the Pit River Canyon Wilderness Study Area. The BLM cannot implement the

land exchange until Congress acts to either designate these lands as wilderness or release the lands. Until Congress acts, BLM cannot complete the land exchange and the licensees cannot construct the required trailhead facilities. For these reasons, the licensees request a stay of five years for article 409 to allow Congress additional time to act on the Pit River Canyon Wilderness Study Area.

l. *Locations of the Application:* A copy of the application is available for inspection and reproduction at the Commission's Public Reference Room, located at 888 First Street NE., Room 2A, Washington, DC 20426, or by calling (202) 502-8371. This filing may also be viewed on the Commission's Web site at <http://www.ferc.gov/docs-filing/elibrary.asp>. Enter the docket number excluding the last three digits in the docket number field to access the document. A copy is also available for inspection and reproduction at the address in item (h) above.

You may also register online at <http://www.ferc.gov/docs-filing/esubscription.asp> to be notified via email of new filings and issuances related to this or other pending projects. For assistance, contact FERC Online Support.

m. Individuals desiring to be included on the Commission's mailing list should so indicate by writing to the Secretary of the Commission.

n. Comments, Protests, or Motions to Intervene: Anyone may submit comments, a protest, or a motion to intervene in accordance with the requirements of Rules of Practice and Procedure, 18 CFR 385.210, .211, .214. In determining the appropriate action to take, the Commission will consider all protests or other comments filed, but only those who file a motion to intervene in accordance with the Commission's Rules may become a party to the proceeding. Any comments, protests, or motions to intervene must be received on or before the specified comment date for the particular application.

o. *Filing and Service of Responsive Documents:* All filings must (1) bear in all capital letters the title "COMMENTS", "PROTEST", or "MOTION TO INTERVENE" as applicable; (2) set forth in the heading the name of the applicant and the project number of the application to which the filing responds; (3) furnish the name, address, and telephone number of the person protesting or intervening; and (4) otherwise comply with the requirements of 18 CFR 385.2001 through 385.2005. All comments, motions to intervene, or

protests must set forth their evidentiary basis and otherwise comply with the requirements of 18 CFR 4.34(b). All comments, motions to intervene, or protests should relate to project works which are the subject of the amendment application. Agencies may obtain copies of the application directly from the applicant. A copy of any protest or motion to intervene must be served upon each representative of the applicant specified in the particular application. If an intervener files comments or documents with the Commission relating to the merits of an issue that may affect the responsibilities of a particular resource agency, they must also serve a copy of the document on that resource agency. A copy of all other filings in reference to this application must be accompanied by proof of service on all persons listed in the service list prepared by the Commission in this proceeding, in accordance with 18 CFR 4.34(b) and 385.2010.

Dated: August 3, 2015.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2015-19423 Filed 8-6-15; 8:45 am]

BILLING CODE 6717-01-P

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

[Docket No. CP15-503-000]

#### **Comanche Trail Pipeline, LLC; Notice of Intent To Prepare an Environmental Assessment for the Proposed San Elizario Crossing Project; Request for Comments on Environmental Issues**

The staff of the Federal Energy Regulatory Commission (FERC or Commission) will prepare an environmental assessment (EA) that will discuss the environmental impacts of the San Elizario Crossing Project involving construction and operation of specific border crossing facilities for the export of natural gas by Comanche Trail Pipeline, LLC (Comanche Trail) in El Paso County, Texas. The Commission will use this EA in its decision-making process to determine whether the project is in the public interest.

This notice announces the opening of the scoping process the Commission will use to gather input from the public and interested agencies on the project. You can make a difference by providing us with your specific comments or concerns about the project. Your comments should focus on the potential environmental effects, reasonable

alternatives, and measures to avoid or lessen environmental impacts. Your input will help the Commission staff determine what issues they need to evaluate in the EA. To ensure that your comments are timely and properly recorded, please send your comments so that the Commission receives them in Washington, DC on or before September 2, 2015.

If you sent comments on this project to the Commission before the opening of this docket on May 29, 2015, you will need to file those comments in Docket No. CP15-503-000 to ensure they are considered as part of this proceeding.

This notice is being sent to the Commission's current environmental mailing list for this project. State and local government representatives should notify their constituents of this proposed project and encourage them to comment on their areas of concern.

Comanche Trail provided landowners with a fact sheet prepared by the FERC entitled "An Interstate Natural Gas Facility On My Land? What Do I Need To Know?". This fact sheet addresses a number of typically-asked questions, including the use of eminent domain and how to participate in the Commission's proceedings. It is also available for viewing on the FERC Web site ([www.ferc.gov](http://www.ferc.gov)).

#### **Public Participation**

For your convenience, there are three methods you can use to submit your comments to the Commission. The Commission encourages electronic filing of comments and has expert staff available to assist you at (202) 502-8258 or [efiling@ferc.gov](mailto:efiling@ferc.gov). Please carefully follow these instructions so that your comments are properly recorded.

(1) You can file your comments electronically using the *eComment* feature on the Commission's Web site ([www.ferc.gov](http://www.ferc.gov)) under the link to *Documents and Filings*. This is an easy method for submitting brief, text-only comments on a project;

(2) You can file your comments electronically by using the *eFiling* feature on the Commission's Web site ([www.ferc.gov](http://www.ferc.gov)) under the link to *Documents and Filings*. With eFiling, you can provide comments in a variety of formats by attaching them as a file with your submission. New eFiling users must first create an account by clicking on "eRegister." If you are filing a comment on a particular project, please select "Comment on a Filing" as the filing type; or

(3) You can file a paper copy of your comments by mailing them to the following address. Be sure to reference the project docket number (CP15-503-

000) with your submission: Kimberly D. Bose, Secretary, Federal Energy Regulatory Commission, 888 First Street NE., Room 1A, Washington, DC 20426.

#### **Summary of the Proposed Project**

Comanche Trail proposes to construct and operate a new border crossing at the international boundary between the United States and Mexico in El Paso County, Texas. The San Elizario Crossing Project would consist of the construction of approximately 1,086 feet of FERC-jurisdictional 42-inch-diameter pipeline, installed using a horizontal directional drill (HDD) beneath the Rio Grande River near the City of San Elizario in El Paso, Texas. The new pipeline would have a maximum design export capacity of approximately 1.1 billion cubic feet per day, in order to transport natural gas to a new delivery interconnect in the vicinity of the City of San Isidro, in the State of Chihuahua, Mexico.

The general location of the project facilities is shown in appendix 1.<sup>1</sup>

#### **Non-Jurisdictional Facilities**

The San Elizario Crossing Project has associated facilities that would be constructed in support of the project, but do not fall under the jurisdiction of the FERC. The proposed Comanche Trail intrastate pipeline facilities, consist of 196 miles of new 42-inch-diameter pipeline, multiple receipt and delivery metering stations, and other auxiliary facilities extending from Pecos County, Texas and terminating at the proposed FERC-jurisdictional project facilities in El Paso County. The intrastate facilities would be subject to the jurisdiction of the Texas Railroad Commission and would be non-jurisdictional to the FERC. In the EA, we will provide available descriptions of the non-jurisdictional facilities and include available environmental impact information under our analysis of cumulative impacts.

#### **Land Requirements for Construction**

Construction of the San Elizario Crossing Project pipeline would affect a total of 4.2 acres of land in the United States, which includes temporary workspace for HDD construction, hydrostatic testing of the pipeline, and project access. Following construction, Comanche Trail would retain 1.3 acres as a 50-foot-wide permanent easement for operation of the FERC-jurisdictional pipeline, and the remaining acreage would be restored and revert to former uses.



## The EA Process

The National Environmental Policy Act (NEPA) requires the Commission to take into account the environmental impacts that could result from an action whenever it considers the issuance of an Authorization. NEPA also requires us<sup>2</sup> to discover and address concerns the public may have about proposals. This process is referred to as “scoping.” The main goal of the scoping process is to focus the analysis in the EA on the important environmental issues. By this notice, the Commission requests public comments on the scope of the issues to address in the EA. We note that many comments were filed prior to this notice. We want to assure those commentors that their concerns will be considered in the scope of our environmental review; you do not need to resubmit comments. We will consider all filed comments during the preparation of the EA.

In the EA we will discuss impacts that could occur as a result of the construction and operation of the proposed project under these general headings:

- Geology and soils;
- land use;
- water resources, fisheries, and wetlands;
- cultural resources;
- vegetation and wildlife;
- air quality and noise;
- endangered and threatened species;
- public safety; and
- cumulative impacts.

We will also evaluate reasonable alternatives to the proposed project or portions of the project, and make recommendations on how to lessen or avoid impacts on the various resource areas.

The EA will present our independent analysis of the issues. The EA will be available in the public record through eLibrary. We will also publish and distribute the EA to the public for an allotted comment period. We will consider all comments on the EA before making our recommendations to the Commission. To ensure we have the opportunity to consider and address your comments, please carefully follow the instructions in the Public Participation section beginning on page 2.

With this notice, we are asking agencies with jurisdiction by law and/or special expertise with respect to the environmental issues of this project to formally cooperate with us in the

preparation of the EA.<sup>3</sup> Agencies that would like to request cooperating agency status should follow the instructions for filing comments provided under the Public Participation section of this notice.

## Consultations Under Section 106 of the National Historic Preservation Act

In accordance with the Advisory Council on Historic Preservation’s implementing regulations for section 106 of the National Historic Preservation Act, we are using this notice to initiate consultation with the applicable State Historic Preservation Office (SHPO), and to solicit their views and those of other government agencies, interested Indian tribes, and the public on the project’s potential effects on historic properties.<sup>4</sup> We will define the project-specific Area of Potential Effects (APE) in consultation with the SHPO as the project develops. On natural gas facility projects, the APE at a minimum encompasses all areas subject to ground disturbance (examples include construction right-of-way, contractor/pipe storage yards, compressor stations, and access roads). Our EA for this project will document our findings on the impacts on historic properties and summarize the status of consultations under section 106.

## Environmental Mailing List

The environmental mailing list includes: Federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American Tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission’s regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project. We will update the environmental mailing list as the analysis proceeds to ensure that we send the information related to this environmental review to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed project.

<sup>3</sup>The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Part 1501.6.

<sup>4</sup>The Advisory Council on Historic Preservation’s regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

When we publish and distribute the EA, copies will be sent to the environmental mailing list for public review and comment. If you would prefer to receive a paper copy of the document instead of the CD version or would like to remove your name from the mailing list, please return the attached Information Request (appendix 2).

## Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an “intervenor” which is an official party to the Commission’s proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission’s final ruling. An intervenor formally participates in the proceeding by filing a request to intervene. Instructions for becoming an intervenor are available on the Commission’s Web site at <http://www.ferc.gov/resources/guides/how-to/intervene.asp>.

## Additional Information

Additional information about the project is available from the Commission’s Office of External Affairs, at (866) 208-FERC, or on the FERC Web site at [www.ferc.gov](http://www.ferc.gov) using the “eLibrary” link. Click on the eLibrary link, click on “General Search” and enter the docket number, excluding the last three digits in the Docket Number field (*i.e.*, CP15-503). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at [FercOnlineSupport@ferc.gov](mailto:FercOnlineSupport@ferc.gov) or toll free at (866) 208-3676, or for TTY, contact (202) 502-8659. The eLibrary link also provides access to the texts of formal documents issued by the Commission, such as orders, notices, and rulemakings.

In addition, the Commission now offers a free service called eSubscription which allows you to keep track of all formal issuances and submittals in specific dockets. This can reduce the amount of time you spend researching proceedings by automatically providing you with notification of these filings, document summaries, and direct links to the documents. Go to [www.ferc.gov/docs-filing/esubscription.asp](http://www.ferc.gov/docs-filing/esubscription.asp).

Finally, public meetings or site visits will be posted on the Commission’s calendar located at [www.ferc.gov/EventCalendar/EventsList.aspx](http://www.ferc.gov/EventCalendar/EventsList.aspx) along with other related information.

<sup>2</sup>“We,” “us,” and “our” refer to the environmental staff of the Commission’s Office of Energy Projects.

Dated: August 3, 2015.

**Nathaniel J. Davis, Sr.,**

*Deputy Secretary.*

[FR Doc. 2015-19420 Filed 8-6-15; 8:45 am]

**BILLING CODE 6717-01-P**

## ENVIRONMENTAL PROTECTION AGENCY

[ER-FRL-9022-3]

### 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 07/27/2015 Through 07/31/2015  
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-enepa-public/action/eis/search>.

*EIS No. 20150208, Final, DOE, AL, PROGRAMMATIC—Engineered High Energy Crop (EHEC) Programs, Review Period Ends: 09/08/2015, Contact: Dr. Jonathan Burbaum 202-287-6413.*

*EIS No. 20150209, Final, USFS, AZ, Prescott National Forest Revision of Land and Resource Management Plan, Review Period Ends: 11/05/2015, Contact: Gabrielle Kenton 928-443-8221.*

*EIS No. 20150210, Draft, USFS, WY, Teton to Snake Fuels Management, Comment Period Ends: 09/21/2015, Contact: Steve Markason 307-739-5431.*

*EIS No. 20150211, Draft, FHWA, LA, Houma-Thibodaux to LA 3127 Connection, Comment Period Ends: 09/21/2015, Contact: Carl Highsmith 225-757-7615.*

*EIS No. 20150212, Draft, BLM, CA, West Of Devers Upgrade Project, Comment Period Ends: 09/21/2015, Contact: Frank McMenimen 760-833-7150.*

*EIS No. 20150213, Final, USFS, CA, Westside Fire Recovery Project, Review Period Ends: 09/08/2015, Contact: Wendy Coats 530-841-4470.*

*EIS No. 20150214, Draft, BR, CA, Coordinated Long-Term Operation of the Central Valley Project and State Water Project, Comment Period Ends: 09/29/2015, Contact: Janice Piñero 916-414-2428.*

Dated: August 4, 2015.

**Karin Leff,**

*Acting Director, NEPA Compliance Division, Office of Federal Activities.*

[FR Doc. 2015-19441 Filed 8-6-15; 8:45 am]

**BILLING CODE 6560-50-P**

## FARM CREDIT ADMINISTRATION

### Farm Credit Administration Board; Sunshine Act; Regular Meeting

**AGENCY:** Farm Credit Administration.

**SUMMARY:** Notice is hereby given, pursuant to the Government in the Sunshine Act, of the regular meeting of the Farm Credit Administration Board (Board).

**DATES:** The regular meeting of the Board will be held at the offices of the Farm Credit Administration in McLean, Virginia, on August 13, 2015, from 9:00 a.m. until such time as the Board concludes its business.

**FOR FURTHER INFORMATION CONTACT:** Dale L. Aultman, Secretary to the Farm Credit Administration Board, (703) 883-4009, TTY (703) 883-4056.

**ADDRESSES:** Farm Credit Administration, 1501 Farm Credit Drive, McLean, Virginia 22102-5090. Submit attendance requests via email to [VisitorRequest@FCA.gov](mailto:VisitorRequest@FCA.gov). See

**SUPPLEMENTARY INFORMATION** for further information about attendance requests.

**SUPPLEMENTARY INFORMATION:** Parts of this meeting of the Board will be open to the public (limited space available), and parts will be closed to the public. Please send an email to [VisitorRequest@FCA.gov](mailto:VisitorRequest@FCA.gov) at least 24 hours before the meeting. In your email include: Name, postal address, entity you are representing (if applicable), and telephone number. You will receive an email confirmation from us. Please be prepared to show a photo identification when you arrive. If you need assistance for accessibility reasons, or if you have any questions, contact Dale L. Aultman, Secretary to the Farm Credit Administration Board, at (703) 883-4009. The matters to be considered at the meeting are:

### Open Session

#### A. Approval of Minutes

- July 8, 2015

#### B. New Business

- Mergers, Consolidations and Charter Amendments of Banks and Associations—Final Rule

### Closed Session \*

- Office of Secondary Market Oversight Quarterly Report

\* Session Closed-Exempt pursuant to 5 U.S.C. Section 552b(c)(8) and (9).

Dated: August 4, 2015.

**Dale L. Aultman,**

*Secretary, Farm Credit Administration Board.*

[FR Doc. 2015-19578 Filed 8-5-15; 4:15 pm]

**BILLING CODE 6705-01-P**

## FEDERAL COMMUNICATIONS COMMISSION

### Federal Advisory Committee Act; Downloadable Security Technology Advisory Committee

**AGENCY:** Federal Communications Commission.

**ACTION:** Notice.

**SUMMARY:** In accordance with the Federal Advisory Committee Act, this notice advises interested persons that the Federal Communications Commission's ("FCC" or "Commission") Downloadable Security Technology Advisory Committee ("DSTAC") will hold a meeting on August 28, 2015. At the meeting, the committee will consider and debate a final DSTAC report and discuss any other DSTAC issues that may arise.

**DATES:** August 28, 2015.

**ADDRESSES:** Federal Communications Commission, Room TW-C305 (Commission Meeting Room), 445 12th Street SW., Washington, DC 20554.

**FOR FURTHER INFORMATION CONTACT:** For additional information on this proceeding, contact Brendan Murray, [Brendan.Murry@fcc.gov](mailto:Brendan.Murry@fcc.gov), of the Media Bureau, Policy Division, (202) 418-1573 or Nancy Murphy, [Nancy.Murphy@fcc.gov](mailto:Nancy.Murphy@fcc.gov), of the Media Bureau, (202) 418-1043.

**SUPPLEMENTARY INFORMATION:** This meeting will be held on August 28, 2015, from 9:30 a.m. to 4:00 p.m. in the Commission Meeting Room of the Federal Communications Commission, Room TW-C305, 445 12th Street SW., Washington, DC 20554.

The DSTAC is a Federal Advisory Committee that will "identify, report, and recommend performance objectives, technical capabilities, and technical standards of a not unduly burdensome, uniform, and technology- and platform-neutral software-based downloadable security system."

The meeting on August 28, 2015, will be the seventh meeting of the DSTAC. The FCC will attempt to accommodate as many attendees as possible; however, admittance will be limited to seating availability. The Commission will provide audio and/or video coverage of the meeting over the Internet from the

FCC's Web page at <http://fcc.gov/live>. The public may submit written comments before the meeting to Brendan Murray, DSTAC Designated Federal Officer, by email to [DSTAC@fcc.gov](mailto:DSTAC@fcc.gov) or by U.S. Postal Service Mail to 445 12th Street SW., Room 4-A726, Washington, DC 20554.

Open captioning will be provided for this event. Other reasonable accommodations for people with disabilities are available upon request. Requests for such accommodations should be submitted via email to [fcc504@fcc.gov](mailto:fcc504@fcc.gov) or by calling the Consumer & Governmental Affairs Bureau at (202) 418-0530 (voice), (202) 418-0432 (tty). Such requests should include a detailed description of the accommodation needed. In addition, please include a way the FCC can contact you if it needs more information. Please allow at least five days' advance notice; last-minute request will be accepted, but may be impossible to fill.

Federal Communications Commission.

**Gloria J. Miles,**

*Federal Register Liaison Officer.*

[FR Doc. 2015-19437 Filed 8-6-15; 8:45 am]

**BILLING CODE 6712-01-P**

## FEDERAL ELECTION COMMISSION

### Sunshine Act Meeting

**AGENCY:** Federal Election Commission.

**DATE AND TIME:** Tuesday, August 11, 2015 at the conclusion of the open meeting, and Thursday, August 13, 2015 at 10:00 a.m.

**PLACE:** 999 E Street NW., Washington, DC.

**STATUS:** This meeting will be closed to the public.

**ITEMS TO BE DISCUSSED:** Compliance matters pursuant to 52 U.S.C. 30109.

Internal personnel rules and internal rules and practices.

Information the premature disclosure of which would be likely to have a considerable adverse effect on the implementation of a proposed Commission action.

Matters concerning participation in civil actions or proceedings or arbitration.

\* \* \* \* \*

**PERSON TO CONTACT FOR INFORMATION:**

Judith Ingram, Press Officer, Telephone: (202) 694-1220.

**Shelley E. Garr,**

*Deputy Secretary of the Commission.*

[FR Doc. 2015-19504 Filed 8-5-15; 11:15 am]

**BILLING CODE 6715-01-P**

## FEDERAL ELECTION COMMISSION

### Sunshine Act Meetings

**AGENCY:** Federal Election Commission

**DATE AND TIME:** Tuesday, August 11, 2015 at 10:00 a.m.

**PLACE:** 999 E Street NW., Washington, DC (Ninth Floor).

**STATUS:** This meeting will be open to the public.

### Items To Be Discussed

Correction and Approval of Minutes for July 16, 2015

Draft Advisory Opinion 2015-03:

Democracy Rules, Inc.

Draft Advisory Opinion 2015-05:

Alexina Shaber

Notice to Respondents of Information

Sharing by the Commission

Public Disclosure of Closed

Enforcement Files

Management and Administrative

Matters

Individuals who plan to attend and require special assistance, such as sign language interpretation or other reasonable accommodations, should contact Shawn Woodhead Werth, Secretary and Clerk, at (202) 694-1040, at least 72 hours prior to the meeting date.

**PERSON TO CONTACT FOR INFORMATION:**

Judith Ingram, Press Officer, Telephone: (202) 694-1220.

Signed:

**Shawn Woodhead Werth,**

*Secretary and Clerk of the Commission.*

[FR Doc. 2015-19505 Filed 8-5-15; 11:15 am]

**BILLING CODE 6715-01P**

## FEDERAL MARITIME COMMISSION

### Notice of Agreement Filed

The Commission hereby gives notice of the filing of the following agreement under the Shipping Act of 1984. Interested parties may submit comments on the agreement to the Secretary, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. A copy of the agreement is available through the Commission's Web site ([www.fmc.gov](http://www.fmc.gov)) or by contacting the Office of Agreements at (202) 523-5793 or [tradeanalysis@fmc.gov](mailto:tradeanalysis@fmc.gov).

*Agreement No.:* 201202-006.

*Title:* Oakland MTO Agreement.

*Parties:* Ports America Outer Harbor Terminal, LLC; Seaside Transportation Service LLC; SSA Terminals, LLC; SSA Terminals (Oakland), LLC; and Trapac, LLC.

*Filing Party:* David F. Smith, Esq.; Cozen O'Connor; 1627 I Street NW.; Suite 1100; Washington, DC 20006.

*Synopsis:* The amendment would authorize the parties to implement an off-peak hours program and describe said program.

By Order of the Federal Maritime Commission.

Dated: August 4, 2015.

**Karen V. Gregory,**

*Secretary.*

[FR Doc. 2015-19447 Filed 8-6-15; 8:45 am]

**BILLING CODE 6731-AA-P**

## FEDERAL RESERVE SYSTEM

### Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than August 24, 2015.

A. Federal Reserve Bank of Richmond (Adam M. Drimer, Assistant Vice President) 701 East Byrd Street, Richmond, Virginia 23261-4528:

1. *Gene B. Dixon, Jr., Dillwyn, Virginia, to individually and as a group acting in concert with Guy B. Dixon Trust of the Separate Grandchild's Trust for the benefit of Guy B. Dixon, Dillwyn, Virginia; Curtis Dixon Colgate, Trustee of the Separate Grandchild's Trust for the benefit of Curtis Dixon Colgate, Virginia Beach, Virginia; Arch Huddle Dixon, Trustee of the Separate Grandchild's Trust for the benefit of Arch Huddle Dixon, Virginia Beach, Virginia; Sharon Newcomb, Merritt Island, Florida; and Erica Vail Dixon, Trustee of the Separate Grandchild's Trust for the benefit of Erica Vail Dixon, Dillwyn, Virginia; to acquire voting shares of BCC Bankshares, Inc., and thereby indirectly acquire voting shares of The Bank of Charlotte County, both in Phenix, Virginia.*

Board of Governors of the Federal Reserve System, August 4, 2015.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2015-19380 Filed 8-6-15; 8:45 am]

BILLING CODE 6210-01-P

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Centers for Medicare & Medicaid Services

[CMS-1641-N]

#### Medicare, Medicaid, and Children's Health Insurance Programs; Membership and Meeting Announcement for the Advisory Panel on Clinical Diagnostic Laboratory Tests

**AGENCY:** Centers for Medicare & Medicaid Services (CMS), HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces 15 membership appointments to the Advisory Panel on Clinical Diagnostic Laboratory Tests (the Panel) and the first meeting date for the Panel. The purpose of the Panel is to advise the Secretary of the Department of Health and Human Services (DHHS) (the Secretary) and the Administrator of the Centers for Medicare & Medicaid Services (CMS) (the Administrator) on issues related to clinical diagnostic laboratory tests. The membership appointments are for 3 years. This notice also announces the first meeting date of the Panel on Wednesday, August 26, 2015.

**DATES:** *Meeting Date:* The first meeting of the Panel is scheduled to take place at CMS's headquarters in Baltimore, MD on Wednesday, August 26, 2015 beginning at 9:00 a.m., Eastern Daylight Time (EDT). The Panel will specifically recommend crosswalks for new laboratory codes, recommend an appropriate coding structure for drugs of abuse testing, and recommend crosswalks for such drugs of abuse testing.

#### Meeting Registration

The public may attend the meeting in-person, view via webcast, or listen via teleconference. Beginning Friday, August 7, 2015 and ending Friday, August 14, 2015 at 5:00 p.m. EDT, registration to attend the meeting in-person may be completed online at <http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html>. On this Web page, under "Related Links,"

double-click the "Clinical Diagnostic Laboratory Tests FACA Panel Meeting Registration" link and enter the required information. All the following information must be submitted when registering:

- Name.
- Company name.
- Postal address.
- Email address.

**Note:** Participants who do not plan to attend the meeting in-person on August 26, 2015, should not register. No registration is required for participants who plan to view the meeting via webcast or listen via teleconference.

#### Presenter Registration and Submission of Presentations and Comments

We are interested in submitted comments or in presentations at the meeting concerning the issues described in the **SUMMARY** section of this notice. The comments and presentations should not duplicate those that were provided at the Annual Clinical Laboratory Public Meeting on July 16, 2015, or submitted through the comment process provided subsequent to the Annual Clinical Laboratory Public Meeting. The deadline to register to be a presenter and to submit written presentations for the meeting is 5:00 p.m. EDT, Monday, August 17, 2015. Presenters may register by phone or via email by contacting the person listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. Presentations should be sent via email to the same person's email address.

For reconsidered and new test codes, presenters should address all of the following items:

- Reconsidered or new test code(s) and descriptor.
- Test purpose and method.
- Costs.
- Charges.
- A recommendation with rationale for one of the two methods (crosswalking or gapfilling) for determining payment for new tests, or a recommendation with rationale for changing the basis or payment amount, as applicable, for reconsidered tests.

Additionally, the presenters should provide the data on which their recommendations are based.

When registering, individuals who want to make a presentation must also specify for which new test codes they will be presenting comments. A confirmation will be sent upon receipt of the registration. Presenters must register by the date specified in the "Meeting Registration" section of this notice.

#### Meeting Location, Webcast, and Teleconference

The meetings will be held in the Auditorium, CMS Central Office, 7500 Security Boulevard, Woodlawn, Maryland 21244-1850. Alternately, the public may either view the meetings via a webcast or listen by teleconference. During the scheduled meeting, webcasting is accessible online at <http://cms.gov/live>. Teleconference dial-in information will appear on the final meeting agenda, which will be posted on the CMS Web site when available at <http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html>.

#### Meeting Format

This meeting is open to the public. The onsite check-in for visitors will be held from 8:30 a.m. to 9:00 a.m. EDT on Wednesday, August 26, 2015, followed by opening remarks. Following the opening remarks, the Panel will hear oral presentations from the public for no more than 1 hour during two sessions. During the first session, registered persons from the public may present recommendations for crosswalks for new laboratory codes for the CY 2016 CLFS. During the second session, registered persons from the public may present recommendations for drugs of abuse testing and crosswalks. Time allotted for each presentation may be limited. If the number of registrants requesting to present is greater than can be reasonably accommodated during the scheduled open public hearing session, we may conduct a lottery to determine the speakers for the scheduled open public hearing session. We will accept written presentations from those who were unable to present due to time constraints.

**ADDRESSES:** *Web site:* For additional information on the Panel, please refer to our Web site at <http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html>.

**FOR FURTHER INFORMATION CONTACT:** Glenn C. McGuirk, Designated Federal Official (DFO), Center for Medicare, Division of Ambulatory Services, CMS, 7500 Security Boulevard, Mail Stop C4-01-26, Baltimore, MD 21244, 410-786-5723, email [Glenn.McGuirk@cms.hhs.gov](mailto:Glenn.McGuirk@cms.hhs.gov). Press inquiries are handled through the CMS Press Office at (202) 690-6145.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

The Advisory Panel on Clinical Diagnostic Laboratory Tests is

authorized by section 1834A(f)(1) of the Social Security Act (the Act) (42 U.S.C. 1395m–1), as established by section 216 of the Protecting Access to Medicare Act of 2014 (PAMA) (Pub. L. 113–93, enacted April 1, 2014). The Panel is subject to the Federal Advisory Committee Act (FACA), as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory panels.

Section 1834A(f)(1) of the Act directs the Secretary of the Department of Health and Human Services (Secretary) to consult with an expert outside advisory panel, established by the Secretary, composed of an appropriate selection of individuals with expertise in issues related to clinical diagnostic laboratory tests. Such individuals may include representatives of clinical laboratories, molecular pathologists, clinical laboratory researchers, and individuals with expertise in laboratory science or health economics.

The Panel will provide input and recommendations to the Secretary and the Administrator, Centers for Medicare & Medicaid Services (CMS), on the following:

- The establishment of payment rates under section 1834A of the Act for new clinical diagnostic laboratory tests, including whether to use crosswalking or gapfilling processes to determine payment for a specific new test;
- The factors used in determining coverage and payment processes for new clinical diagnostic laboratory tests; and
- Other aspects of the new payment system under section 1834A of the Act.

The Panel charter provides that panel meetings will be held up to four times annually. The Panel will consist of up to 15 individuals and a Chair. The Panel Chair will facilitate meetings and the DFO or DFO's designee must be present at all meetings. Meetings will be open to the public except as determined otherwise by the Secretary or other official to whom the authority has been delegated in accordance with the Sunshine Act of 1976 (5 U.S.C. 552b(c)) and FACA. Notice of all meetings will be published in the **Federal Register** as required by applicable laws and Departmental regulations. Meetings will be conducted, and records of the proceedings kept, as required by applicable laws and Departmental regulations.

In order to conduct the business of the Panel, a quorum is required. A quorum exists when a majority of currently appointed members is present at full Panel or subcommittee meetings or is participating in conference calls.

## II. Provisions of This Notice

We published a notice in the **Federal Register** on October 27, 2014, entitled “Medicare, Medicaid, and Children’s Health Insurance Programs; Advisory Panel on Clinical Diagnostic Laboratory Tests and Request for Nominations” (79 FR 63919 through 63920). The notice solicited nominations for up to 15 members and a Chair to serve on this Panel. This notice announces 16 new members to the Panel. Their appointments are for 3-year terms beginning July 1, 2015.

The Panel will consist of the following members and a Chair:

- Steve Phurrough M.D., Panel Chair, CMS Medical Officer
- Geoffrey Baird, M.D., Ph.D.
- Vickie Baselski, Ph.D.
- Stephen N. Bauer, M.D.
- William Clarke, Ph.D., M.B.A., DABCC, FACB
- Judith Davis, M.S.
- Stanley R. Hamilton, M.D.
- Curtis A. Hanson, M.D.
- Kandice Kottke-Marchant, M.D., Ph.D.
- Raju Kucherlapati, Ph.D.
- Bryan A. Loy, M.D., M.B.A.
- Gail Marcus, M.S.E., M.B.A.
- Carl Morrison, M.D., D.V.M.
- Victoria M. Pratt, Ph.D., FACMG
- Michele M. Schoonmaker, Ph.D.
- Rebecca Sutphen, M.D.

## III. Meeting Attendance

The first meeting (August 26, 2015) is open to the public; however, attendance is limited to space available. Priority will be given to those who pre-register and attendance may be limited based on the number of registrants and the space available.

Persons wishing to attend this meeting, which is located on federal property, must register by following the instructions in the “Meeting Registration” section of this notice. A confirmation email will be sent to the registrants shortly after completing the registration process.

## IV. Security, Building, and Parking Guidelines

The following are the security, building, and parking guidelines:

- Persons attending the meeting, including presenters, must be pre-registered and on the attendance list by the prescribed date.
- Individuals who are not pre-registered in advance may not be permitted to enter the building and may be unable to attend the meeting.
- Attendees must present a government-issued photo identification to the Federal Protective Service or Guard Service personnel before entering

the building. Without a current, valid photo ID, persons may not be permitted entry to the building.

- Security measures include inspection of vehicles, inside and out, at the entrance to the grounds.
- All persons entering the building must pass through a metal detector.
- All items brought into CMS including personal items, for example, laptops and cell phones are subject to physical inspection.
- The public may enter the building 30 to 45 minutes before the meeting convenes each day.
- All visitors must be escorted in areas other than the lower and first-floor levels in the Central Building.
- The main-entrance guards will issue parking permits and instructions upon arrival at the building.

## V. Special Accommodations

Individuals requiring special accommodations must include the request for these services during registration.

## VI. Panel Recommendations and Discussions

The Panel’s recommendations will be posted to our Web site after the meeting.

## VII. Copies of the Charter

The Secretary’s Charter for the Advisory Panel on Clinical Diagnostic Laboratory Tests is available on the CMS Web site at <http://cms.gov/Regulations-and-Guidance/Guidance/FACA/AdvisoryPanelonClinicalDiagnosticLaboratoryTests.html> or you may obtain a copy of the charter by submitting a request to the contact listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice.

## VIII. Collection of Information Requirements

This document does not impose information collection requirements, that is, reporting, recordkeeping or third-party disclosure requirements. Consequently, there is no need for review by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).

Dated: August 3, 2015.

**Andrew M. Slavitt,**

*Acting Administrator, Centers for Medicare & Medicaid Services.*

[FR Doc. 2015–19498 Filed 8–6–15; 8:45 am]

**BILLING CODE 4120–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2014-N-1051]

#### Modified Risk Tobacco Product Applications: Applications for 10 Products Submitted by Swedish Match North America Inc.; Reopening of Comment Period; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of July 31, 2015 (80 FR 45661). The document reopened the period for public comment on modified risk tobacco product applications (MRTPAs) submitted by Swedish Match North America Inc. for 10 tobacco products and announced the availability for public comment of amendments to the MRTPAs. The document was published with an incorrect paragraph in the *Comments* section. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** Lisa Granger, Office of Policy and Planning, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993-0002, 301-796-9115.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2015-18782, appearing in the **Federal Register** of Friday, July 31, 2015, the following correction is made:

On page 45661, in the third column, the first paragraph of the *Comments* section is corrected to read:

#### A. General Information About Submitting Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document.

#### B. Public Availability of Comments

Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>. As a matter of Agency practice, FDA generally does not post comments submitted by individuals in their individual capacity on <http://www.regulations.gov>. This is determined by information indicating

that the submission is written by an individual, for example, the comment is identified with the category "Individual Consumer" under the field entitled "Category (Required)," on the "Your Information" page on <http://www.regulations.gov>. For this docket, however, FDA will not be following this general practice. Instead, FDA will post on <http://www.regulations.gov> comments to this docket that have been submitted by individuals in their individual capacity. If you wish to submit any information under a claim of confidentiality, please refer to 21 CFR 10.20.

#### C. Information Identifying the Person Submitting the Comment

Please note that your name, contact information, and other information identifying you will be posted on <http://www.regulations.gov> if you include that information in the body of your comments. For electronic comments submitted to <http://www.regulations.gov>, FDA will post the body of your comment on <http://www.regulations.gov> along with your state/province and country (if provided), the name of your representative (if any), and the category identifying you (e.g., individual, consumer, academic, industry). For written submissions submitted to the Division of Dockets Management, FDA will post the body of your comments on <http://www.regulations.gov>, but you can put your name and/or contact information on a separate cover sheet and not in the body of your comments.

Dated: August 3, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-19418 Filed 8-6-15; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-D-2537]

#### Request for Quality Metrics; Notice of Draft Guidance Availability and Public Meeting; Request for Comments; Correction

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice; correction.

**SUMMARY:** The Food and Drug Administration (FDA) is correcting a notice that appeared in the **Federal Register** of July 28, 2015 (80 FR 44973). The document published with an

incorrect docket number. This document corrects that error.

**FOR FURTHER INFORMATION CONTACT:** Lisa Granger, Office of Policy, Planning, Legislation, and Analysis, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 3330, Silver Spring, MD 20993-0002, 301-796-9115.

**SUPPLEMENTARY INFORMATION:** In FR Doc. 2015-18448, appearing on page 44973, in the **Federal Register** of Tuesday, July 28, 2015, the following correction is made:

On page 44973, in the first column, in the headings section of the document, "[Docket No. FDA-2014-D-2537]" is corrected to read "FDA-2015-D-2537".

Dated: August 3, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-19487 Filed 8-6-15; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### 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 of a decision to designate a class of employees from the Westinghouse Electric Corporation in Bloomfield, New Jersey, 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 1-877-222-7570. Information requests can also be submitted by email to [DCAS@CDC.GOV](mailto:DCAS@CDC.GOV).

**SUPPLEMENTARY INFORMATION:**

**Authority:** 42 U.S.C. 7384q(b). 42 U.S.C. 7384l(14)(C).

On July 31, 2015, 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 Westinghouse Electric Corp., in Bloomfield, New Jersey, during the period from February

1, 1958, through May 31, 1958, or during the period from June 1, 1959, through June 30, 1959, 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 will become effective on August 27, 2015, unless Congress provides otherwise prior to the effective date. After this effective date, HHS will publish a notice in the **Federal Register** reporting the addition of this class to the SEC or the result of any provision by Congress regarding the decision by HHS to add the class to the SEC.

**John Howard,**

*Director, National Institute for Occupational Safety and Health.*

[FR Doc. 2015-19471 Filed 8-6-15; 8:45 am]

**BILLING CODE 4163-19-P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Indian Health Service**

**Notice of Service Delivery Area Designation for the Koi Nation of Northern California Formerly Known as the Lower Lake Rancheria**

**AGENCY:** Indian Health Service, HHS.

**ACTION:** Notice.

**SUMMARY:** This Notice advises the public that the Indian Health Service (IHS) proposes the geographic boundaries of the Service Delivery Area (SDA) for the reaffirmed Koi Nation of Northern California, formerly known as the Lower Lake Rancheria, California (Indian Entities Recognized and Eligible to Receive Services From the United States Bureau of Indian Affairs, 80 **Federal Register** 1942 Jan. 14, 2015). The Koi Nation's Federal recognition was reaffirmed by the Assistant Secretary of Indian Affairs on December 29, 2000. The Koi Nation SDA is to be comprised of Lake and Sonoma Counties in the State of California. The counties listed are designated administratively as the SDA, to function as a Purchased/ Referred Care (PRC), formerly known as contract health services, SDA, for the

purposes of operating a PRC program pursuant to the Indian Self-Determination and Education Assistance Act (ISDEAA), Pub. L. 93-638.

**DATES:** This notice is effective 30 days after date of publication in the **Federal Register** (FR).

**ADDRESSES:** Comments may be mailed to Ms. Betty Gould, Regulations Officer, Indian Health Service, 801 Thompson Avenue, Suite 450, Rockville, Maryland 20852. Comments will be made available for public inspection at this address from 8:30 a.m. to 5:00 p.m. Monday-Friday beginning approximately two weeks after publication of this notice.

**FOR FURTHER INFORMATION CONTACT:** Mr. Carl Harper, Director, Office of Resource Access and Partnerships, Indian Health Service, 801 Thompson Avenue, Suite 360, Rockville, Maryland 20852. Telephone 301/443-2694 (This is not a toll free number).

**SUPPLEMENTAL INFORMATION:** The IHS currently provides services under regulations in effect on September 15, 1987 and IHS republished at 42 CFR part 136, subparts A through C. Many of the newly recognized/restored/reaffirmed Tribes do not have reservations and either Congress has legislatively designated counties to serve as SDAs or the Director, IHS, exercised reasonable administrative discretion to designate SDAs to effectuate the intent of Congress for these Tribes. The Director, IHS, published notice of the establishment of SDAs in the June 21, 2007 FR Notice (72 FR 34262-01). The SDAs function as PRC SDAs for the purposes of operating a PRC program pursuant to the ISDEAA, Pub. L. 93-638. Thus, the PRC SDA list incorporates the SDAs that operate as PRC SDAs for newly recognized/restored/reaffirmed Tribes. At 42 CFR part 136 Subpart C, a PRC SDA is defined as the geographic area within which PRC will be made available by the IHS to members of an identified Indian community who reside in the area. Residence within a PRC SDA by a person who is within the scope of the Indian health program, as set forth in 42 CFR 136.12 creates no legal entitlement to PRC but only potential eligibility for

services. Services needed but not available at an IHS/Tribal facility are provided under the PRC program depending on the availability of funds, the person's relative medical priority, and the actual availability and accessibility of alternate resources in accordance with the regulations.

As applicable to the Tribes, these regulations provide that, unless otherwise designated, a PRC SDA shall consist of a county which includes all or part of a reservation and any county or counties which have a common boundary with the reservation (42 CFR 136.22(a)(6) (2014). On December 29, 2000 the Assistant Secretary of Indian Affairs reaffirmed the Federal recognition of the Koi Nation (Tribe), formerly known as the Lower Lake Rancheria, and the government-to-government relationship between the United States and the Tribe. The Koi Nation is located in Lake and Sonoma Counties in the State of California. After consultation with the Tribal governing body, the SDA for the Tribe was agreed upon. The purpose of this FR notice is to notify the public that the IHS now administratively designates Lake and Sonoma Counties as the Koi Nation's SDA.

Under 42 CFR 136.23 those otherwise eligible Indians who do not reside on a reservation but reside within a PRC SDA must be either members of the Tribe or maintain close economic and social ties with the Tribe. In this case, the Tribe estimated the eligible user population to be 72 enrolled Koi Nation members who are actively involved with the Tribe.

The Koi Nation's Tribal office is located in the city of Santa Rosa, Sonoma County, in the State of California. A significant number of the Koi Nation SDA eligible user population also resides in Lake County in the State of California. There are other Federally recognized Tribes in Lake and Sonoma Counties and both counties are currently part of other Tribes' PRC SDA. The Koi Nation only seeks to provide health care services to its members who reside in Lake and Sonoma Counties.

This notice does not contain reporting or recordkeeping requirements subject to prior approval by the Office of Management and Budget under the Paperwork Reduction Act of 1980.

**PURCHASED/REFERRED CARE SERVICE DELIVERY AREAS AND SERVICE DELIVERY AREAS**

Tribe/reservation	County/state
Ak Chin Indian Community of the Maricopa (Ak Chin) Indian Reservation, Arizona.	Pinal, AZ.
Alabama-Coushatta Tribes of Texas .....	Polk, TX. <sup>1</sup>
Alaska .....	Entire State. <sup>2</sup>
Arapahoe Tribe of the Wind River Reservation, Wyoming .....	Hot Springs, WY, Fremont, WY, Sublette, WY.

## PURCHASED/REFERRED CARE SERVICE DELIVERY AREAS AND SERVICE DELIVERY AREAS—Continued

Tribe/reservation	County/state
Aroostook Band of Micmacs .....	Aroostook, ME. <sup>3</sup>
Assiniboine and Sioux Tribes of the Fort Peck Indian Reservation, Montana .....	Daniels, MT, McCone, MT, Richland, MT, Roosevelt, MT, Sheridan, MT, Valley, MT.
Bad River Band of the Lake Superior Tribe of Chippewa Indians of the Bad River Reservation, Wisconsin .....	Ashland, WI, Iron, WI.
Bay Mills Indian Community, Michigan .....	Chippewa, MI.
Blackfeet Tribe of the Blackfeet Indian Reservation of Montana .....	Glacier, MT, Pondera, MT.
Brigham City Intermountain School Health Center, Utah .....	( <sup>4</sup> )
Burns Paiute Tribe .....	Harney, OR.
California .....	Entire State, except for the counties listed in the footnote. <sup>5</sup>
Catawba Indian Nation .....	All Counties in SC, <sup>6</sup> Cabarrus, NC, Cleveland, NC, Gaston, NC, Mecklenburg, NC, Rutherford, NC, Union, NC.
Cayuga Nation .....	Allegany, NY, <sup>7</sup> Cattaraugus, NY, Chautauqua, NY, Erie, NY, Warren, PA.
Cheyenne River Sioux Tribe of the Cheyenne River Reservation, South Dakota .....	Corson, SD, Dewey, SD, Haakon, SD, Meade, SD, Perkins, SD, Potter, SD, Stanley, SD, Sully, SD, Walworth, SD, Ziebach, SD.
Chippewa-Cree Indians of the Rocky Boy's Reservation, Montana .....	Chouteau, MT, Hill, MT, Liberty, MT.
Chitimacha Tribe of Louisiana .....	St. Mary Parish, LA.
Cocopah Tribe of Arizona .....	Yuma, AZ, Imperial, CA.
Coeur D'Alene Tribe .....	Benewah, ID, Kootenai, ID, Latah, ID, Spokane, WA, Whitman, WA.
Colorado River Indian Tribes of the Colorado River Indian Reservation, Arizona and California .....	La Paz, AZ, Riverside, CA, San Bernardino, CA, Yuma, AZ.
Confederated Salish and Kootenai Tribes of the Flathead Reservation .....	Flathead, MT, Lake, MT, Missoula, MT, Sanders, MT.
Confederated Tribes and Bands of the Yakama Nation .....	Klickitat, WA, Lewis, WA, Skamania, WA, <sup>8</sup> Yakima, WA.
Confederated Tribes of Siletz Indians of Oregon .....	Benton, OR, <sup>9</sup> Clackamas, OR, Lane, OR, Lincoln, OR, Linn, OR, Marion, OR, Multnomah, OR, Polk, OR, Tillamook, OR, Washington, OR, Yam Hill, OR.
Confederated Tribes of the Chehalis Reservation .....	Grays Harbor, WA, Lewis, WA, Thurston, WA.
Confederated Tribes of the Colville Reservation, Washington .....	Chelan, WA, <sup>10</sup> Douglas, WA, Ferry, WA, Grant, WA, Lincoln, WA, Okanogan, WA, Stevens, WA.
Confederated Tribes of the Coos, Lower Umpqua and Siuslaw Indians .....	Coos, OR, <sup>11</sup> Curry, OR, Douglas, OR, Lane, OR, Lincoln, OR.
Confederated Tribes of the Goshute Reservation, Nevada and Utah .....	Nevada, Juab, UT, Toole, UT.
Confederated Tribes of the Grand Ronde Community of Oregon .....	Polk, OR, <sup>12</sup> Washington, OR, Marion, OR, Yamhill, OR, Tillamook, OR, Multnomah, OR.
Confederated Tribes of the Umatilla Indian Reservation .....	Umatilla, OR, Union, OR.
Confederated Tribes of the Warm Springs Reservation of Oregon .....	Clackamas, OR, Jefferson, OR, Linn, OR, Marion, OR, Wasco, OR.
Coquille Indian Tribe .....	Coos, OR, Curry, OR, Douglas, OR, Jackson, OR, Lane, OR.
Coushatta Tribe of Louisiana .....	Allen Parish, LA, Elton, LA. <sup>13</sup>
Cow Creek Band of Umpqua Tribe of Indians .....	Coos, OR, <sup>14</sup> Deshutes, OR, Douglas, OR, Jackson, OR, Josephine, OR, Klamath, OR, Lane, OR.
Cowlitz Indian Tribe .....	Clark, WA, Cowlitz, WA, King, WA, Lewis, WA, Pierce, WA, Skamania, WA, Thurston, WA, Columbia, OR, <sup>15</sup> Kittitas, WA, Wahkiakum, WA.
Crow Creek Sioux Tribe of the Crow Creek Reservation, South Dakota .....	Brule, SD, Buffalo, SD, Hand, SD, Hughes, SD, Hyde, SD, Lyman, SD, Stanley, SD.
Crow Tribe of Montana .....	Big Horn, MT, Carbon, MT, Treasure, MT, <sup>16</sup> Yellowstone, MT, Big Horn, WY, Sheridan, WY.
Eastern Band of Cherokee Indians .....	Cherokee, NC, Graham, NC, Haywood, NC, Jackson, NC, Swain, NC.
Flandreau Santee Sioux Tribe of South Dakota .....	Moody, SD.
Forest County Potawatomi Community, Wisconsin .....	Forest, WI, Marinette, WI, Oconto, WI.
Fort Belknap Indian Community of the Fort Belknap Reservation of Montana .....	Blaine, MT, Phillips, MT.
Fort McDermitt Paiute and Shoshone Tribes of the Fort McDermitt Indian Reservation, Nevada and Oregon .....	Nevada, Malheur, OR.
Fort McDowell Yavapai Nation, Arizona .....	Maricopa, AZ.
Fort Mojave Indian Tribe of Arizona, California and Nevada .....	Nevada, Mohave, AZ, San Bernardino, CA.
Gila River Indian Community of the Gila River Indian Reservation, Arizona .....	Maricopa, AZ, Pinal, AZ.
Grand Traverse Band of Ottawa and Chippewa Indians, Michigan .....	Antrim, MI, <sup>17</sup> Benzie, MI, Charlevoix, MI, Grand Traverse, MI, Leelanau, MI, Manistee, MI.
Hannahville Indian Community, Michigan .....	Delta, MI, Menominee, MI.
Haskell Indian Health Center .....	Douglas, KS. <sup>18</sup>
Havasupai Tribe of the Havasupai Reservation, Arizona .....	Coconino, AZ.
Ho-Chunk Nation of Wisconsin .....	Adams, WI, <sup>19</sup> Clark, WI, Columbia, WI, Crawford, WI, Dane, WI, Eau Claire, WI, Houston, MN, Jackson, WI, Juneau, WI, La Crosse, WI, Marathon, WI, Monroe, WI, Sauk, WI, Shawano, WI, Vernon, WI, Wood, WI.
Hoh Indian Tribe .....	Jefferson, WA.
Hopi Tribe of Arizona .....	Apache, AZ, Coconino, AZ, Navajo, AZ.
Houlton Band of Maliseet Indians .....	Aroostook, ME. <sup>20</sup>
Hualapai Indian Tribe of the Hualapai Indian Reservation, Arizona .....	Coconino, AZ, Mohave, AZ, Yavapai, AZ.
Iowa Tribe of Kansas and Nebraska .....	Brown, KS, Doniphan, KS, Richardson, NE.
Jamestown S'Klallam Tribe .....	Clallam, WA, Jefferson, WA.



## PURCHASED/REFERRED CARE SERVICE DELIVERY AREAS AND SERVICE DELIVERY AREAS—Continued

Tribe/reservation	County/state
Jena Band of Choctaw Indians .....	Grand Parish, LA, <sup>21</sup> LaSalle Parish, LA, Rapides Parish, LA.
Jicarilla Apache Nation, New Mexico .....	Archuleta, CO, Rio Arriba, NM, Sandoval, NM.
Kaibab Band of Paiute Indians of the Kaibab Indian Reservation, Arizona.	Coconino, AZ, Mohave, AZ, Kane, UT.
Kalispel Indian Community of the Kalispel Reservation .....	Pend Oreille, WA, Spokane, WA.
Kewa Pueblo, New Mexico .....	Sandoval, NM, Santa Fe, NM.
Keweenaw Bay Indian Community, Michigan .....	Baraga, MI, Houghton, MI, Ontonagon, MI.
Kickapoo Traditional Tribe of Texas .....	Maverick, TX. <sup>22</sup>
Kickapoo Tribe of Indians of the Kickapoo Reservation in Kansas .....	Brown, KS, Jackson, KS.
Klamath Tribes .....	Klamath, OR. <sup>23</sup>
Koi Nation of Northern California (formerly known as Lower Lake Rancheria, California).	Lake, CA, Sonoma, CA. <sup>24</sup>
Kootenai Tribe of Idaho .....	Boundary, ID.
Lac Courte Oreilles Band of Lake Superior Chippewa Indians of Wisconsin.	Sawyer, WI.
Lac du Flambeau Band of Lake Superior Chippewa Indians of the Lac du Flambeau Reservation of Wisconsin.	Iron, WI, Oneida, WI, Vilas, WI.
Lac Vieux Desert Band of Lake Superior Chippewa Indians of Michigan	Gogebic, MI.
Little River Band of Ottawa Indians, Michigan .....	Kent, MI, <sup>25</sup> Muskegon, MI, Newaygo, MI, Oceana, MI, Ottawa, MI, Manistee, MI, Mason, MI, Wexford, MI, Lake, MI.
Little Traverse Bay Bands of Odawa Indians, Michigan .....	Alcona, MI, <sup>25</sup> Alger, MI, Alpena, MI, Antrim, MI, Benzie, MI, Charlevoix, MI, Cheboygan, MI, Chippewa, MI, Crawford, MI, Delta, MI, Emmet, MI, Grand Traverse, MI, Iosco, MI, Kalkaska, MI, Leelanau, MI, Luce, MI, Mackinac, MI, Manistee, MI, Missaukee, MI, Montmorency, MI, Ogemaw, MI, Oscoda, MI, Otsego, MI, Presque Isle, MI, Schoolcraft, MI, Roscommon, MI, Wexford, MI.
Lower Brule Sioux Tribe of the Lower Brule Reservation, South Dakota	Brule, SD, Buffalo, SD, Hughes, SD, Lyman, SD, Stanley, SD.
Lower Elwha Tribal Community .....	Clallam, WA.
Lower Sioux Indian Community in the State of Minnesota .....	Redwood, MN, Renville, MN.
Lummi Tribe of the Lummi Reservation .....	Whatcom, WA.
Makah Indian Tribe of the Makah Indian Reservation .....	Clallam, WA.
Mashantucket Pequot Tribe .....	New London, CT. <sup>26</sup>
Mashpee Wampanoag Tribe .....	Barnstable, MA, Bristol, MA, Norfolk, MA, Plymouth, MA, Suffolk, MA. <sup>27</sup>
Match-e-be-nash-she-wish Band of Pottawatomis Indians of Michigan ....	Allegan, MI, <sup>28</sup> Barry, MI, Kalamazoo, MI, Kent, MI, Ottawa, MI.
Menominee Indian Tribe of Wisconsin .....	Langlade, WI, Menominee, WI, Oconto, WI, Shawano, WI.
Mescalero Apache Tribe of the Mescalero Reservation, New Mexico ....	Chaves, NM, Lincoln, NM, Otero, NM.
Micosaukee Tribe of Indians .....	Broward, FL, Collier, FL, Miami-Dade, FL, Hendry, FL.
Minnesota Chippewa Tribe, Minnesota Bois Forte Band (Nett Lake) ....	Itasca, MN, Koochiching, MN, St. Louis, MN.
Minnesota Chippewa Tribe, Minnesota Fond du Lac Band .....	Carlton, MN, St. Louis, MN.
Minnesota Chippewa Tribe, Minnesota Grand Portage Band .....	Cook, MN.
Minnesota Chippewa Tribe, Minnesota Leech Lake Band .....	Beltrami, MN, Cass, MN, Hubbard, MN, Itasca, MN.
Minnesota Chippewa Tribe, Minnesota Mille Lacs Band .....	Aitkin, MN, Kanebec, MN, Mille Lacs, MN, Pine, MN.
Minnesota Chippewa Tribe, Minnesota White Earth Band .....	Becker, MN, Clearwater, MN, Mahanomen, MN, Norman, MN, Polk, MN.
Mississippi Band of Choctaw Indians .....	Attala, MS, Jasper, MS, <sup>29</sup> Jones, MS, Kemper, MS, Leake, MS, Neshoba, MS, Newton, MS, Noxubee, MS, <sup>29</sup> Scott, MS, <sup>30</sup> Winston, MS.
Mohegan Tribe of Indians of Connecticut .....	Fairfield, CT, Hartford, CT, Litchfield, CT, Middlesex, CT, New Haven, CT, New London, CT, Tolland, CT, Windham, CT.
Muckleshoot Indian Tribe .....	King, WA, Pierce, WA.
Narragansett Indian Tribe .....	Washington, RI. <sup>31</sup>
Navajo Nation, Arizona, New Mexico & Utah .....	Apache, AZ, Bernalillo, NM, Cibola, NM, Coconino, AZ, Kane, UT, McKinley, NM, Montezuma, CO, Navajo, AZ, Rio Arriba, NM, Sandoval, NM, San Juan, NM, San Juan, UT, Socorro, NM, Valencia, NM.
Nevada .....	Entire State. <sup>32</sup>
Nez Perce Tribe .....	Clearwater, ID, Idaho, ID, Latah, ID, Lewis, ID, Nez Perce, ID.
Nisqually Indian Tribe .....	Pierce, WA, Thurston, WA.
Nooksack Indian Tribe .....	Whatcom, WA.
Northern Cheyenne Tribe of the Northern Cheyenne Indian Reservation, Montana.	Big Horn, MT, Carter, MT, <sup>33</sup> Rosebud, MT.
Northwestern Band of Shoshoni Nation .....	Box Elder, UT. <sup>34</sup>
Nottawaseppi Huron Band of the Potawatomi, Michigan .....	Allegan, MI, <sup>35</sup> Barry, MI, Branch, MI, Calhoun, MI, Kalamazoo, MI, Kent, MI, Ottawa, MI.
Oglala Sioux Tribe .....	Bennett, SD, Cherry, NE, Custer, SD, Dawes, NE, Fall River, SD, Jackson, SD, <sup>36</sup> Melleete, SD, Pennington, SD, Shannon, SD, Sheridan, NE, Todd, SD.
Ohkay Owingeh, New Mexico .....	Rio Arriba, NM.
Oklahoma .....	Entire State. <sup>37</sup>
Omaha Tribe of Nebraska .....	Burt, NE, Cuming, NE, Monona, IA, Thurston, NE, Wayne, NE.
Oneida Nation of New York .....	Chenango, NY, Cortland, NY, Herkimer, NY, Madison, NY, Oneida, NY, Onondaga, NY.

## PURCHASED/REFERRED CARE SERVICE DELIVERY AREAS AND SERVICE DELIVERY AREAS—Continued

Tribe/reservation	County/state
Oneida Tribe of Indians of Wisconsin .....	Brown, WI, Outagamie, WI.
Onondaga Nation .....	Onondaga, NY.
Paiute Indian Tribe of Utah .....	Iron, UT, <sup>38</sup> Millard, UT, Sevier, UT, Washington, UT.
Pascua Yaqui Tribe of Arizona .....	Pima, AZ, <sup>39</sup>
Passamaquoddy Tribe .....	Aroostook, ME, <sup>40,41</sup> Washington, ME.
Penobscot Nation .....	Aroostook, ME, <sup>40</sup> Penobscot, ME.
Poarch Band of Creeks .....	Baldwin, AL, <sup>42</sup> Elmore, AL, Escambia, AL, Mobile, AL, Monroe, AL, Escambia, FL.
Pokagon Band of Potawatomi Indians, Michigan and Indiana .....	Allegan, MI, <sup>43</sup> Berrien, MI, Cass, MI, Elkhart, IN, Kosciusko, IN, La Porte, IN, Marshall, IN, St. Joseph, IN, Starke, IN, Van Buren, MI.
Ponca Tribe of Nebraska .....	Boyd, NE, <sup>44</sup> Burt, NE, Charles Mix, SD, Douglas, NE, Hall, NE, Holt, NE, Knox, NE, Lancaster, NE, Madison, NE, Platte, NE, Pottawattomie, IA, Sarpy, NE, Stanton, NE, Wayne, NE, Woodbury, IA.
Port Gamble S'Klallam Tribe .....	Kitsap, WA.
Prairie Band of Potawatomi Nation .....	Jackson, KS.
Prairie Island Indian Community in the State of Minnesota .....	Goodhue, MN.
Pueblo of Acoma, New Mexico .....	Cibola, NM.
Pueblo of Cochiti, New Mexico .....	Sandoval, NM, Santa Fe, NM.
Pueblo of Isleta, New Mexico .....	Bernalillo, NM, Tarrant, NM, Valencia, NM.
Pueblo of Jemez, New Mexico .....	Sandoval, NM.
Pueblo of Laguna, New Mexico .....	Bernalillo, NM, Cibola, NM, Sandoval, NM, Valencia, NM.
Pueblo of Nambe, New Mexico .....	Santa Fe, NM.
Pueblo of Picuris, New Mexico .....	Taos, NM.
Pueblo of Pojoaque, New Mexico .....	Rio Arriba, NM, Santa Fe, NM.
Pueblo of San Felipe, New Mexico .....	Sandoval, NM.
Pueblo of San Ildefonso, New Mexico .....	Los Alamos, NM, Rio Arriba, NM, Sandoval, NM, Santa Fe, NM.
Pueblo of Sandia, New Mexico .....	Bernalillo, NM, Sandoval, NM.
Pueblo of Santa Ana, New Mexico .....	Sandoval, NM.
Pueblo of Santa Clara, New Mexico .....	Los Alamos, NM, Sandoval, NM, Santa Fe, NM.
Pueblo of Taos, New Mexico .....	Colfax, NM, Taos, NM.
Pueblo of Tesuque, New Mexico .....	Santa Fe, NM.
Pueblo of Zia, New Mexico .....	Sandoval, NM.
Puyallup Tribe of the Puyallup Reservation .....	King, WA, Pierce, WA, Thurston, WA.
Quechan Tribe of the Fort Yuma Indian Reservation, California and Arizona.	Yuma, AZ, Imperial, CA.
Quileute Tribe of the Quileute Reservation .....	Clallam, WA, Jefferson, WA.
Quinault Indian Nation .....	Grays Harbor, WA, Jefferson, WA.
Rapid City, South Dakota .....	Pennington, SD, <sup>45</sup>
Red Cliff Band of Lake Superior Chippewa Indians of Wisconsin .....	Bayfield, WI.
Red Lake Band of Chippewa Indians, Minnesota .....	Beltrami, MN, Clearwater, MN, Koochiching, MN, Lake of the Woods, MN, Marshall, MN, Pennington, MN, Polk, MN, Roseau, MN.
Rosebud Sioux Tribe of the Rosebud Indian Reservation, South Dakota	Bennett, SD, Cherry, NE, Gregory, SD, Lyman, SD, Mellette, SD, Todd, SD, Tripp, SD.
Sac & Fox Nation of Missouri in Kansas and Nebraska .....	Brown, KS, Richardson, NE.
Sac & Fox Tribe of the Mississippi in Iowa .....	Tama, IA.
Saginaw Chippewa Indian Tribe of Michigan .....	Arenac, MI, <sup>46</sup> Clare, MI, Isabella, MI, Midland, MI, Missaukee, MI.
Saint Regis Mohawk Tribe .....	Franklin, NY, St. Lawrence, NY.
Salt River Pima-Maricopa Indian Community of the Salt River Reservation, Arizona.	Maricopa, AZ.
Samish Indian Tribe Nation .....	Clallam, WA, <sup>47</sup> Island, WA, Jefferson, WA, King, WA, Kitsap, WA, Pierce, WA, San Juan, WA, Skagit, WA, Snohomish, WA, Whatcom, WA.
San Carlos Apache Tribe of the San Carlos Reservation, Arizona .....	Apache, AZ, Cochise, AZ, Gila, AZ, Graham, AZ, Greenlee, AZ, Pinal, AZ.
San Juan Southern Paiute Tribe of Arizona .....	Coconino, AZ, San Juan, UT.
Santee Sioux Nation, Nebraska .....	Bon Homme, SD, Knox, NE.
Sauk-Suiattle Indian Tribe .....	Snohomish, WA, Skagit, WA.
Sault Ste. Marie Tribe of Chippewa Indians, Michigan .....	Alger, MI, <sup>48</sup> Chippewa, MI, Delta, MI, Luce, MI, Mackinac, MI, Marquette, MI, Schoolcraft, MI.
Seminole Tribe of Florida .....	Broward, FL, Collier, FL, Miami-Dade, FL, Glades, FL, Hendry, FL.
Seneca Nation of Indians .....	Allegany, NY, Cattaraugus, NY, Chautauqua, NY, Erie, NY, Warren, PA.
Shakopee Mdewakanton Sioux Community of Minnesota .....	Scott, MN.
Shinnecock Indian Nation .....	Nassau, NY, <sup>49</sup> Suffolk, NY.
Shoalwater Bay Tribe of the Shoalwater Bay Indian Reservation .....	Pacific, WA.
Shoshone Tribe of the Wind River Reservation, Wyoming .....	Hot Springs, WY, Fremont, WY, Sublette, WY.
Shoshone-Bannock Tribes of the Fort Hall Reservation .....	Bannock, ID, Bingham, ID, Caribou, ID, Lemhi, ID, <sup>50</sup> Power, ID.
Shoshone-Paiute Tribes of the Duck Valley Reservation, Nevada .....	Nevada, Owyhee, ID.
Sisseton-Wahpeton Oyate of the Lake Traverse Reservation, South Dakota.	Codington, SD, Day, SD, Grant, SD, Marshall, SD, Richland, ND, Roberts, SD, Sargent, ND, Traverse, MN.
Skokomish Indian Tribe .....	Mason, WA.

PURCHASED/REFERRED CARE SERVICE DELIVERY AREAS AND SERVICE DELIVERY AREAS—Continued

Tribe/reservation	County/state
Skull Valley Band of Goshute Indians of Utah .....	Tooele, UT.
Snoqualmie Indian Tribe .....	King, WA, <sup>51</sup> Snohomish, WA, Pierce, WA, Island, WA, Mason, WA.
Sokaogon Chippewa Community, Wisconsin .....	Forest, WI.
Southern Ute Indian Tribe of the Southern Ute Reservation, Colorado ..	Archuleta, CO, La Plata, CO, Montezuma, CO, Rio Arriba, NM, San Juan, NM.
Spirit Lake Tribe, North Dakota .....	Benson, ND, Eddy, ND, Nelson, ND, Ramsey, ND.
Spokane Tribe of the Spokane Reservation .....	Ferry, WA, Lincoln, WA, Stevens, WA.
Squaxin Island Tribe of the Squaxin Island Reservation .....	Mason, WA.
St. Croix Chippewa Indians of Wisconsin .....	Barron, WI, Burnett, WI, Pine, MN, Polk, WI, Washburn, WI.
Standing Rock Sioux Tribe of North & South Dakota .....	Adams, ND, Campbell, SD, Corson, SD, Dewey, SD, Emmons, ND, Grant, ND, Morton, ND, Perkins, SD, Sioux, ND, Walworth, SD, Ziebach, SD.
Stillaguamish Tribe of Indians of Washington .....	Snohomish, WA.
Stockbridge Munsee Community, Wisconsin .....	Menominee, WI, Shawano, WI.
Suquamish Indian Tribe of the Port Madison Reservation .....	Kitsap, WA.
Swinomish Indian Tribal Community .....	Skagit, WA.
Tejon Indian Tribe .....	Kern, CA, <sup>52</sup>
Three Affiliated Tribes of the Fort Berthold Reservation, North Dakota ..	Dunn, ND, Mercer, ND, McKenzie, ND, McLean, ND, Mountrail, ND, Ward, ND.
Tohono O'odham Nation of Arizona .....	Maricopa, AZ, Pima, AZ, Pinal, AZ.
Tonawanda Band of Seneca .....	Genesee, NY, Erie, NY, Niagara, NY.
Tonto Apache Tribe of Arizona .....	Gila, AZ.
Trenton Service Unit, North Dakota and Montana .....	Divide, ND, <sup>53</sup> McKenzie, ND, Williams, ND, Richland, MT, Roosevelt, MT, Sheridan, MT.
Tulalip Tribes of Washington .....	Snohomish, WA.
Tunica-Biloxi Indian Tribe .....	Avoyelles, LA, Rapides, LA, <sup>54</sup>
Turtle Mountain Band of Chippewa Indians of North Dakota .....	Rolette, ND.
Tuscarora Nation .....	Niagara, NY.
Upper Sioux Community, Minnesota .....	Chippewa, MN, Yellow Medicine, MN.
Upper Skagit Indian Tribe .....	Skagit, WA.
Ute Indian Tribe of the Uintah & Ouray Reservation, Utah .....	Carbon, UT, Daggett, UT, Duchesne, UT, Emery, UT, Grand, UT, Rio Blanco, CO, Summit, UT, Uintah, UT, Utah, UT, Wasatch, UT.
Ute Mountain Tribe of the Ute Mountain Reservation, Colorado, New Mexico & Utah.	Apache, AZ, La Plata, CO, Montezuma, CO, San Juan, NM, San Juan, UT.
Wampanoag Tribe of Gay Head (Aquinnah) .....	Dukes, MA. <sup>55</sup>
Washoe Tribe of Nevada & California .....	Nevada, California except for the counties listed in footnote.
White Mountain Apache Tribe of the Fort Apache Reservation, Arizona	Apache, AZ, Coconino, AZ, Gila, AZ, Graham, AZ, Greenlee, AZ, Navajo, AZ.
Wilton Rancheria, California .....	Sacramento, CA. <sup>56</sup>
Winnebago Tribe of Nebraska .....	Dakota, NE, Dixon, NE, Monona, IA, Thurston, NE, Wayne, NE, Woodbury, IA.
Yankton Sioux Tribe of South Dakota .....	Bon Homme, SD, Boyd, NE, Charles Mix, SD, Douglas, SD, Gregory, SD, Hutchinson, SD, Knox, NE.
Yavapai-Apache Nation of the Camp Verde Indian Reservation, Arizona.	Yavapai, AZ.
Yavapai-Prescott Indian Tribe .....	Yavapai, AZ.
Ysleta Del Sur Pueblo of Texas .....	El Paso, TX. <sup>1</sup>
Zuni Tribe of the Zuni Reservation, New Mexico .....	Apache, AZ, Cibola, NM, McKinley, NM, Valencia, NM

<sup>1</sup> Public Law 100-89, Restoration Act for Ysleta Del Sur and Alabama and Coushatta Tribes of Texas establishes service areas for "members of the Tribe" by sections 101(3) and 105(a) for the Pueblo and sections 201(3) and 206(a) respectively.

<sup>2</sup> Entire State of Alaska is included as a CHSDA by regulation (42 CFR 136.22(a)(1)).

<sup>3</sup> Aroostook Band of Micmacs was recognized by Congress on November 26, 1991 through the Aroostook Band of Micmac Settlement Act. Aroostook County, ME, was defined as the SDA.

<sup>4</sup> Special programs have been established by Congress irrespective of the eligibility regulations. Eligibility for services at these facilities is based on the legislative history of the appropriation of funds for the particular facility rather than the eligibility regulations. Historically services have been provided at Brigham City Intermountain School Health Center, Utah (Public Law 88-358).

<sup>5</sup> Entire State of California, excluding the counties of Alameda, Contra Costa, Los Angeles, Marin, Orange, Sacramento, San Francisco, San Mateo, Santa Clara, Kern, Merced, Monterey, Napa, San Benito, San Joaquin, San Luis Obispo, Santa Cruz, Solano, Stanislaus, and Ventura, is designated a CHSDA (25 U.S.C. 1680).

<sup>6</sup> The counties were recognized after the January 1984 CHSDA FRN was published, in accordance with Public Law 103-116, Catawba Indian Tribe of South Carolina Land Claims Settlement Act of 1993, dated October 27, 1993.

<sup>7</sup> There is no reservation for the Cayuga Nation; the service delivery area consists of those counties identified by the Cayuga Nation.

<sup>8</sup> Skamania County, WA, has historically been a part of the Yakama Service Unit population since 1979.

<sup>9</sup> In order to carry out the Congressional intent of the Siletz Restoration Act, Public Law 95-195, as expressed in H. Report No. 95-623, at page 4, members of the Confederated Tribes of Siletz Indians of Oregon residing in these counties are eligible for contract health services.

<sup>10</sup> Chelan County, WA, has historically been a part of the Colville Service Unit population since 1970.

<sup>11</sup> Pursuant to Public Law 98-481 (H. Rept. No. 98-904), Coos, Lower Umpqua and Siuslaw Restoration Act, members of the Tribe residing in these counties were specified as eligible for Federal services and benefits without regard to the existence of a Federal Indian reservation.

<sup>12</sup> The Confederated Tribes of Grand Ronde Community of Oregon were recognized by Public Law 98-165 which was signed into law on November 22, 1983, and provides for eligibility in these six counties without regard to the existence of a reservation.

<sup>13</sup> The CHSDA for the Coushatta Tribe of Louisiana was expanded administratively by the Director, IHS, through regulation (42 CFR 136.22(6)) to include city limits of Elton, LA.

<sup>14</sup> Cow Creek Band of Umpqua Tribe of Indians recognized by Public Law 97-391, signed into law on December 29, 1983. House Rept. No. 97-862 designates Douglas, Jackson, and Josephine Counties as a service area without regard to the existence of a reservation. The IHS later administratively expanded the CHSDA to include the counties of Coos, OR, Deshutes, OR, Klamath, OR, and Lane, OR.

<sup>15</sup> The Cowlitz Indian Tribe was recognized in July 2002 as documented at 67 FR 46329, July 12, 2002. The counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93-638. The CHSDA was administratively expanded to include Columbia County, OR, Kittitas, WA, and Wahkiakum County, WA, as published at 67884 FR December 21, 2009.

<sup>16</sup> Treasure County, MT, has historically been a part of the Crow Service Unit population.

<sup>17</sup> The counties listed have historically been a part of the Grand Traverse Service Unit population since 1980.

<sup>18</sup> Haskell Indian Health Center has historically been a part of Kansas Service Unit since 1979. Special programs have been established by Congress irrespective of the eligibility regulations. Eligibility for services at these facilities is based on the legislative history of the appropriation of funds for the particular facility rather than the eligibility regulations. Historically services have been provided at Haskell Indian Health Center (H. Rept. No. 95-392).

<sup>19</sup> CHSDA counties for the Ho-Chunk Nation of Wisconsin were designated by regulation (42 CFR 136.22(a)(5)). Dane County, WI, was added to the reservation by the Bureau of Indian Affairs in 1986.

<sup>20</sup> Public Law 97-428 provides that any member of the Houlton Band of Maliseet Indians in or around the Town of Houlton shall be eligible without regard to existence of a reservation.

<sup>21</sup> The Jena Band of Choctaw Indian was Federally acknowledged as documented at 60 FR 28480, May 31, 1995. The counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93-638.

<sup>22</sup> Kickapoo Traditional Tribe of Texas, formerly known as the Texas Band of Kickapoo, was recognized by Public Law 97-429, signed into law on January 8, 1983. The Act provides for eligibility for Kickapoo Tribal members residing in Maverick County without regard to the existence of a reservation.

<sup>23</sup> The Klamath Indian Tribe Restoration Act (Pub. L. 99-398, Sec. 2(2)) states that for the purpose of Federal services and benefits "members of the tribe residing in Klamath County shall be deemed to be residing in or near a reservation".

<sup>24</sup> The Koi Nation of Northern California, formerly known as the Lower Lake Rancheria, was reaffirmed by the Secretary of the Bureau of Indian Affairs on December 29, 2000. The counties listed are designated administratively as the SDA, to function as a PRC SDA, for the purposes of operating a PRC program pursuant to the ISDEAA, Public Law 93-638.

<sup>25</sup> The Little Traverse Bay Bands of Odawa Indians and the Little River Band of Ottawa Indians Act recognized the Little River Band of Ottawa Indians and the Little Traverse Bay Bands of Odawa Indians. Pursuant to Public Law 103-324, Sec. 4 (b) the counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93-638.

<sup>26</sup> Mashantucket Pequot Indian Claims Settlement Act, Public Law 98-134, signed into law on October 18, 1983, provides a reservation for the Mashantucket Pequot Indian Tribe in New London County, CT.

<sup>27</sup> The Mashpee Wampanoag Tribe was recognized in February 2007, as documented at 72 FR 8007, February 22, 2007. The counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93-638.

<sup>28</sup> The Match-e-be-nash-she-wish Band of Pottawatomis Indians of Michigan was recognized in October 1998, as documented at 63 FR 56936, October 23, 1998. The counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93-638.

<sup>29</sup> Members of the Mississippi Band of Choctaw Indians residing in Jasper and Noxubee Counties, MS, are eligible for contract health services; these two counties were inadvertently omitted from 42 CFR 136.22.

<sup>30</sup> Scott County, MS, has historically been a part of the Choctaw Service Unit population since 1970.

<sup>31</sup> The Narragansett Indian Tribe was recognized by Public Law 95-395, signed into law September 30, 1978. Lands in Washington County, RI, are now Federally restricted and the Bureau of Indian Affairs considers them as the Narragansett Indian Reservation.

<sup>32</sup> Entire State of Nevada is included as a CHSDA by regulation (42 CFR 136.22 (a)(2)).

<sup>33</sup> Carter County, MT, has historically been a part of the Northern Cheyenne Service Unit population since 1979.

<sup>34</sup> Land of Box Elder County, Utah, was taken into trust for the Northwestern Band of Shoshoni Nation in 1986.

<sup>35</sup> The Nottawaseppi Huron Band of the Potawatomi, Michigan, formerly known as the Huron Band of Potawatomi, Inc., was recognized in December 1995, as documented at 60 FR 66315, December 21, 1995. The counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93-638.

<sup>36</sup> Washabaugh County, SD, merged and became part of Jackson County, SD, in 1983; both were/are CHSA counties for the Oglala Sioux Tribe.

<sup>37</sup> Entire State of Oklahoma is included as a CHSDA by regulation (42 CFR 136.22 (a)(3)).

<sup>38</sup> Paiute Indian Tribe of Utah Restoration Act, Public Law 96-227, provides for the extension of services for the Paiute Indian Tribe of Utah to these four counties without regard to the existence of a reservation.

<sup>39</sup> Legislative history (H.R. Report No. 95-1021) to Public Law 95-375, Extension of Federal Benefits to Pascua Yaqui Indians, Arizona, expresses congressional intent that lands conveyed to the Pascua Yaqui Tribe of Arizona pursuant to Act of October 8, 1964. (Pub. L. 88-350) shall be deemed a Federal Indian Reservation.

<sup>40</sup> The Maine Indian Claims Settlement Act of 1980 (Pub. L. 96-420; H. Rept. 96-1353) includes the intent of Congress to fund and provide contract health services to the Passamaquoddy Tribe and the Penobscot Nation.

<sup>41</sup> The Passamaquoddy Tribe has two reservations. The PRC SDA for the Passamaquoddy Tribe of Indian Township, ME, is Aroostook County, ME, and Washington County, ME. The PRC SDA for the Passamaquoddy Tribe of Pleasant Point, ME, is Washington County, ME, south of State Route.

<sup>42</sup> Counties in the Service Unit designated by Congress for the Poarch Band of Creek Indians (see H. Rept. 98-886, June 29, 1984; Cong. Record, October 10, 1984, Pg. H11929).

<sup>43</sup> Public Law 103-323 restored Federal recognition to the Pokagon Band of Potawatomi Indians, Michigan and Indiana, in 1994 and identified counties to serve as the SDA.

<sup>44</sup> The Ponca Restoration Act, Public Law 101-484, recognized members of the Ponca Tribe of Nebraska in Boyd, Douglas, Knox, Madison or Lancaster counties of Nebraska or Charles Mix county of South Dakota as residing on or near a reservation. Public Law 104-109 made technical corrections to laws relating to Native Americans and added Burt, Hall, Holt, Platte, Sarpy, Stanton, and Wayne counties of Nebraska and Pottawatomie and Woodbury counties of Iowa to the Ponca Tribe of Nebraska SDA.

<sup>45</sup> Special programs have been established by Congress irrespective of the eligibility regulations. Eligibility for services at these facilities is based on the legislative history of the appropriation of funds for the particular facility, rather than the eligibility regulations. Historically services have been provided at Rapid City (S. Rept. No. 1154, FY 1967 Interior Approp. 89th Cong. 2d Sess.).

<sup>46</sup> Historically part of Isabella Reservation Area for the Saginaw Chippewa Indian Tribe of Michigan and the Eastern Michigan Service Unit population since 1979.

<sup>47</sup> The Samish Indian Tribe Nation was Federally acknowledged in April 1996 as documented at 61 FR 15825, April 9, 1996. The counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93-638.

<sup>48</sup> CHSDA counties for the Sault Ste. Marie Tribe of Chippewa Indians, Michigan, were designated by regulation (42 CFR 136.22(a)(4)).

<sup>49</sup> The Shinnecock Indian Nation was Federally acknowledged in June 2010 as documented at 75 FR 34760, June 18, 2010. The counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93-638.

<sup>50</sup> Lemhi County, ID, has historically been a part of the Fort Hall Service Unit population since 1979.

<sup>51</sup> The Snoqualmie Indian Tribe was Federally acknowledged in August 1997 as documented at 62 FR 45864, August 29, 1997. The counties listed were designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93–638.

<sup>52</sup> On December 30, 2011 the Office of Assistant Secretary-Indian Affairs reaffirmed the Federal recognition of the Tejon Indian Tribe. The county listed was designated administratively as the SDA, to function as a CHSDA, for the purposes of operating a CHS program pursuant to the ISDEAA, Public Law 93–638.

<sup>53</sup> The Secretary acting through the Service is directed to provide contract health services to Turtle Mountain Band of Chippewa Indians that reside in Trenton Service Unit, North Dakota and Montana, in Divide, Mackenzie, and Williams counties in the state of North Dakota and the adjoining counties of Richland, Roosevelt, and Sheridan in the state of Montana (Sec. 815, Pub. L. 94–437).

<sup>54</sup> Rapides County, LA, has historically been a part of the Tunica Biloxi Service Unit population since 1982.

<sup>55</sup> According to Public Law 100–95, Sec. 12, members of the Wampanoag Tribe of Gay Head (Aquinnah) residing on Martha's Vineyard are deemed to be living on or near an Indian reservation for the purposes of eligibility for Federal services.

<sup>56</sup> The Wilton Rancheria, California had Federal recognition restored in July 2009 as documented at 74 FR 33468, July 13, 2009. Sacramento County, CA, was designated administratively as the SDA, to function as a CHSDA. Sacramento County was not covered when Congress originally established the State of California as a CHSDA excluding certain counties including Sacramento County (25 U.S.C. 1680).

Dated: July 30, 2015.

**Robert G. McSwain,**

*Deputy Director, Indian Health Service.*

[FR Doc. 2015–19467 Filed 8–6–15; 8:45 am]

**BILLING CODE 4165–16–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Eye Institute; 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 Eye Council.

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/or contract proposals 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 and/or contract proposals, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

*Name of Committee:* National Advisory Eye Council.

*Date:* October 8, 2015.

*Open:* 8:30 a.m. to 1:00 p.m.

*Agenda:* Following opening remarks by the Director, NEI, there will be presentations by the staff of the Institute and discussions concerning Institute programs.

*Place:* National Institutes of Health, Terrace Level Conference Rooms, 5635 Fishers Lane, Bethesda, MD 20892.

*Closed:* 1:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institutes of Health, Terrace Level Conference Rooms, 5635 Fishers Lane, Bethesda, MD 20892.

*Contact Person:* Anne E. Schaffner, Ph.D., Chief, Scientific Review Branch, Division of Extramural Research, National Eye Institute, National Institutes of Health, 5635 Fishers Lane Suite 1300, MSC 9300, Bethesda, MD 20892–9300, (301) 451–2020, [aes@nei.nih.gov](mailto:aes@nei.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.

Information is also available on the Institute's/Center's home page: [www.nei.nih.gov](http://www.nei.nih.gov), where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: August 4, 2015.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015–19450 Filed 8–6–15; 8:45 am]

**BILLING CODE 4140–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Cancer Institute; 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 Cancer Institute Special Emphasis Panel; Cancer Detection, Diagnostic and Treatment Technologies for Global Health.

*Date:* August 18, 2015.

*Time:* 2 p.m. to 3 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Cancer Institute Shady Grove, 9609 Medical Center Drive, Room 7W030, Rockville, MD 20850 (Telephone Conference Call).

*Contact Person:* Gerard Lacourciere, Ph.D., Scientific Review Officer, Research Technology and Contract Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W246, Rockville, MD 20850, 240–276–6374, [gerard.lacourciere@nih.gov](mailto:gerard.lacourciere@nih.gov).

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

*Name of Committee:* National Cancer Institute Special Emphasis Panel; NCI Spore Review.

*Date:* September 29–30, 2015.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Hilton Washington DC/Rockville, 1750 Rockville Pike, Rockville, MD 20852.

*Contact Person:* Wlodek Lopaczynski, MD, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W608, Rockville, MD 20892, 240–276–6458, [lopacw@mail.nih.gov](mailto:lopacw@mail.nih.gov).

*Name of Committee:* National Cancer Institute Special Emphasis Panel; Omnibus SEP–10.

*Date:* October 7–8, 2015.

*Time:* 8 a.m. to 5 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* Bethesda North Marriott Hotel & Conference Center, 5701 Marinelli Road, Bethesda, MD 20852.

*Contact Person:* Shakeel Ahmad, Ph.D., Scientific Review Officer, Research Programs Review Branch, Division of Extramural Activities, National Cancer Institute, NIH, 9609 Medical Center Drive, Room 7W122, Bethesda, MD 20892–8328, 240–276–6349, [ahmads@mail.nih.gov](mailto:ahmads@mail.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction;

93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: August 4, 2015.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015-19438 Filed 8-6-15; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Workshop on Alternative Approaches for Identifying Acute Systemic Toxicity: Moving From Research to Regulatory Testing; Notice of Public Meeting; Registration Information

**SUMMARY:** The National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM) announces the workshop “Alternative Approaches for Identifying Acute Systemic Toxicity: Moving from Research to Regulatory Testing.” Workshop attendees will discuss the state of the science of alternative approaches for identifying acute systemic toxicity and explore ways to facilitate their implementation.

**DATES:** *Meeting:* September 24–25, 2015, from 9:00 a.m. to approximately 5:00 p.m. Eastern Daylight Time (EDT).

*Meeting Registration:* Deadline is September 11, 2015.

**ADDRESSES:** Meeting Location: Porter Neuroscience Conference Center, National Institutes of Health, Bethesda, MD 20892.

Meeting Web page: The preliminary agenda, registration, and other meeting materials are at <http://ntp.niehs.nih.gov/go/atwksp-2015>.

**FOR FURTHER INFORMATION CONTACT:** Dr. Warren S. Casey, Director, NICEATM; email: [warren.casey@nih.gov](mailto:warren.casey@nih.gov); telephone: (919) 316-4729.

#### SUPPLEMENTARY INFORMATION:

##### Background

Acute systemic toxicity tests, which evaluate the propensity of a substance to produce lethality when administered orally, dermally, or by inhalation, are the most commonly performed type of safety test worldwide. This workshop will explore and discuss alternative approaches that could replace, reduce, or refine the use of animals for

identifying chemicals that may cause acute systemic toxicity.

During the workshop, participants will (1) review the regulatory guidelines to define when and how acute systemic toxicity data are used; (2) review the science of alternative approaches for identifying acute systemic toxicity, including mechanism-based models, *in vitro* and *in silico* approaches, and lower vertebrate and invertebrate models; and (3) identify mechanisms of acute toxicity for promoting development of adverse outcome pathways (AOPs) for acute toxicity. The workshop steering committee is comprised of members from government and nongovernment stakeholder organizations including NICEATM, Physicians Committee for Responsible Medicine, People for the Ethical Treatment of Animals International Science Consortium Ltd., The Dow Chemical Company, U.S. Environmental Protection Agency, and Rutgers University.

#### Preliminary Agenda and Other Meeting Information

A preliminary agenda and additional information are available at <http://ntp.niehs.nih.gov/go/atwksp-2015>.

#### Meeting and Registration

This meeting is open to the public, free of charge, with attendance limited only by available meeting space. Individuals who plan to attend should register at <http://ntp.niehs.nih.gov/go/atwksp-2015> by September 11, 2015, to facilitate planning. Interested individuals are encouraged to visit this Web page to stay abreast of the most current information about the meeting.

Visitor and security information for visitors to NIH is available at <http://www.nih.gov/about/visitor/index.htm>. Individuals with disabilities who need accommodation to participate in this event should contact Dr. Elizabeth Maull at telephone: (919) 316-4668 or email: [maull@niehs.nih.gov](mailto:maull@niehs.nih.gov). TTY users should contact the Federal TTY Relay Service at (800) 877-8339. Requests should be made at least five business days in advance of the event.

#### Background Information on NICEATM

NICEATM conducts data analyses, workshops, independent validation studies, and other activities to assess new, revised, and alternative test methods and strategies. NICEATM also provides support for the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM). The ICCVAM Authorization Act of 2000 (42 U.S.C. 285l-3) provides authority for ICCVAM and NICEATM in

the development of alternative test methods. Information about NICEATM and ICCVAM is found at <http://ntp.niehs.nih.gov/go/niceatm> and <http://ntp.niehs.nih.gov/go/iccvam>, respectively.

Dated: August 3, 2015.

**John R. Bucher,**

*Associate Director, National Toxicology Program.*

[FR Doc. 2015-19379 Filed 8-6-15; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Center for Substance Abuse Prevention; Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given for the meeting of the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention National Advisory Council (CSAP NAC) on August 26, 2015.

The Council was established to advise the Secretary, Department of Health and Human Services (HHS); the Administrator, SAMHSA; and Center Director, CSAP concerning matters relating to the activities carried out by and through the Center and the policies respecting such activities.

The meeting will be open to the public and will include discussion of the alignment of substance abuse and mental illness prevention within the context of overall healthcare, and CSAP program developments.

The meeting will be held in Rockville, Maryland. Attendance by the public will be limited to the space available. Interested persons may present data, information, or views, orally or in writing, on issues pending before the Council. Written submissions should be forwarded to the contact person on or before one week prior to the meeting. Oral presentations from the public will be scheduled at the conclusion of the meeting. Individuals interested in making oral presentations are encouraged to notify the contact on or before one week prior to the meeting. Five minutes will be allotted for each presentation.

To attend onsite, submit written or brief oral comments, or request special accommodations for persons with disabilities, please register at the SAMHSA Committees' Web site, <http://nac.samhsa.gov/Registration/meetingsRegistration.aspx>, or communicate with the CSAP Council's

Designated Federal Officer (see contact information below).

Substantive program information may be obtained after the meeting by accessing the SAMHSA Committee Web site, <http://nac.samhsa.gov/>, or by contacting the Designated Federal Officer.

**Committee Name:** Substance Abuse and Mental Health Services, Administration, Center for Substance Abuse Prevention, National Advisory Council.

**Date/Time/Type:** August 26, 2015, from 10 a.m. to 3:30 p.m. EDT: (Open).

**Place:** SAMHSA, 1 Choke Cherry Road, Great Falls Conference Room (Lobby Level), Rockville, MD 20857, Adobe Connect Webcast: <https://samhsa-csap.adobeconnect.com/nac/>.

**Contact:** Matthew J. Aumen, Designated Federal Officer, SAMHSA CSAP NAC, 1 Choke Cherry Road, Rockville, MD 20857, Telephone: 240-276-2419, Fax: 240-276-2430, Email: [matthew.umen@samhsa.hhs.gov](mailto:matthew.umen@samhsa.hhs.gov).

**Cathy J. Friedman,**

*Public Health Analyst, SAMHSA.*

[FR Doc. 2015-19415 Filed 8-6-15; 8:45 am]

**BILLING CODE 4162-20-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given that the Substance Abuse and Mental Health Services Administration's (SAMHSA) Center for Substance Abuse Prevention (CSAP) National Advisory Council will meet on August 12, 2015, 2 p.m.-3 p.m., via teleconference.

The meeting will include the review, discussion, and evaluation of grant applications reviewed by the Initial Review Group, and involve an examination of confidential financial and business information as well as personal information concerning the applicants. Therefore, these meetings will be closed to the public as determined by the SAMHSA Administrator, in accordance with Title 5 U.S.C. 552b(c)(4) and (c)(6) and (c)(9)(B); and 5 U.S.C. App. 2, Section 10(d).

**Committee Name:** Substance Abuse and Mental Health Services Administration; Center for Substance Abuse Prevention National Advisory Council.

**Date/Time/Type:** August 12, 2015 2 p.m.-3 p.m. (CLOSED).

**Place:** SAMHSA Building, 1 Choke Cherry Road, Rockville, MD 20857.

**Contact:** Matthew J. Aumen, Designated Federal Officer, SAMHSA/CSAP National Advisory Council, 1 Choke Cherry Road, Room 4-1068, Rockville, MD 20857, Email: [Matthew.Aumen@samhsa.hhs.gov](mailto:Matthew.Aumen@samhsa.hhs.gov).

**Cathy J. Friedman,**

*Public Health Analyst, SAMHSA.*

[FR Doc. 2015-19416 Filed 8-6-15; 8:45 am]

**BILLING CODE 4162-20-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Substance Abuse and Mental Health Services Administration

#### Advisory Committee for Women's Services (ACWS); Notice of Meeting

Pursuant to Public Law 92-463, notice is hereby given of a meeting of the Substance Abuse and Mental Health Services Administration's (SAMHSA) Advisory Committee for Women's Services (ACWS) on August 26, 2015.

The meeting will include discussions on behavioral health for Pregnant and Postpartum Women (PPW) and their families; disparities in behavioral health services for women; and a conversation with the SAMHSA Administrator.

The meeting is open to the public and will be held at SAMHSA, 1 Choke Cherry Road, Rockville, MD 20857, in the VTC Room. Attendance by the public will be limited to space available. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions should be forwarded to the contact person (below) on or before August 14, 2015. Oral presentations from the public will be scheduled at the conclusion of the meeting. Individuals interested in making oral presentations are encouraged to notify the contact person on or before August 14, 2015. Five minutes will be allotted for each presentation.

The meeting may be accessed via telephone. To attend on site, obtain the call-in number and access code, submit written or brief oral comments, or request special accommodations for persons with disabilities, please register on-line at <http://nac.samhsa.gov/Registration/meetingsRegistration.aspx>, or communicate with SAMHSA's Designated Federal Officer, Ms. Nadine Benton (see contact information below).

Substantive meeting information and a roster of Committee members may be obtained either by accessing the SAMHSA Committees' Web site <http://www.samhsa.gov/about-us/advisory-councils/advisory-committee-women>

or by contacting Ms. Benton.

**Committee Name:** Substance Abuse and Mental Health Services Administration; Advisory Committee for Women's Services (ACWS).

**Date/Time/Type:** Wednesday, August 26, 2015, from: 1 p.m. to 4:15 p.m. EDT.

**Open:**

**Place:** SAMHSA, 1 Choke Cherry Road, SAMHSA, Rock Creek, VTC Room, Rockville, Maryland 20857, Conference Number: 800-369-1956, Passcode: ACWS.

**Contact:** Nadine Benton, Designated Federal Official, SAMHSA's Advisory Committee for Women's Services, 1 Choke Cherry Road, Rockville, Maryland 20857 Telephone: (240) 276-0127, Fax: (240) 276-2252, Email: [nadine.benton@samhsa.hhs.gov](mailto:nadine.benton@samhsa.hhs.gov).

**Cathy J. Friedman,**

*Public Health Analyst, Substance Abuse and Mental Health Services Administration.*

[FR Doc. 2015-19417 Filed 8-6-15; 8:45 am]

**BILLING CODE 4162-20-P**

## DEPARTMENT OF HOMELAND SECURITY

### Federal Emergency Management Agency

[Internal Agency Docket No. FEMA-4223-DR; Docket ID FEMA-2015-0002]

#### Texas; Amendment No. 10 to Notice of a Major Disaster Declaration

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the State of Texas (FEMA-4223-DR), dated May 29, 2015, and related determinations.

**DATES:** *Effective Date:* July 21, 2015.

**FOR FURTHER INFORMATION CONTACT:** Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646-2833.

**SUPPLEMENTARY INFORMATION:** The notice of a major disaster declaration for the State of Texas is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of May 29, 2015.

Red River County for Individual Assistance.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA);

97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

**W. Craig Fugate,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. 2015–19491 Filed 8–6–15; 8:45 am]

**BILLING CODE 9111–23–P**

**DEPARTMENT OF HOMELAND SECURITY**

**Federal Emergency Management Agency**

[Internal Agency Docket No. FEMA–4231–DR; Docket ID FEMA–2015–0002]

**New Jersey; Major Disaster and Related Determinations**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This is a notice of the Presidential declaration of a major disaster for the State of New Jersey (FEMA–4231–DR), dated July 22, 2015, and related determinations.

**DATES:** *Effective Date:* July 22, 2015.

**FOR FURTHER INFORMATION CONTACT:** Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that, in a letter dated July 22, 2015, the President issued a major disaster declaration under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the “Stafford Act”), as follows:

I have determined that the damage in certain areas of the State of New Jersey resulting from a severe storm on June 23, 2015, is of sufficient severity and magnitude to warrant a major disaster declaration under the Robert T. Stafford Disaster Relief and Emergency Assistance Act, 42 U.S.C. 5121 *et seq.* (the “Stafford Act”). Therefore, I declare that such a major disaster exists in the State of New Jersey.

In order to provide Federal assistance, you are hereby authorized to allocate from funds available for these purposes such amounts as you find necessary for Federal disaster assistance and administrative expenses.

You are authorized to provide Public Assistance in the designated areas and

Hazard Mitigation throughout the State. Consistent with the requirement that Federal assistance be supplemental, any Federal funds provided under the Stafford Act for Hazard Mitigation will be limited to 75 percent of the total eligible costs. Federal funds provided under the Stafford Act for Public Assistance also will be limited to 75 percent of the total eligible costs, with the exception of projects that meet the eligibility criteria for a higher Federal cost-sharing percentage under the Public Assistance Alternative Procedures Pilot Program for Debris Removal implemented pursuant to section 428 of the Stafford Act.

Further, you are authorized to make changes to this declaration for the approved assistance to the extent allowable under the Stafford Act.

The Federal Emergency Management Agency (FEMA) hereby gives notice that pursuant to the authority vested in the Administrator, under Executive Order 12148, as amended, Seamus K. Leary, of FEMA is appointed to act as the Federal Coordinating Officer for this major disaster.

The following areas of the State of New Jersey have been designated as adversely affected by this major disaster:

Atlantic, Burlington, Camden, Gloucester Counties for Public Assistance.

All areas within the State of New Jersey are eligible for assistance under the Hazard Mitigation Grant Program.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

**W. Craig Fugate,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. 2015–19489 Filed 8–6–15; 8:45 am]

**BILLING CODE 9111–23–P**

**DEPARTMENT OF HOMELAND SECURITY**

**Federal Emergency Management Agency**

[Internal Agency Docket No. FEMA–4223–DR; Docket ID FEMA–2015–0002]

**Texas; Amendment No. 8 to Notice of a Major Disaster Declaration**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the State of Texas (FEMA–4223–DR), dated May 29, 2015, and related determinations.

**DATES:** *Effective Date:* July 17, 2015.

**FOR FURTHER INFORMATION CONTACT:** Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–2833.

**SUPPLEMENTARY INFORMATION:** The notice of a major disaster declaration for the State of Texas is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of May 29, 2015.

Shelby County for Individual Assistance. Hood, Madison, and Wharton Counties for Individual Assistance (already designated for Public Assistance).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050 Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

**W. Craig Fugate,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. 2015–19493 Filed 8–6–15; 8:45 am]

**BILLING CODE 9111–23–P**



**DEPARTMENT OF HOMELAND SECURITY****Federal Emergency Management Agency**

[Internal Agency Docket No. FEMA-4228-DR; Docket ID FEMA-2015-0002]

**Louisiana; Amendment No. 1 to Notice of a Major Disaster Declaration**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the State of Louisiana (FEMA-4228-DR), dated July 13, 2015, and related determinations.

**DATES:** *Effective Date:* July 21, 2015.

**FOR FURTHER INFORMATION CONTACT:** Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646-2833.

**SUPPLEMENTARY INFORMATION:** The notice of a major disaster declaration for the State of Louisiana is hereby amended to include the following area among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of July 13, 2015.

Rapides Parish for Public Assistance. The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

**W. Craig Fugate,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. 2015-19488 Filed 8-6-15; 8:45 am]

**BILLING CODE 9111-23-P**

**DEPARTMENT OF HOMELAND SECURITY****Federal Emergency Management Agency**

[Internal Agency Docket No. FEMA-4223-DR; Docket ID FEMA-2015-0002]

**Texas; Amendment No. 9 to Notice of a Major Disaster Declaration**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster for the State of Texas (FEMA-4223-DR), dated May 29, 2015, and related determinations.

**DATES:** *Effective Date:* July 21, 2015.

**FOR FURTHER INFORMATION CONTACT:** Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646-2833.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that the incident period is now May 4, 2015, through and including June 22, 2015.

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

**W. Craig Fugate,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. 2015-19494 Filed 8-6-15; 8:45 am]

**BILLING CODE 9110-12-P**

**DEPARTMENT OF HOMELAND SECURITY****Federal Emergency Management Agency**

[Internal Agency Docket No. FEMA-4223-DR; Docket ID FEMA-2015-0002]

**Texas; Amendment No. 11 to Notice of a Major Disaster Declaration**

**AGENCY:** Federal Emergency Management Agency, DHS.

**ACTION:** Notice.

**SUMMARY:** This notice amends the notice of a major disaster declaration for the State of Texas (FEMA-4223-DR), dated May 29, 2015, and related determinations.

**DATES:** *Effective Date:* July 23, 2015.

**FOR FURTHER INFORMATION CONTACT:** Dean Webster, Office of Response and Recovery, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646-2833.

**SUPPLEMENTARY INFORMATION:** The notice of a major disaster declaration for the State of Texas is hereby amended to include the following areas among those areas determined to have been adversely affected by the event declared a major disaster by the President in his declaration of May 29, 2015.

Austin, Brown, Delta, DeWitt, Gonzales, Hopkins, Jack, Jones, Orange, Robertson, San Augustine, Starr, Tarrant, Throckmorton, and Waller Counties for Public Assistance.

Ellis, Red River, and Wichita Counties for Public Assistance (already designated for Individual Assistance).

The following Catalog of Federal Domestic Assistance Numbers (CFDA) are to be used for reporting and drawing funds: 97.030, Community Disaster Loans; 97.031, Cora Brown Fund; 97.032, Crisis Counseling; 97.033, Disaster Legal Services; 97.034, Disaster Unemployment Assistance (DUA); 97.046, Fire Management Assistance Grant; 97.048, Disaster Housing Assistance to Individuals and Households In Presidentially Declared Disaster Areas; 97.049, Presidentially Declared Disaster Assistance—Disaster Housing Operations for Individuals and Households; 97.050, Presidentially Declared Disaster Assistance to Individuals and Households—Other Needs; 97.036, Disaster Grants—Public Assistance (Presidentially Declared Disasters); 97.039, Hazard Mitigation Grant.

**W. Craig Fugate,**

*Administrator, Federal Emergency Management Agency.*

[FR Doc. 2015-19490 Filed 8-6-15; 8:45 am]

**BILLING CODE 9111-23-P**

**DEPARTMENT OF HOMELAND SECURITY**

[Docket No. DHS-2015-0023]

**The Critical Infrastructure Partnership Advisory Council**

**AGENCY:** National Protection and Programs Directorate, DHS.

**ACTION:** Quarterly Critical Infrastructure Partnership Advisory Council membership update.

**SUMMARY:** The Department of Homeland Security (DHS) announced the establishment of the Critical Infrastructure Partnership Advisory

Council (CIPAC) in a Federal Register Notice (71 FR 14930–14933) dated March 24, 2006, which identified the purpose of CIPAC, as well as its membership. This notice provides: (i) quarterly CIPAC membership updates; (ii) instructions on how the public can obtain the CIPAC membership roster and other information on the council; and (iii) information on recently completed CIPAC meetings.

**FOR FURTHER INFORMATION CONTACT:**

Larry May, Alternate Designated Federal Officer, Critical Infrastructure Partnership Advisory Council, Sector Outreach and Programs Division, Office of Infrastructure Protection, National Protection and Programs Directorate, U.S. Department of Homeland Security, 245 Murray Lane, Mail Stop 0607, Arlington, VA 20598–0607; telephone: (703) 603–5070; email: [CIPAC@dhs.gov](mailto:CIPAC@dhs.gov).

*Responsible DHS Official:* Larry May, Alternate Designated Federal Officer for the CIPAC.

**SUPPLEMENTARY INFORMATION:**

*Purpose and Activity:* The CIPAC facilitates interaction between government officials and representatives of the community of owners and/or operators for each of the critical infrastructure sectors defined by Presidential Policy Directive (PPD) 21 and identified in *National Infrastructure Protection Plan 2013: Partnering for Critical Infrastructure Security and Resilience*. The activities covered by the CIPAC include: planning; coordinating among government and critical infrastructure owner and operator partners; implementing security and resilience program initiatives; conducting operational activities related to critical infrastructure security and resilience measures, incident response and recovery; reconstituting critical infrastructure assets and systems from manmade and naturally occurring events; sharing threat, vulnerability, risk mitigation, and business continuity information; and distributing best practices and lessons learned at the classified and unclassified levels.

*Organizational Structure:* CIPAC members are organized into 16 critical infrastructure sectors. These sectors have a Government Coordinating Council (GCC) whose membership includes: (i) a lead federal agency that is defined as the Sector-Specific Agency (SSA); (ii) all relevant federal, state, local, tribal, and/or territorial government agencies (or their representative bodies) whose mission interests also involve the scope of the CIPAC activities for that particular sector; and (iii) a Sector Coordinating Council (SCC), where applicable, whose

membership includes critical infrastructure owners and/or operators or their representative trade associations.

*CIPAC Membership:* CIPAC Membership may include:

(i) Critical Infrastructure owner and operator members of a DHS-recognized SCC, including their representative trade associations or equivalent organization members of a SCC as determined by the SCC.

(ii) Federal, state, local, and tribal governmental entities comprising the members of the GCC for each sector, including their representative organizations; members of the State, Local, Tribal, and Territorial Government Coordinating Council; and representatives of other federal agencies with responsibility for critical infrastructure activities.

CIPAC membership is organizational. Multiple individuals may participate in CIPAC activities on behalf of a member organization.

*CIPAC Membership Roster and Council Information:* The current roster of CIPAC members is published on the CIPAC Web site (<http://www.dhs.gov/cipac>) and is updated as the CIPAC membership changes. Members of the public may visit the CIPAC Web site at any time to view current CIPAC membership, as well as the current and historic lists of CIPAC meetings and agendas.

Dated: July 31, 2015.

**Larry May,**

*Alternate Designated Federal Officer for the CIPAC.*

[FR Doc. 2015–19393 Filed 8–6–15; 8:45 am]

**BILLING CODE 9110–9P–P**

**DEPARTMENT OF HOMELAND SECURITY**

[Docket No. DHS–2015–0041]

**Office for Interoperability and Compatibility Seeks Nominations for the Project 25 Compliance Assessment Program (P25 CAP) Advisory Panel**

**AGENCY:** Science and Technology Directorate, DHS.

**ACTION:** Notice.

**SUMMARY:** The Department of Homeland Security (DHS) is seeking nominations and expressions of interest for membership on the Project 25 Compliance Assessment Program Advisory Panel (P25 CAP AP). The activities of the P25 CAP AP are expected to commence in fall 2015.

P25 is a standard which enables interoperability among digital two-way

land mobile radio communications products created by and for public safety professionals. P25 CAP is a formal, independent process, created by DHS and operated in collaboration with the National Institute of Standards and Technology (NIST), for ensuring that communications equipment that is declared by the supplier to be P25 compliant, in fact, is tested against the standards with publicly published results. The P25 CAP AP would provide a resource by which DHS could gain insight into the collective interest of organizations that procure P25-compliant equipment and a resource in DHS's continuing to establish the policies of the P25 CAP along with assisting the DHS Office for Interoperability and Compatibility (OIC) in the administration of the Program.

**DATES:** All responses must be received within 30 days from the date of this notice at the address listed below.

**ADDRESSES:** Expressions of interest and nominations should be submitted to [SandTFRG@hq.dhs.gov](mailto:SandTFRG@hq.dhs.gov).

• Instructions: All submissions received must include the words “Department of Homeland Security” and DHS–2015–0041, the docket number for this action.

**FOR FURTHER INFORMATION CONTACT:** John Merrill, Director, Office for Interoperability and Compatibility, Science and Technology Directorate, Department of Homeland Security, 202–254–5604 (O), [John.Merrill@hq.dhs.gov](mailto:John.Merrill@hq.dhs.gov).

**SUPPLEMENTARY INFORMATION:**

**Background**

TIA–102/Project 25 (P25) is a standards development process for the design, manufacture, and evaluation of interoperable digital two-way land mobile radio communications products created by and for public safety professionals. The goal of P25 is to specify formal standards for interfaces and features between the various components of a land mobile radio system commonly used by public safety agencies in portable handheld and mobile vehicle-mounted devices. The P25 standard enables interoperability among different suppliers' products.

P25 CAP was developed by DHS and the National Institute of Standards and Technology (NIST) to test equipment designed to comply with P25 standards. The program provides public safety agencies with evidence that the communications equipment they are purchasing is tested against and complies with the P25 standards for performance, conformance, and interoperability.

P25 CAP is a voluntary system that provides a mechanism for the recognition of testing laboratories based on internationally accepted standards. It identifies competent P25 CAP testing laboratories for DHS-recognition through assessments by DHS-authorized accreditation bodies and promotes the acceptance of compliant test results from these laboratories.

As a voluntary program, P25 CAP allows suppliers to publicly attest to their products' compliance with a selected group of requirements through Summary Test Report (STR) and Supplier's Declaration of Compliance (SDOC) documents based on the Detailed Test Report (DTR) from the DHS-recognized laboratory (ies) that performed the product testing. In turn, P25 CAP makes these documents available to the first response community to inform their purchasing decisions via the *FirstResponder.gov/P25CAP* Web site.

#### Membership

The Science and Technology Directorate (S&T) of the DHS is forming the P25 CAP Advisory Panel to provide S&T with the views of active local, state, tribal, territorial and Federal government officials who use or whose offices use portable handheld and mobile vehicle-mounted radios. Those government officials selected to participate in the P25 CAP AP will be selected based on their experience with the management and procurement of land mobile radio systems or knowledge of conformity assessment programs and methods. OIC will select candidates in light of the desire to balance viewpoints required to effectively address P25 CAP issues under consideration. OIC is particularly interested in receiving nominations and expressions of interest from individuals in the following categories:

- State, tribal, territorial, or local government agencies and organizations with expertise in communications issues and technologies.
- Federal government agencies with expertise in communications or homeland security matters.

While OIC can call for a meeting of the P25 CAP AP as it deems necessary and appropriate, for member commitment and planning purposes, it is anticipated that the P25 CAP AP will meet approximately 3–4 times annually in their role of providing guidance and support to the P25 CAP.

Those selected to serve on the P25 CAP AP will be required to sign a gratuitous services agreement and will not be paid or reimbursed for their participation; however, DHS S&T will

reimburse the travel expenses associated with the participation of non-Federal members in accordance with Federal Travel Regulations. OIC reserves the right to select primary and alternate members to the P25 CAP AP for terms appropriate for the accomplishment of the Board's mission. Members serve at the pleasure of the OIC Director.

Registered lobbyists pursuant to the Lobbying Disclosure Act of 1995 are not eligible for membership on the P25 CAP AP and will not be considered.

#### Roles and Responsibilities

The duties of the P25 CAP AP will include providing recommendations of its individual members to OIC regarding actions and steps OIC could take to promote the P25 CAP. The duties of the P25 CAP AP may include but are not limited to its members reviewing, commenting on, and advising on:

- The laboratory component of the P25 CAP under established, documented laboratory recognition guidelines.
- Proposed Compliance Assessment Bulletins (CABs).
- Proposed updates to previously approved CABs, as Notices of Proposed CABs, to enable comment and input on the proposed CAB modifications.
- OIC updates to existing test documents or establishing new test documents for new types of P25 equipment.
- Best practices associated with improvement of the policies and procedures by which the P25 CAP operates.
- Existing test documents including but not limited to Supplier Declarations of Compliance (SDOCs) and Summary Test Reports (STRs) posted on the *FirstResponder.gov/P25CAP* Web site.
- Proposed P25 user input for improving functionality through the standards-making process.

#### Nominations/Expressions of Interest Procedures and Deadline

Nominations and expressions of interest shall be received by OIC no later than 30 days from the date of this notice at the address listed above (*SandTFRG@hq.dhs.gov*). Nominations and expressions of interest received after this date shall not be considered. Each nomination and expression of interest must provide the following information as part of the submission:

- A cover letter that highlights a history of proven leadership within the public safety community including, if applicable, a description of prior experience with law enforcement, fire response, emergency medical services, emergency communications, National

Guard, or other first responder roles and how the use of communications in those roles qualifies the nominee to participate on the P25 CAP AP.

- Name, title, and organization of the nominee.
- A resume summarizing the nominee's contact information (including the mailing address, phone number, facsimile number, and email address), qualifications, and expertise to explain why the nominee should be appointed to the P25 CAP AP.
- The resume must demonstrate a minimum of ten years (10) years of experience directly using P25 systems in an operational environment in support of established public safety communications or from a system implementer/administrator perspective; a bachelor's or associate degree with an emphasis in communications and engineering may be substituted for three (3) years, a master's/professional certification for seven (7) years, and a Ph.D. for ten (10) years of the requirement.
- The resume must discuss the nominee's familiarity with the current P25 CAP, including documents that are integral to the process such as the SDOCs, STRs, and CABs referenced in this notice.
- A letter from the nominee's supervisor indicating the nominee's agency's support for the nominee to participate on the P25 CAP AP.
- Disclosure of Federal boards, commissions, committees, task forces, or work groups on which the nominee currently serves or has served within the past 12 months.
- A statement confirming that the nominee is not registered as a lobbyist pursuant to the Lobbying Disclosure Act of 1995.

Additional information can be found as follows:

#### Project 25 Compliance Assessment Program and Compliance Assessment Bulletins

<http://www.firstresponder.gov/P25%20CAP%20Resources/Pages/P25CAPResources.aspx>

<http://www.firstresponder.gov/P25%20CAP%20Resources/Pages/Policy.aspx>

Dated: July 31, 2015.

#### Reginald Brothers,

*Under Secretary, DHS Science and Technology Directorate.*

[FR Doc. 2015-19396 Filed 8-6-15; 8:45 am]

**BILLING CODE 9110-9F-P**

**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

[Docket No. FR-5828-N-32]

**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; COE: Mr. Scott Whiteford, Army Corps of Engineers, Real Estate, CEMP-CR, 441 G Street NW., Washington, DC 20314; (202) 761-5542; GSA: Mr. Flavio Peres, General Services Administration, Office of Real Property Utilization and Disposal, 1800 F Street NW., Room 7040, Washington, DC 20405, (202) 501-0084; HEALTH AND HUMAN SERVICES: 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; 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: July 30, 2015.

**Brian P. Fitzmaurice**

*Director, Division of Community Assistance, Office of Special Needs Assistance Programs.*

**TITLE V, FEDERAL SURPLUS PROPERTY PROGRAM FEDERAL REGISTER REPORT FOR 08/07/2015****Suitable/Available Properties***Building*

North Carolina

2 Buildings

East of NC Hwy 33

Hobucken NC 28537

Landholding Agency: Navy

Property Number: 77201530011

Status: Excess

Directions: 200' Communication Tower;

Tower Support Facility

Comments: off-site removal only; contact

Navy for information

Oklahoma

SWT-Roberts S. Kerr Lake

Applegate Crave

HC61 Box 238

Sallisaw OK 74955

Landholding Agency: COE

Property Number: 31201530001

Status: Unutilized

Comments: 263.97 sq. ft.; toilet; 43+ yrs.-old;

poor conditions; contact COE for more information

*Land*

Tennessee

Parcels ED-13, 3A, 16

Portions of D-8 & ED-4

N. Side of Oak Ridge Turnpike (State Rte. 58)

Oak Ridge TN 37763

Landholding Agency: GSA

Property Number: 54201530001

Status: Surplus

GSA Number: 4-B-TN-0664-AF

Directions: Energy: Landholding Agency;

GSA: Disposal Agency

Comments: 168 ± acres; legal constraints:

ingress/egress utility easement;

groundwater constraints; contact GSA for more information

**Unsuitable Properties***Building*

## Arizona

11 Buildings

Marine Corps Air Station Yuma

Yuma AZ 85369

Landholding Agency: Navy

Property Number: 77201530003

Status: Unutilized

Directions: Building's 90, 92, 97, 98, 99, 102, 107, 110, 111, 113, 118

Comments: Public access denied and no alternative method to gain access without compromising national security.

Reasons: Secured Area

11 Buildings

Marine Corps Air Station Yuma

Yuma AZ 85369

Landholding Agency: Navy

Property Number: 77201530004

Status: Unutilized

Directions: Building's 501, 600, 2100, 2101, 2102, 2103, 2104, 2105, 2106, 2107, 619

Comments: Public access denied and no alternative method to gain access without compromising national security.

Reasons: Secured Area

10 Buildings

Marine Corps Air Station Yuma

Yuma AZ 85369

Landholding Agency: Navy

Property Number: 77201530005

Status: Unutilized

Directions: Building's 2108, 2111, 2113, 2115, 2116, 2117, 2118, 2119, 2120, 2125

Comments: Public access denied and no alternative method to gain access without compromising national security.

Reasons: Secured Area

## Hawaii

3 Buildings

Joint Base Pearl Harbor Hickam

Honolulu HI 96860

Landholding Agency: Navy

Property Number: 77201530009

Status: Excess

Directions: 1237—NEX Services Outlet;

1417—Radioactive Waste Steam Plant;

1660—Dry-dock 4 Support Facility

Comments: Public access denied and no alternative method to gain access w/out compromising national security

Reasons: Secured Area

3 Buildings

Rainbow Hale Child Development

Center

JBPHH HI

Landholding Agency: Navy

Property Number: 77201530010

Status: Excess

Directions: 2266; 2267; 2268

Comments: Documented deficiencies: significant structural/exterior/interior damage due to termite infestation; documentation provided represents a clear threat to personal safety

Reasons: Extensive deterioration

## New York

3 Buildings

Stewart Enclave, Stewart ANGB

700 Aviation Ave.

New Windsor NY

Landholding Agency: Navy

Property Number: 77201530007

Status: Underutilized

Directions: 801, 807; and 811

Comments: Public access denied and no alternative method to gain access w/out compromising national security

Reasons: Secured Area

2 Buildings

4856 Clair Rd.

Millport NY 14864

Landholding Agency: Coast Guard

Property Number: 88201530005

Status: Excess

Directions: Backup Power Generator Hut E-(OV1) [44732] Elmira High Level Site; Equipment Hut (OW01) [813823]

Comments: Public access denied and no alternative method to gain access w/out compromising national security

Reasons: Secured Area

## Pennsylvania

Building 108—Warehouse

(PAPR0108)

626 Cochrans Mill Rd.

Pittsburgh PA 15236

Landholding Agency: HHS

Property Number: 57201530001

Status: Excess

Comments: CDC'S secured campus; public access denied and no alternative method to gain access without compromising national security

Reasons: Secured Area

Building 142-Lab

(PAPR0142)

626 Cochrans Mill Rd.

Pittsburgh PA 15236

Landholding Agency: HHS

Property Number: 57201530002

Status: Excess

Comments: CDC'S secured campus; public access denied and no alternative method to gain access without compromising national security

Reasons: Secured Area

Building 161-Lab

(PAPR0161)

626 Cochrans Mill Rd.

Pittsburgh PA 15236

Landholding Agency: HHS

Property Number: 57201530003

Status: Excess

Comments: CDC'S secured campus; public access denied and no alternative method to gain access without compromising national security

Reasons: Secured Area

Building 211-Warehouse

(PAPR0211)

626 Cochrans Mill Rd.

Pittsburgh PA 15236

Landholding Agency: HHS

Property Number: 57201530004

Status: Excess

Comments: CDC'S secured campus; public access denied and no alternative method to gain access without compromising national security

Reasons: Secured Area

Building 222-Explosive

Magazine (PAPR0222)

626 Cochrans Mill Rd.

Pittsburgh PA 15236

Landholding Agency: HHS

Property Number: 57201530005

Status: Excess

Comments: CDC'S secured campus; public access denied and no alternative method to gain access without compromising national security

Reasons: Secured Area

Building 6-Lab

(PAPR00006)

626 Cochrans Mill Rd.

Pittsburgh PA 15236

Landholding Agency: HHS

Property Number: 57201530006

Status: Excess

Comments: CDC'S secured campus; public access denied and no alternative method to gain access without compromising national security

Reasons: Secured Area

Building 39-Warehouse

(PAPR0039)

626 Cochrans Mill Rd.

Pittsburgh PA

Landholding Agency: HHS

Property Number: 57201530007

Status: Excess

Comments: CDC'S secured campus; public access denied and no alternative method to gain access without compromising national security

Reasons: Secured Area

Building 102-Warehouse

(PAPR0102)

626 Cochrans Mill Rd.

Pittsburgh PA 15236

Landholding Agency: HHS

Property Number: 57201530008

Status: Excess

Comments: CDC'S secured campus; public access denied and no alternative method to gain access without compromising national security

Reasons: Secured Area

Building 229-Explosive

Magazine (PAPR0229)

626 Cochrans Mill Rd.

Pittsburgh PA 15236

Landholding Agency: HHS

Property Number: 57201530009

Status: Excess

Comments: CDC'S secured campus; public access denied and no alternative method to gain access without compromising national security

Reasons: Secured Area

*Land*

## Indiana

9 Hole Golf Course &amp;

Adjacent Vacant Land

Naval Support Activity Crane

Crane IN 47522

Landholding Agency: Navy

Property Number: 77201530008

Status: Underutilized

Comments: Public access denied and no alternative method to gain access w/out compromising national security

Reasons: Secured Area

[FR Doc. 2015-19216 Filed 8-6-15; 8:45 am]

BILLING CODE 4210-67-P

**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

[Docket No. FR-5847-N-02]

**Mortgage and Loan Insurance Programs Under the National Housing Act—Debenture Interest Rates**

**AGENCY:** Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

**ACTION:** Notice.

**SUMMARY:** This notice announces changes in the interest rates to be paid on debentures issued with respect to a loan or mortgage insured by the Federal Housing Administration under the provisions of the National Housing Act (the Act). The interest rate for debentures issued under section 221(g)(4) of the Act during the 6-month period beginning July 1, 2015, is 2 1/8 percent. The interest rate for debentures issued under any other provision of the Act is the rate in effect on the date that the commitment to insure the loan or mortgage was issued, or the date that the loan or mortgage was endorsed (or initially endorsed if there are two or more endorsements) for insurance, whichever rate is higher. The interest rate for debentures issued under these other provisions with respect to a loan or mortgage committed or endorsed during the 6-month period beginning July 1, 2015, is 2 7/8 percent. However, as a result of an amendment to section 224 of the Act, if an insurance claim relating to a mortgage insured under sections 203 or 234 of the Act and endorsed for insurance after January 23, 2004, is paid in cash, the debenture interest rate for purposes of calculating a claim shall be the monthly average yield, for the month in which the default on the mortgage occurred, on United States Treasury Securities adjusted to a constant maturity of 10 years.

**FOR FURTHER INFORMATION CONTACT:**

Yong Sun, Department of Housing and Urban Development, 451 Seventh Street SW., Room 5148, Washington, DC 20410-8000; telephone (202) 402-4778 (this is not a toll-free number). Individuals with speech or hearing impairments may access this number through TTY by calling the toll-free Federal Information Relay Service at (800) 877-8339.

**SUPPLEMENTARY INFORMATION:** Section 224 of the National Housing Act (12 U.S.C. 1715o) provides that debentures issued under the Act with respect to an insured loan or mortgage (except for debentures issued pursuant to section 221(g)(4) of the Act) will bear interest at the rate in effect on the date the

commitment to insure the loan or mortgage was issued, or the date the loan or mortgage was endorsed (or initially endorsed if there are two or more endorsements) for insurance, whichever rate is higher. This provision is implemented in HUD's regulations at 24 CFR 203.405, 203.479, 207.259(e)(6), and 220.830. These regulatory provisions state that the applicable rates of interest will be published twice each year as a notice in the **Federal Register**.

Section 224 further provides that the interest rate on these debentures will be set from time to time by the Secretary of HUD, with the approval of the Secretary of the Treasury, in an amount not in excess of the annual interest rate determined by the Secretary of the Treasury pursuant to a statutory formula based on the average yield of all outstanding marketable Treasury obligations of maturities of 15 or more years.

The Secretary of the Treasury (1) has determined, in accordance with the provisions of section 224, that the statutory maximum interest rate for the period beginning July 1, 2015, is 2 7/8 percent; and (2) has approved the establishment of the debenture interest rate by the Secretary of HUD at 2 7/8 percent for the 6-month period beginning July 1, 2015. This interest rate will be the rate borne by debentures issued with respect to any insured loan or mortgage (except for debentures issued pursuant to section 221(g)(4)) with insurance commitment or endorsement date (as applicable) within the latter 6 months of 2015.

For convenience of reference, HUD is publishing the following chart of debenture interest rates applicable to mortgages committed or endorsed since January 1, 1980:

Effective interest rate	on or after	prior to
9 1/2	Jan. 1, 1980	July 1, 1980
9 7/8	July 1, 1980	Jan. 1, 1981
11 3/4	Jan. 1, 1981	July 1, 1981
12 7/8	July 1, 1981	Jan. 1, 1982
12 3/4	Jan. 1, 1982	Jan. 1, 1983
10 1/4	Jan. 1, 1983	July 1, 1983
10 3/8	July 1, 1983	Jan. 1, 1984
11 1/2	Jan. 1, 1984	July 1, 1984
13 3/8	July 1, 1984	Jan. 1, 1985
11 5/8	Jan. 1, 1985	July 1, 1985
11 1/8	July 1, 1985	Jan. 1, 1986
10 1/4	Jan. 1, 1986	July 1, 1986
8 1/4	July 1, 1986	Jan. 1, 1987
8	Jan. 1, 1987	July 1, 1987
9	July 1, 1987	Jan. 1, 1988
9 1/8	Jan. 1, 1988	July 1, 1988
9 3/8	July 1, 1988	Jan. 1, 1989
9 1/4	Jan. 1, 1989	July 1, 1989
9	July 1, 1989	Jan. 1, 1990
8 1/8	Jan. 1, 1990	July 1, 1990

Effective interest rate	on or after	prior to
9	July 1, 1990	Jan. 1, 1991
8 3/4	Jan. 1, 1991	July 1, 1991
8 1/2	July 1, 1991	Jan. 1, 1992
8	Jan. 1, 1992	July 1, 1992
8	July 1, 1992	Jan. 1, 1993
7 3/4	Jan. 1, 1993	July 1, 1993
7	July 1, 1993	Jan. 1, 1994
6 5/8	Jan. 1, 1994	July 1, 1994
7 3/4	July 1, 1994	Jan. 1, 1995
8 3/8	Jan. 1, 1995	July 1, 1995
7 1/4	July 1, 1995	Jan. 1, 1996
6 1/2	Jan. 1, 1996	July 1, 1996
7 1/4	July 1, 1996	Jan. 1, 1997
6 3/4	Jan. 1, 1997	July 1, 1997
7 1/8	July 1, 1997	Jan. 1, 1998
6 3/8	Jan. 1, 1998	July 1, 1998
6 1/8	July 1, 1998	Jan. 1, 1999
5 1/2	Jan. 1, 1999	July 1, 1999
6 1/8	July 1, 1999	Jan. 1, 2000
6 1/2	Jan. 1, 2000	July 1, 2000
6 1/2	July 1, 2000	Jan. 1, 2001
6	Jan. 1, 2001	July 1, 2001
5 7/8	July 1, 2001	Jan. 1, 2002
5 1/4	Jan. 1, 2002	July 1, 2002
5 3/4	July 1, 2002	Jan. 1, 2003
5	Jan. 1, 2003	July 1, 2003
4 1/2	July 1, 2003	Jan. 1, 2004
5 1/8	Jan. 1, 2004	July 1, 2004
5 1/2	July 1, 2004	Jan. 1, 2005
4 7/8	Jan. 1, 2005	July 1, 2005
4 1/2	July 1, 2005	Jan. 1, 2006
4 7/8	Jan. 1, 2006	July 1, 2006
5 3/8	July 1, 2006	Jan. 1, 2007
4 3/4	Jan. 1, 2007	July 1, 2007
5	July 1, 2007	Jan. 1, 2008
4 1/2	Jan. 1, 2008	July 1, 2008
4 5/8	July 1, 2008	Jan. 1, 2009
4 1/8	Jan. 1, 2009	July 1, 2009
4 1/8	July 1, 2009	Jan. 1, 2010
4 1/4	Jan. 1, 2010	July 1, 2010
4 1/8	July 1, 2010	Jan. 1, 2011
3 7/8	Jan. 1, 2011	July 1, 2011
4 1/8	July 1, 2011	Jan. 1, 2012
2 7/8	Jan. 1, 2012	July 1, 2012
2 3/4	July 1, 2012	Jan. 1, 2013
2 1/2	Jan. 1, 2013	July 1, 2013
2 7/8	July 1, 2013	Jan. 1, 2014
3 5/8	Jan. 1, 2014	July 1, 2014
3 1/4	July 1, 2014	Jan. 1, 2015
3	Jan. 1, 2015	July 1, 2015
2 7/8	July 1, 2015	Jan. 1, 2016

Section 215 of Division G, Title II of Public Law 108-199, enacted January 23, 2004 (HUD's 2004 Appropriations Act) amended section 224 of the Act, to change the debenture interest rate for purposes of calculating certain insurance claim payments made in cash. Therefore, for all claims paid in cash on mortgages insured under section 203 or 234 of the National Housing Act and endorsed for insurance after January 23, 2004, the debenture interest rate will be the monthly average yield, for the month in which the default on the mortgage occurred, on United States Treasury Securities adjusted to a constant maturity of 10 years, as found in Federal Reserve Statistical Release H-

15. The Federal Housing Administration has codified this provision in HUD regulations at 24 CFR 203.405(b) and 24 CFR 203.479(b).

Section 221(g)(4) of the Act provides that debentures issued pursuant to that paragraph (with respect to the assignment of an insured mortgage to the Secretary) will bear interest at the "going Federal rate" in effect at the time the debentures are issued. The term "going Federal rate" is defined to mean the interest rate that the Secretary of the Treasury determines, pursuant to a statutory formula based on the average yield on all outstanding marketable Treasury obligations of 8- to 12-year maturities, for the 6-month periods of January through June and July through December of each year. Section 221(g)(4) is implemented in the HUD regulations at 24 CFR 221.255 and 24 CFR 221.790.

The Secretary of the Treasury has determined that the interest rate to be borne by debentures issued pursuant to section 221(g)(4) during the 6-month period beginning July 1, 2015, is 2½ percent.

The subject matter of this notice falls within the categorical exemption from HUD's environmental clearance procedures set forth in 24 CFR 50.19(c)(6). For that reason, no environmental finding has been prepared for this notice.

**Authority:** Sections 211, 221, 224, National Housing Act, 12 U.S.C. 1715b, 1715l, 1715o; Section 7(d), Department of HUD Act, 42 U.S.C. 3535(d).

Dated: July 23, 2015.

**Edward L. Golding,**

*Principal Deputy Assistant Secretary for Housing.*

[FR Doc. 2015-19391 Filed 8-6-15; 8:45 am]

**BILLING CODE 4210-67-P**

## DEPARTMENT OF THE INTERIOR

### Fish and Wildlife Service

[FWS-R8-ES-2015-N124: FF08ENVD00-FXES1113080000-156]

#### Endangered and Threatened Wildlife and Plants; Enhancement of Survival Permit Application; Greater Sage-Grouse Candidate Conservation Agreement With Assurances for Smith Creek Ranch LTD

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice of availability; request for comments.

**SUMMARY:** We, the U.S. Fish and Wildlife Service (Service), have received an application for an enhancement of

survival permit (EOS) under the Endangered Species Act of 1973, as amended (ESA). The permit application includes a draft candidate conservation agreement with assurances (CCAA) between Smith Creek Ranch LTD and the Service for the greater sage-grouse on private rangelands in Churchill and Lander Counties, Nevada. We invite comments from all interested parties on the application, including the draft CCAA, and a draft environmental action statement (EAS) prepared pursuant to the requirements of the National Environmental Policy Act (NEPA).

**DATES:** To ensure consideration, written comments must be received from interested parties no later than September 8, 2015.

**ADDRESSES:** To request further information or submit written comments, please use one of the following methods, and note that your information request or comments are in reference to the Smith Creek Ranch LTD CCAA.

*Internet:* Documents may be viewed on the Internet at <http://www.fws.gov/nevada>.

*Email:* [marcy\\_haworth@fws.gov](mailto:marcy_haworth@fws.gov). Include "Smith Creek Ranch CCAA" in the subject line of the message or comments.

*U.S. Mail:* U.S. Fish and Wildlife Service, Reno Fish and Wildlife Office, 1340 Financial Boulevard, Suite 234, Reno, NV 89502.

*Fax:* 775-861-6301. Include "Smith Creek Ranch CCAA" in the subject line of the message or comments.

*In-Person Viewing or Pickup:* Documents will be available for public inspection by appointment during normal business hours at the Reno Fish and Wildlife Office (address above).

**FOR FURTHER INFORMATION CONTACT:** Edward D. Koch, Field Supervisor, Reno Fish and Wildlife Office (see **ADDRESSES**); by telephone (775-861-6300), or by facsimile (775-861-6301). If you use a telecommunications device for the deaf (TDD), please call the Federal Information Relay Service at 800-877-8339.

**SUPPLEMENTARY INFORMATION:** We have received an application from Smith Creek Ranch LTD for an EOS permit under the ESA. The permit application includes a CCAA between the applicant and the Service for the greater sage-grouse (*Centrocercus urophasianus*) in Churchill and Lander Counties, Nevada. The Service and the applicant prepared the CCAA to provide the applicant with the opportunity to voluntarily conserve the greater sage-grouse and its habitat while carrying out ranch operations. We have made a preliminary determination

that the proposed CCAA and permit issuance are eligible for categorical exclusion under NEPA. The basis for our preliminary determination is contained in an EAS. We invite comments from all interested parties on the application, including the CCAA and the EAS.

### Background Information

Private and other non-Federal property owners are encouraged to enter into CCAAs, in which they voluntarily undertake management activities on their properties to enhance, restore, or maintain habitat benefiting species that are proposed for listing under the ESA, candidates for listing, or species that may become candidates or proposed for listing. Through a CCAA and its associated EOS permit, the Service provides assurances to property owners that they will not be subjected to increased land use restrictions if the covered species become listed under the ESA in the future, provided the CCAA is being properly implemented and the EOS permit conditions are met. Application requirements and issuance criteria for EOS permits for CCAAs are found in the Code of Regulations (CFR) at 50 CFR 17.22(d) and 17.32 (d), respectively. See also our joint policy on CCAAs, which we published in the **Federal Register** with the Department of Commerce's National Oceanic and Atmospheric Administration, National Marine Fisheries Service (64 FR 32726; June 17, 1999), as well as our revisions to that policy (69 FR 24084; May 3, 2004).

On March 23, 2010, the Service published a 12-month finding in the **Federal Register** (75 FR 13910) that the greater sage-grouse warrants listing under the ESA as threatened or endangered throughout its range, but this action was precluded by other higher priority listing actions. In anticipation of a future listing decision by the Service, the applicant requested assistance from the Service in developing a CCAA addressing the needs of the greater sage-grouse on lands owned in Churchill and Lander Counties, Nevada. Under the proposed CCAA, the applicant will address threats to the greater sage-grouse through implementation of conservation measures that are consistent with their land use activities and the CCAA. Through the issuance of an EOS permit, pursuant to section 10(a)(1)(A) of the ESA, the applicant would be authorized to incidentally take greater sage-grouse in the course of implementing the CCAA if the species becomes listed under the ESA in the future, as long as

the terms and conditions of the permit and the CCAA are followed.

### Proposed Action

The Service proposes to approve the CCAA and to issue an EOS permit, both with a term of 20 years, to Smith Creek Ranch LTD for incidental take of greater sage-grouse caused by covered activities, if permit issuance criteria are met. The area to be addressed under this proposed CCAA (*i.e.*, covered lands) includes approximately 2,200 acres in Churchill and Lander Counties, Nevada. Greater sage-grouse currently use suitable habitat on the covered lands for nesting, early and late brood-rearing, and wintering. The proposed CCAA describes the threats to the greater sage-grouse that have been identified on the enrolled lands, and the conservation measures the applicant will implement to address these threats. Implementation of the conservation measures identified in the CCAA is expected to benefit the greater sage-grouse by (1) Maintaining tracts of unfragmented and undeveloped land; (2) managing weeds and invasive plant species; and (3) maintaining healthy, intact nesting, brood-rearing and wintering habitats. The CCAA has been developed in support of a EOS permit under section 10(a)(1)(A) of the ESA.

Consistent with our CCAA Policy (64 FR 32726), the conservation goal of the proposed CCAA is to encourage enhancement and protection of greater sage-grouse habitat on non-Federal lands by either maintaining or modifying existing land uses so that they are consistent with the conservation needs of the greater sage-grouse. We can meet this conservation goal with the use of a CCAA by giving non-Federal landowners incentives to implement conservation measures, primarily through regulatory certainty concerning land-use restrictions that might otherwise apply should the greater sage-grouse become listed under the ESA.

We have made a preliminary determination that the proposed CCAA and permit issuance are eligible for categorical exclusion under NEPA. The basis for our preliminary determination is contained in an EAS, which is available for public review (see **ADDRESSES**).

### Public Comments

We request data, comments, new information, or suggestions from the public, other concerned governmental agencies, the scientific community, Tribes, industry, or any other interested party on this notice. We particularly seek comments on the following: (1)

Biological information concerning the greater sage-grouse; (2) relevant data concerning this species; (3) additional information concerning the range, distribution, population size, and population trends of the greater sage-grouse; (4) current or planned activities in the covered area and their possible impacts on the species; (5) identification of any other environmental issues that should be considered with regard to the proposed permit action; and (6) information regarding the adequacy of the CCAA pursuant to the requirements for permits at 50 CFR parts 13 and 17.

### Public Availability of Comments

All comments and materials we receive become part of the public record associated with this action. Before including your address, phone number, email address, or other personal identifiable information (PII) in your comments, you should be aware that your entire comment—including your PII—may be made publically available at any time. While you can ask us in your comment to withhold your PII from public review, we cannot guarantee we will be able to do so. Comments and materials we receive, as well as supporting documentation we used in preparing the draft EAS, will be available for public inspection by appointment, during normal business hours, at our Reno Fish and Wildlife Office (see **ADDRESSES**).

### Next Steps

We will evaluate the permit application, associated documents, and comments we receive to determine whether the permit application meets the requirements of section 10(a)(1)(A) of the ESA and NEPA and their implementing regulations. We will also evaluate whether issuance of an EOS permit would comply with section 7 of the ESA by conducting an intra-Service section 7 consultation on the proposed permit action. If we determine that all requirements are met, we will sign the proposed CCAA and issue an EOS permit under section 10(a)(1)(A) of the ESA to Smith Creek Ranch LTD for incidental take of greater sage-grouse that is likely to occur with implementation of the CCAA. We will not make our final decision until after the end of the 30-day public comment period, and we will fully consider all comments we receive during the public comment period.

### Authority

We provide this notice in accordance with the requirements of section 10(c) of the ESA (16 U.S.C. 1531 *et seq.*) and NEPA (42 U.S.C. 4321 *et seq.*) and their

implementing regulations (50 CFR 17.22 and 40 CFR 1506.6, respectively).

**Edward D. Koch,**

*Field Supervisor, Reno Fish and Wildlife Office, U.S. Fish and Wildlife Service, Reno, Nevada.*

[FR Doc. 2015–19469 Filed 8–6–15; 8:45 am]

**BILLING CODE 4310–55–P**

## DEPARTMENT OF THE INTERIOR

### Geological Survey

[GX15BA02EEW0200]

### Agency Information Collection Activities: Request for Comments; USA National Phenology Network— The Nature's Notebook Plant and Animal Observing Program

**AGENCY:** U.S. Geological Survey (USGS), Interior.

**ACTION:** Notice of a revision of a currently approved information collection.

**SUMMARY:** We (the U.S. Geological Survey) will ask the Office of Management and Budget (OMB) to approve the information collection (IC) described below. As required by the Paperwork Reduction Act (PRA) of 1995, and as part of our continuing efforts to reduce paperwork and respondent burden, we invite the general public and other Federal agencies to take this opportunity to comment on this IC. This collection is scheduled to expire on January 31, 2016.

**DATES:** To ensure that your comments are considered, we must receive them on or before October 6, 2015.

**ADDRESSES:** You may submit comments on this information collection to the Information Collection Clearance Officer, U.S. Geological Survey, 12201 Sunrise Valley Drive MS 807, Reston, VA 20192 (mail); (703) 648–7197 (fax); or *gs-info\_collections@usgs.gov* (email). Please reference 'Information Collection 1028–0103, USA National Phenology Network—The Nature's Notebook Plant and Animal Observing Program' in all correspondence.

**FOR FURTHER INFORMATION CONTACT:** Jake Weltzin, U.S. Geological Survey, 1955 East 6th Street, Tucson, AZ 85721 (mail); (520) 626–3821 (phone); or *jwteltzin@usgs.gov* (email). You may also find information about this ICR at *www.reginfo.gov*.

### SUPPLEMENTARY INFORMATION:

#### I. Abstract

The USA–NPN is a program sponsored by the USGS that uses



standardized forms for tracking plant and animal activity as part of a project called Nature's Notebook. The Nature's Notebook forms are used to record phenology (e.g., timing of leafing or flowering of plants and reproduction or migration of animals) as part of a nationwide effort to understand and predict how plants and animals respond to environmental variation and changes in weather and climate. Contemporary data collected through Nature's Notebook are quality-checked, described and made publicly available; data are used to inform decision-making in a variety of contexts, including agriculture, drought monitoring, and wildfire risk assessment. Phenological information is also critical for the management of wildlife, invasive species, and agricultural pests, and for understanding and managing risks to human health and welfare, including allergies, asthma, and vector-borne diseases. Participants may contribute phenology information to Nature's Notebook through a browser-based web application or via mobile applications for iPhone and Android operating systems, meeting GPEA requirements. The web application interface consists several components: User registration, a searchable list of 1,016 plant and animal species which can be observed; a "profile" for each species that contains information about the species including its description and the appropriate monitoring protocols; a series of interfaces for registering as an observer, registering a site, registering plants and animals at a site, generating datasheets to take to the field, and a data entry page that mimics the datasheets.

## II. Data

*OMB Control Number:* 1028-0103.

*Form Number:* Various (4 forms).

*Title:* USA National Phenology Network—The Nature's Notebook Plant and Animal Observing Program.

*Type of Request:* Notice of an extension of a currently approved information collection.

*Affected Public:* Members of the public, registered with Nature's Notebook.

*Respondent's Obligation:* None. Participation is voluntary.

*Frequency of Collection:* On occasion. During the Spring and Fall seasons when phenology is changing quickly, we recommend respondents make observations twice per week.

*Estimated Total Number of Annual Responses:* We project that 6,478 responders will register with Nature's Notebook, and of those 648 will watch the training videos. The same 6,478 responders will contribute 2,627,155

observation records. In total, this will result in 2,634,269 responses.

*Estimated Time per Response:* When joining the program, responders spend 13 minutes each to register and read guidelines and 83 minutes to watch all training videos. After that responders may spend about 2 minutes per record to observe and submit phenophase status record.

*Estimated Annual Burden Hours:* 89,871.

*Estimated Reporting and Recordkeeping "Non-Hour Cost" Burden:* We estimate the total annual non-hour cost burden to be \$11,447. This cost applies to new observers and includes material used to mark sites or plants during the first observation. Marking helps to ensure reporting consistency for future observations.

*Public Disclosure Statement:* The PRA (44 U.S.C. 3501, *et seq.*) provides that an agency may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number and current expiration date.

## III. Request for Comments

We are soliciting comments as to: (a) Whether the proposed collection of information is necessary for the agency to perform its duties, including whether the information is useful; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, usefulness, and clarity of the information to be collected; and (d) how to minimize the burden on the respondents, including the use of automated collection techniques or other forms of information technology.

Please note that the comments submitted in response to this notice are a matter of public record. Before including your personal mailing address, phone number, email address, or other personally identifiable information in your comment, you should be aware that your entire comment, including your personally identifiable information, may be made publicly available at any time. While you can ask us in your comment to withhold your personally identifiable information from public view, we cannot guarantee that we will be able to do so.

**Jake Weltzin,**

*Program Manager, Status & Trends Program and Executive Director, USA National Phenology Network.*

[FR Doc. 2015-19400 Filed 8-6-15; 8:45 am]

**BILLING CODE 4311-AM-P**

## DEPARTMENT OF THE INTERIOR

### Geological Survey

[GX15EE000101000]

#### Agency Information Collection Activities: Request for Comments: National Spatial Data Infrastructure Cooperative Agreements Program (NSDI CAP)

**AGENCY:** U.S. Geological Survey (USGS), Interior.

**ACTION:** Notice of a new information collection.

**SUMMARY:** We (the U.S. Geological Survey) will ask the Office of Management and Budget (OMB) to approve the information collection (IC) described below. As required by the Paperwork Reduction Act (PRA) of 1995, and as part of our continuing efforts to reduce paperwork and respondent burden, we invite the general public and other Federal agencies to take this opportunity to comment on this IC.

**DATES:** To ensure that your comments are considered, we must receive them on or before October 6, 2015.

**ADDRESSES:** You may submit comments on this information collection to the Information Collection Clearance Officer, U.S. Geological Survey, 12201 Sunrise Valley Drive MS 807, Reston, VA 20192 (mail); (703) 648-7197 (fax); or *gs-info\_collections@usgs.gov* (email). Please reference 'Information Collection 1028-NEW, NSDI CAP in all correspondence.

**FOR FURTHER INFORMATION CONTACT:** Brigitta Urban-Mathieux, Federal Geographic Data Committee Office of the Secretariat, U.S. Geological Survey, 12201 Sunrise Valley Drive, Mail Stop 590, Reston, VA 20192 (mail); 703-648-5175 (phone); or *burbanma@usgs.gov* (email). You may also find information about this ICR at *www.reginfo.gov*.

#### SUPPLEMENTARY INFORMATION:

##### I. Abstract

Respondents are submitting proposals to acquire funding for projects to help build the infrastructure necessary for the geospatial data community to effectively discover, access, share, manage, and use digital geographic data. The National Spatial Data Infrastructure (NSDI) consists of the technologies, policies, organizations, and people necessary to promote cost-effective production, and the ready availability and greater utilization of geospatial data among a variety of sectors, disciplines, and communities. Specific NSDI areas of emphasis include: Metadata

documentation, clearinghouse establishment, geospatial data framework development, standards implementation, and geographic information system (GIS) organizational coordination.

We will issue a request for proposal (RFP) via Grant.gov. The incoming proposals will be reviewed and scored based on the responses to the questions in the RFP. Responses are voluntary. No questions of a “sensitive” nature are asked. We will protect information from respondents considered proprietary under the Freedom of Information Act (5 U.S.C. 552) and its implementing regulations (43 CFR part 2), and under regulations at 30 CFR 250.197, “Data and information to be made available to the public or for limited inspection.” We intend to release the project abstracts and primary investigators for awarded/funded projects only.

## II. Data

*OMB Control Number:* 1028—NEW.  
*Form Number:* NA

*Title:* National Spatial Data Infrastructure Cooperative Agreements Program (NSDI CAP).

*Type of Request:* New information collection.

*Affected Public:* Private Sector; State, Local, and Tribal governments; Academia, and Non-profit organizations.

*Respondent's Obligation:* None. Participation is voluntary.

*Frequency of Collection:* This is an annual offer.

*Estimated Total Number of Annual Responses:* 60

*Estimated Time per Response:* 25 hours

*Estimated Annual Burden Hours:* 1,500 hours.

*Estimated Reporting and Recordkeeping “Non-Hour Cost” Burden:* None.

*Public Disclosure Statement:* The PRA (44 U.S.C. 3501, *et seq.*) provides that an agency may not conduct or sponsor and you are not required to respond to a collection of information unless it displays a currently valid OMB control number and current expiration date.

## III. Request for Comments

We are soliciting comments as to: (a) Whether the proposed collection of information is necessary for the agency to perform its duties, including whether the information is useful; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, usefulness, and clarity of the information to be collected; and (d) how to minimize the burden on the

respondents, including the use of automated collection techniques or other forms of information technology. Please note that the comments submitted in response to this notice are a matter of public record. Before including your personal mailing address, phone number, email address, or other personally identifiable information in your comment, you should be aware that your entire comment, including your personally identifiable information, may be made publicly available at any time. While you can ask us in your comment to withhold your personally identifiable information from public view, we cannot guarantee that we will be able to do so.

**Ivan DeLoatch,**

*Executive Director, Federal Geographic Data Committee, Core Science Systems.*

[FR Doc. 2015–19384 Filed 8–6–15; 8:45 am]

**BILLING CODE 4311-AM-P**

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

**[LLCA942000 L57000000.BX0000 13X L5017AR]**

#### Filing of Plats of Survey: California

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice.

**SUMMARY:** The plats of survey of lands described below are scheduled to be officially filed in the Bureau of Land Management, California State Office, Sacramento, California.

**DATES:** September 8, 2015.

**ADDRESSES:** A copy of the plats may be obtained from the California State Office, Bureau of Land Management, 2800 Cottage Way, Sacramento, California 95825, upon required payment.

#### FOR FURTHER INFORMATION CONTACT:

Chief, Branch of Geographic Services, Bureau of Land Management, California State Office, 2800 Cottage Way W–1623, Sacramento, California 95825, (916) 978–4310. 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:** A person or party who wishes to protest a survey

must file a notice that they wish to protest with the Chief, Branch of Geographic Services. A statement of reasons for a protest may be filed with the notice of protest and must be filed with the Chief, Branch of Geographic Services within thirty days after the protest is filed. If a protest against the survey is received prior to the date of official filing, the filing will be stayed pending consideration of the protest. A plat will not be officially filed until the day after all protests have been dismissed or otherwise resolved. 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.

#### Humboldt Meridian, California

T. 11 N., R. 3 E., supplemental plat of the S ½ of the SE ¼ of section 7, accepted July 29, 2015.

#### Mount Diablo Meridian, California

T. 23 N., R. 13 W., metes-and-bounds survey of lots in section 36, accepted July 21, 2015.

T. 17 S., R. 8 E., dependent resurvey and subdivision of section 6, accepted July 28, 2015.

#### San Bernardino Meridian, California

T. 9 N., R. 23 E., supplemental plat of the NW ¼ of the NE ¼ of section 31, accepted July 14, 2015.

T. 9 S., R. 14 E., supplemental plat of the SW ¼ of section 32, accepted July 15, 2015.

T. 2 N., R. 9 E., dependent resurvey and subdivision of section 34, accepted July 21, 2015.

**Authority:** 43 U.S.C., Chapter 3.

Dated: July 31, 2015.

**Lance J. Bishop,**

*Chief Cadastral Surveyor, California.*

[FR Doc. 2015–19463 Filed 8–6–15; 8:45 am]

**BILLING CODE 4310-40-P**

**DEPARTMENT OF THE INTERIOR****Bureau of Land Management**

[LLCAD06000.L51010000.  
ER0000.15XL5017AP.LVRWB15B5410]

**Notice of Availability of the Draft Joint Environmental Impact Report and Environmental Impact Statement for the West of Devers Upgrade Project, Riverside and San Bernardino Counties, CA**

**AGENCY:** Bureau of Land Management, Interior.

**ACTION:** Notice of Availability.

**SUMMARY:** In accordance with the National Environmental Policy Act of 1969, as amended, the Bureau of Land Management (BLM) has prepared a Draft Environmental Impact Statement (EIS) for the West of Devers Upgrade Project (WOD UP) and by this notice is announcing the opening of the comment period. This document is also an Environmental Impact Report (EIR) prepared by the California Public Utilities Commission (CPUC) under the California Environmental Quality Act (CEQA).

**DATES:** To ensure comments will be considered, the BLM must receive written comments on the West of Devers Upgrade Project Draft Joint EIR/EIS within 45 days following the date the Environmental Protection Agency publishes its Notice of Availability in the **Federal Register**. The BLM will announce future meetings or hearings and any other public involvement activities at least 15 days in advance through public notices, media releases, and/or mailings.

**ADDRESSES:** You may submit comments related to the WOD UP by any of the following methods:

- Web site: <http://www.blm.gov/ca/st/en/fo/palmsprings/transmission/WestOfDeversProject.html>.
- Email: [blm\\_ca\\_west\\_of\\_devers@blm.gov](mailto:blm_ca_west_of_devers@blm.gov).
- Fax: 760-833-7199.
- Mail: WOD Project Manager; BLM Palm Springs-South Coast Field Office, 1201 Bird Center Drive, Palm Springs, CA 92262

Copies of the Draft Joint EIR/EIS for the WOD UP are available in the Palm Springs/South Coast Field Office at the above address and the BLM California Desert District Office, 22835 Calle San Juan De Los Lagos, Moreno Valley, CA 92553.

**FOR FURTHER INFORMATION CONTACT:** Frank McMenimen, Project Manager, telephone 760-833-7150; address 1201 Bird Center Drive, Palm Springs, CA

92262; email [fmcmenimen@blm.gov](mailto:fmcmenimen@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:** Southern California Edison (SCE) proposes to upgrade and adjust the routes of the following existing 220 kV transmission lines within SCE's existing West of Devers right-of-way corridor in incorporated and unincorporated areas of Riverside and San Bernardino Counties, including: Devers-El Casco, El Casco-San Bernardino, Devers-San Bernardino, Devers-Vista No. 1 and No. 2, Etiwanda-San Bernardino, and San Bernardino-Vista.

Of the overall 48-mile length of the transmission corridor, approximately 6 miles would cross Trust Lands (Reservation) of the Morongo Band of Mission Indians and approximately 1 mile is on BLM-administered public lands. The BLM lands are located east of the City of Banning and west of the City of Desert Hot Springs in Riverside County.

In addition to the transmission line improvements, substation equipment at Devers, El Casco, Etiwanda, San Bernardino, Timoteo and Tennessee and Vista Substations would be upgraded to accommodate the project changes to transmission and subtransmission systems. Construction of the WOD UP would facilitate the full deliverability of new renewable energy generation resources now being developed in eastern Riverside County, including the BLM's Riverside East Solar Energy Zone, into the Los Angeles area.

The WOD UP would facilitate progress towards meeting California's Renewable Portfolio Standard goals requiring utilities to produce 33 percent of their electricity sales from renewable energy sources by 2020. Utility-scale solar energy development in eastern Riverside County plays an important role in meeting California's renewable energy goals, allowing for immediate and sizeable deployment, driving costs down and taking advantage of the State's best renewable energy resources. Additionally, these upgrades are required to comply with transmission reliability standards and will support integration of small scale electricity generation.

In addition to the Proposed Project, the WOD UP Draft Joint EIR/EIS

considers three project alternatives and a No Action/No Project alternative, as well as connected actions enabled by the project. The first alternative moves towers away from residences. The second alternative would place portions of the line underground. The third alternative would use fewer towers, and would not remove all the old towers and poles, leaving future expansion opportunities. Based on the small amount of BLM lands involved, and because of the lack of apparent resource conflicts for the BLM among the alternatives, the BLM has not identified a preferred alternative. The BLM will identify a preferred alternative for the Final EIS based on feedback on the Draft EIS from the public and cooperating agencies.

During the public scoping process, BLM personnel, Federal, State, local agencies, and other stakeholders identified issues for the EIR/EIS, including aesthetics/visual effects; conflicts with existing land uses; social and economic effects, including property values; fire, electric and magnetic fields, and other hazards; construction-related impacts from dust and traffic; slope stability; effects on biological resources; and possible curtailment of electric generation during construction.

Please note that public comments and information submitted including names, street addresses, and email addresses of persons who submit comments will be available for public review and disclosure at the above address during regular business hours (8 a.m. to 4 p.m.), Monday through Friday, except holidays.

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.

**Authority:** 40 CFR 1506.6, 40 CFR 1506.10.

**Danielle Chi,**

*Associate Deputy State Director.*

[FR Doc. 2015-19497 Filed 8-6-15; 8:45 am]

**BILLING CODE 4310-40-P**

**DEPARTMENT OF THE INTERIOR****Bureau of Land Management**

[LLNV912. L12100000.PH0000  
LXSS006F0000 261A; 14-08807; MO#  
4500082128]

**Notice of Public Meetings: Sierra  
Front-Northwestern Great Basin  
Resource Advisory Council, Nevada**

**AGENCY:** Bureau of Land Management,  
Interior.

**ACTION:** Notice of public meetings.

**SUMMARY:** In accordance with the Federal Land Policy and Management Act (FLPMA) and the Federal Advisory Committee Act of 1972 (FACA), the U.S. Department of the Interior, Bureau of Land Management (BLM) Sierra Front-Northwestern Great Basin Resource Advisory Council (RAC), will hold a meeting in Nevada, in September 2015. The meeting is open to the public.

**DATES AND TIMES:** September 17 and 18 at the BLM Winnemucca, Nevada District. A meeting will be held on Thursday, September 17, at the Winnemucca BLM District Office (5100 East Winnemucca Blvd.) in Winnemucca, Nevada. Approximate meeting times are 8 a.m. to 4 p.m. However, meetings could end earlier if discussions and presentations conclude before 4 p.m. The meeting will include a public comment period at approximately 11:30 a.m. A field trip will be held on Friday, September 18 within the Winnemucca BLM District.

**FOR FURTHER INFORMATION CONTACT:** Lisa Ross, Public Affairs Specialist, Carson City District Office, 5665 Morgan Mill Road, Carson City, NV 89701, telephone: (775) 885-6107, email: [lross@blm.gov](mailto:lross@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 15-member Council advises the Secretary of the Interior, through the BLM, on a variety of planning and management issues associated with public land management in Nevada. Topics for discussion at the meeting will include, but are not limited to:

- September 17-18 (Carson City)—landscape vegetative management, rangeland health assessments, Fire Invasive Assessment Tool (FIAT), sage grouse, drought, and fire restoration.

Managers' reports of district office activities will be distributed at each meeting. The Council may raise other topics at the meetings.

Final agendas will be posted on-line at the BLM Sierra Front-Northwestern Great Basin RAC Web site at [http://www.blm.gov/nv/st/en/res/resource\\_advisory.html](http://www.blm.gov/nv/st/en/res/resource_advisory.html) and will be published in local and regional media sources at least 14 days before each meeting.

Individuals who need special assistance such as sign language interpretation or other reasonable accommodations, or who wish to receive a copy of each agenda, may contact Lisa Ross no later than 10 days prior to each meeting.

**Stephen Clutter,**  
*Chief, Office of Communications.*

[FR Doc. 2015-19464 Filed 8-6-15; 8:45 am]

**BILLING CODE 4310-HC-P**

**DEPARTMENT OF THE INTERIOR****Bureau of Reclamation**

[RR02030000, 15XR0687NA,  
RX185279046000000]

**Notice of Availability of the Final  
Environmental Impact Statement and  
Final Feasibility Report for the Shasta  
Lake Water Resources Investigation,  
Shasta and Tehama Counties,  
California**

**AGENCY:** Bureau of Reclamation,  
Interior.

**ACTION:** Notice.

**SUMMARY:** The Bureau of Reclamation has prepared the Final Environmental Impact Statement (FEIS) for the Shasta Lake Water Resources Investigation (SLWRI). The purpose of the proposed action is to improve operational flexibility of the Sacramento-San Joaquin Delta watershed system by modifying the existing Shasta Dam and Reservoir to meet specified objectives. Primary objectives are to increase the survival of anadromous fish populations in the upper Sacramento River and increase water supply and water supply reliability for agricultural, municipal and industrial, and environmental purposes. Secondary planning objectives are to: Conserve, restore, and enhance ecosystem resources in the primary study area; reduce flood damage along the Sacramento River; develop additional hydropower generation capabilities at Shasta Dam; maintain and increase recreation opportunities at Shasta Lake; and maintain or improve water quality conditions in the Sacramento River

downstream from Shasta Dam and in the Sacramento-San Joaquin Delta. The companion Final Feasibility Report is also available, and together, these documents are provided to inform the Congress and the public of the technical studies conducted to date.

**DATES:** Ultimately, if the project is authorized by Congress, the Secretary may issue a Record of Decision (ROD) at least 30 days after release of the FEIS. The ROD will state the action that will be implemented, consistent with Congressional authorization, and will discuss all factors leading to the decision.

**ADDRESSES:** The FEIS may be viewed at the SLWRI Web site at [www.usbr.gov/mp/slwri](http://www.usbr.gov/mp/slwri). See the **SUPPLEMENTARY INFORMATION** section for locations where copies of the FEIS are available for public review.

**FOR FURTHER INFORMATION CONTACT:** Ms. Katrina Chow, Reclamation Project Manager, Bureau of Reclamation, 2800 Cottage Way, Sacramento, CA 95825; 916-978-5067, TDD 916-978-5608; via fax at 916-978-5094; or email to [bor-mpr-slwri@usbr.gov](mailto:bor-mpr-slwri@usbr.gov).

**SUPPLEMENTARY INFORMATION:** A Notice of Availability of the Draft Environmental Impact Statement (DEIS) was published in the **Federal Register** on July 1, 2013 (78 FR 39315). The comment period on the DEIS ended on September 30, 2013. The FEIS contains responses to all comments received and reflects comments and any additional information received during the review period. The Final Feasibility Report and FEIS incorporate clarifying information in consideration of comments received.

Shasta Dam was completed in 1945 to serve multiple purposes, including flood control; water supply for agricultural, municipal and industrial, and environmental purposes; and hydropower generation. In addition, extensive recreational opportunities in and around Shasta Lake significantly contribute to the regional economy.

Authorization for the investigation comes from Public Law (Pub. L.) 96-375, 1980, directing the Secretary of the Interior to engage in feasibility studies related to enlarging Shasta Dam and Reservoir. Related legislation includes Title 34 of Pub. L. 102-575 (the Central Valley Project Improvement Act) and Pub. L. 108-361, the CALFED Bay-Delta Authorization Act. In addition, enlargement of Shasta Dam was identified in the CALFED Programmatic Environmental Impact Report/Statement and Record of Decision.

With the release of the FEIS, the Final Feasibility Report and FEIS will be provided to Congress. The following

planning objectives apply to the proposed action/project modification.

### Planning Objectives

- Primary Planning objectives: (1) Increase the survival of anadromous fish populations in the Sacramento River, primarily upstream from the Red Bluff Diversion Dam, and (2) increase water supply and water supply reliability for agricultural, municipal and industrial, and environmental purposes to help meet future water demands, with a focus on enlarging Shasta Dam and Reservoir. Action alternatives were formulated to address these primary planning objectives.

- Secondary Planning Objectives. The following actions, operations, or features are included to the extent possible and consistent with the primary planning objectives: (1) Conserve, restore, and enhance ecosystem resources in the Shasta Lake area and along the upper Sacramento River, (2) reduce flood damage along the Sacramento River, (3) develop additional hydropower generation capabilities at Shasta Dam, (4) maintain and increase recreation opportunities at Shasta Lake, and (5) maintain or improve water quality conditions in the Sacramento River downstream from Shasta Dam and in the Sacramento-San Joaquin Delta.

### Final Environmental Impact Statement

The FEIS documents a reasonable range of alternatives and evaluates the potential direct, indirect, and cumulative environmental effects of alternative plans. Evaluation of six alternatives is documented in the FEIS, including a No-Action Alternative and five action alternatives. The FEIS displays the potential project-related impacts, including the effects of project construction and operation on the following resource areas: Geology, air quality, hydrology, water quality, noise, hazards and hazardous materials, important agricultural lands, fish, vegetation and wildlife, cultural resources, Indian Trust Assets, socioeconomic, land use, recreation, visual resources, traffic and circulation, utilities, public services, power and energy, environmental justice, and wild and scenic rivers; and identifies the Preferred Alternative, pursuant to the National Environmental Policy Act.

Potential project-related impacts include the construction-related effects of the dam enlargement, reservoir area relocations, and other alternative features; water operations-related effects within the reservoir area (e.g., including additional inundation areas); and associated effects to operations of other

Central Valley Project and State Water Project facilities. Project operations may directly or indirectly affect the resources of the Sacramento River, its tributaries, the San Joaquin River, its tributaries, and the Sacramento-San Joaquin Delta. The FEIS also evaluates potential growth-inducing impacts for the Central Valley Project and State Water Project water service areas. Potential cumulative effects associated with reasonably foreseeable actions are also evaluated for each resource area.

Copies of the FEIS and Final Feasibility Report are available for public review at the following locations:

- Bureau of Reclamation, Regional Library, 2800 Cottage Way, Sacramento, CA 95825.
- Bureau of Reclamation, Northern California Area Office, 16349 Shasta Dam Boulevard, Shasta Lake, CA 96019.
- Natural Resources Library, Department of the Interior, 1849 C Street NW., Main Interior Building, Washington, DC 20240.
- Shasta County Main Library, 1855 Shasta Street, Redding, CA 96001.

Copies of the FEIS and Final Feasibility Report are available on-line via the SLWRI Web site, at: [www.usbr.gov/mp/slwri](http://www.usbr.gov/mp/slwri).

### Public Disclosure

Before including your address, phone number, email address, or other personal identifying information in any correspondence, you should be aware that your entire correspondence—including your personal identifying information—may be made publicly available at any time. While you can ask us in your correspondence to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: July 30, 2015.

**Jason Phillips,**

*Deputy Regional Director, Mid-Pacific Region.*

[FR Doc. 2015-19472 Filed 8-6-15; 8:45 am]

**BILLING CODE 4310-MN-P**

## INTERNATIONAL TRADE COMMISSION

[Investigation No. 332-555]

### Economic Impact of Trade Agreements Implemented Under Trade Authorities Procedures, 2016 Report

**AGENCY:** United States International Trade Commission.

**ACTION:** Institution of investigation and scheduling of public hearing.

**SUMMARY:** The Commission has instituted investigation No. 332-555,

Economic Impact of Trade Agreements Implemented Under Trade Authorities Procedures, 2016 Report, for the purpose of preparing the first of two reports required by section 105(f)(2) of the Bipartisan Congressional Trade Priorities and Accountability Act of 2015 (Public Law 114-26). Section 105(f)(2) requires that the Commission submit to the House Committee on Ways and Means and the Senate Committee on Finance two reports, one by June 29, 2016, and a second by June 29, 2020, on the economic impact on the United States of all trade agreements with respect to which Congress has enacted an implementing bill under trade authorities procedures since January 1, 1984.

### DATES:

November 2, 2015: Deadline for filing requests to appear at the public hearing.

November 4, 2015: Deadline for filing pre-hearing briefs and statements.

November 17, 2015: Public hearing.

November 30, 2015: Deadline for filing post-hearing briefs.

February 5, 2016: Deadline for filing all other written statements.

June 29, 2016: Transmittal of Commission report to the House Committee on Ways and Means and the Senate Committee on Finance.

**ADDRESSES:** All Commission offices, including the Commission's hearing rooms, are located in the United States International Trade Commission Building, 500 E Street SW., Washington, DC. All written submissions should be addressed to the Secretary, United States International Trade Commission, 500 E Street SW., Washington, DC 20436. The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at <https://edis.usitc.gov/edis3-internal/app>.

### FOR FURTHER INFORMATION CONTACT:

Project Leaders Tamar Khachaturian (202-205-3299 or [tamar.khachaturian@usitc.gov](mailto:tamar.khachaturian@usitc.gov)) and David Riker (202-205-2201 or [david.riker@usitc.gov](mailto:david.riker@usitc.gov)) or Deputy Project Leader Ravinder Ubee (202-205-3493 or [ravinder.ubee@usitc.gov](mailto:ravinder.ubee@usitc.gov)) for information specific to this investigation. For information on the legal aspects of these investigations, contact William Gearhart of the Commission's Office of the General Counsel (202-205-3091 or [william.gearhart@usitc.gov](mailto:william.gearhart@usitc.gov)). The media should contact Margaret O'Laughlin, Office of External Relations (202-205-1819 or [margaret.olaughlin@usitc.gov](mailto:margaret.olaughlin@usitc.gov)). Hearing-impaired individuals may obtain information on this matter by contacting the Commission's TDD

terminal at 202–205–1810. General information concerning the Commission may also be obtained by accessing its Internet server (<http://www.usitc.gov>). Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000.

**Background:** On June 29, 2015, the President signed the Bipartisan Congressional Trade Priorities and Accountability Act of 2015 (TPA). Section 105(f)(2) of the Act requires the Commission to submit two reports to the House Committee on Ways and Means and the Senate Committee on Finance, one in 2016 and a second not later than mid-2020, on the economic impact of trade agreements implemented under trade authorities procedures since 1984. Section 105(f)(2) provides as follows:

(2) REPORT ON IMPACT OF TRADE PROMOTION AUTHORITY.— Not later than one year after the date of the enactment of this Act, and not later than 5 years thereafter, the United States International Trade Commission shall submit to the Committee on Ways and Means of the House of Representatives and the Committee on Finance of the Senate a report on the economic impact on the United States of all trade agreements with respect to which Congress has enacted an implementing bill under trade authorities procedures since January 1, 1984.

The Commission will submit its first report by June 29, 2016, and the second report by June 29, 2020. This notice pertains only to the procedures relating to preparation of the first report.

For purposes of this report the Commission considers the trade agreements covered to include the Uruguay Round Agreements, the North American Free Trade Agreement (NAFTA—Canada and Mexico), and U.S. free trade agreements (FTAs) with Australia, Bahrain, Canada, Chile, Colombia, the Dominican Republic and five Central American countries (Costa Rica, El Salvador, Guatemala, Honduras, and Nicaragua), Israel, Jordan, Korea, Morocco, Oman, Panama, Peru, and Singapore.

The Commission has instituted an investigation under section 332(g) of the Tariff Act of 1930 (19 U.S.C. 1332(g)) for the purpose of preparing this report and also for the purpose of assisting the public in the filing and inspection of documents and also to make the report more readily accessible to the public through the Commission's Web site.

**Public Hearing:** The Commission will hold a public hearing in connection with this investigation at the U.S.

International Trade Commission Building, 500 E Street SW., Washington, DC, beginning at 9:30 a.m. on November 17, 2015. Requests to appear at the public hearing should be filed with the Secretary, no later than 5:15 p.m., November 2, 2015, in accordance with the requirements in the "Submissions" section below. All pre-hearing briefs and statements should be filed no later than 5:15 p.m., November 4, 2015; and all post-hearing briefs and statements should be filed not later than 5:15 p.m., November 30, 2015. In the event that, as of the close of business on November 2, 2015, no witnesses are scheduled to appear at the hearing, the hearing will be canceled. Any person interested in attending the hearing as an observer or nonparticipant should contact the Office of the Secretary at 202–205–2000 after November 2, 2015, for information concerning whether the hearing will be held.

**Written Submissions:** In lieu of or in addition to participating in the hearing, interested parties are invited to file written submissions concerning this investigation. All written submissions should be addressed to the Secretary. Except in the case of requests to appear at the hearing and pre- and post-hearing briefs, all written submissions should be received no later than 5:15 p.m., February 5, 2016. All written submissions must conform to the provisions of section 201.8 of the *Commission's Rules of Practice and Procedure* (19 CFR 201.8). Section 201.8 and the Commission's Handbook on Filing Procedures require that interested parties file documents electronically on or before the filing deadline and submit eight (8) true paper copies by 12:00 p.m. eastern time on the next business day. In the event that confidential treatment of a document is requested, interested parties must file, at the same time as the eight paper copies, at least four (4) additional true paper copies in which the confidential information must be deleted (see the following paragraph for further information regarding confidential business information). Persons with questions regarding electronic filing should contact the Secretary (202–205–2000).

Any submissions that contain confidential business information (CBI) must also conform to the requirements of section 201.6 of the *Commission's Rules of Practice and Procedure* (19 CFR 201.6). Section 201.6 of the rules requires that the cover of the document and the individual pages be clearly marked as to whether they are the "confidential" or "non-confidential" version, and that the confidential business information is clearly

identified by means of brackets. All written submissions, except for confidential business information, will be made available for inspection by interested parties. Any confidential business information received by the Commission in this investigation and used in preparing this report will not be published in a manner that would reveal the operations of the firm supplying the information.

**Summaries of Written Submissions:** The Commission intends to publish summaries of the positions of interested persons in an appendix to its report. Persons wishing to have a summary of their position included in the appendix should include a summary with their written submission. The summary may not exceed 500 words, should be in MSWord format or a format that can be easily converted to MSWord, and should not include any confidential business information. The summary will be published as provided if it meets these requirements and is germane to the subject matter of the investigation. In the appendix the Commission will identify the name of the organization furnishing the summary, and will include a link to the Commission's Electronic Document Information System (EDIS) where the full written submission can be found.

By order of the Commission.

Issued: August 4, 2015.

**Lisa R. Barton,**

*Secretary to the Commission.*

[FR Doc. 2015–19436 Filed 8–6–15; 8:45 am]

BILLING CODE 7020–02–P

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## DEPARTMENT OF JUSTICE

### Antitrust Division

#### **United States and State of New York v. Twin America, LLC, et al.; Public Comment and Response on Proposed Final Judgment**

Pursuant to the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)–(h), the United States hereby publishes below the comment received on the proposed Final Judgment in *United States and State of New York v. Twin America, LLC, et al.*, Civil Action No. 12-cv-8989 (ALC) (GWG) (S.D.N.Y.), together with the Response of the United States to Public Comment.

Copies of the comment and the United States' Response are available for inspection at the Department of Justice Antitrust Division, 450 Fifth Street NW., Suite 1010, Washington, DC 20530 (telephone: 202–514–2481), on the Department of Justice's Web site at

<http://www.justice.gov/atr/case/us-and-state-new-york-v-twin-america-llc-et-al>, and at the Office of the Clerk of the United States District Court for the Southern District of New York, Daniel Patrick Moynihan United States Courthouse, 500 Pearl Street, New York, NY 10007. Copies of any of these materials may also be obtained upon request and payment of a copying fee.

**Patricia A. Brink,**

*Director of Civil Enforcement.*

**UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF  
NEW YORK**

UNITED STATES OF AMERICA, AND  
STATE OF NEW YORK, *Plaintiffs*, v.  
TWIN AMERICA, LLC, et al.  
*Defendants.*

Civil Action No. 12-cv-8989 (ALC)  
(GWG)  
ECF Case

**RESPONSE OF PLAINTIFF UNITED  
STATES TO PUBLIC COMMENT ON  
THE PROPOSED FINAL JUDGMENT**

Pursuant to the requirements of the Antitrust Procedures and Penalties Act, 15 U.S.C. 16(b)-(h) (“Tunney Act”), the United States hereby files the single public comment received concerning the proposed Final Judgment in this case and the United States’ response to the comment. After careful consideration of the submitted comment, the United States continues to believe that the proposed Final Judgment provides an effective and appropriate remedy for the violations alleged in the Complaint. The United States will move the Court for entry of the proposed Final Judgment after the public comment and this Response have been published in the **Federal Register** pursuant to 15 U.S.C. 16(d).

**I. PROCEDURAL HISTORY**

On March 17, 2009, Defendants Coach USA, Inc. (through subsidiary International Bus Services, Inc.) and CitySights LLC (through subsidiary City Sights Twin, LLC) formed Twin America, LLC (“Twin America”), a joint venture that combined their hop-on, hop-off bus tour operations in New York City.

Defendants subsequently applied to the federal Surface Transportation Board (“STB”) for approval of the Twin America transaction, which would have conferred antitrust immunity. After more than two years of proceedings, the STB rejected the joint venture as anticompetitive. However, while Defendants ceased operating the nominal interstate service that had formed the basis for the STB’s

jurisdiction, they continued operating their hop-on, hop-off bus tour operations in New York City.

In December 2012, the United States and the State of New York (collectively, “Plaintiffs”) filed this civil antitrust action, alleging that the formation of Twin America substantially lessened competition in the market for hop-on, hop-off bus tours in New York City in violation of Section 7 of the Clayton Act, 15 U.S.C. 18, and also violated Section 1 of the Sherman Act, 15 U.S.C. 1, Section 340 of the Donnelly Act, N.Y. Gen. Bus. Law § 340, and Section 63(12) of the New York Executive Law, N.Y. Exec. Law § 63(12). The Complaint sought to remedy the harm to competition and disgorge the ill-gotten gains Defendants had obtained from operating Twin America in violation of the antitrust laws.

In December 2014, the parties adjourned a February 2015 trial date to facilitate settlement discussions. These discussions culminated in the proposed Final Judgment, which was filed on March 16, 2015 (Dkt. No. 127-1).<sup>1</sup> As required by the Tunney Act, the United States published the proposed Final Judgment and Competitive Impact Statement in the **Federal Register** on March 27, 2015, 80 FR 16427 (Mar. 27, 2015), and caused to be published summaries of the terms of the proposed Final Judgment and Competitive Impact Statement, together with directions for the submission of written comments relating to the proposed Final Judgment, in *The Washington Post* and the *New York Daily News* for seven days (March 24 through March 30, 2015). The 60-day period for public comments ended on May 29, 2015. The United States received one comment, which is described below and attached hereto as Exhibit 1.

**II. THE PROPOSED SETTLEMENT**

The Complaint alleged that the formation of Twin America had the purpose and effect of creating a monopoly in the hop-on, hop-off bus tour market in New York City. The joint venture eliminated substantial head-to-head competition between Coach and City Sights that had benefitted consumers in the form of discounts, increased product offerings, and service improvements. The joint venture also enabled Defendants to increase hop-on, hop-off bus tour prices by

approximately 10%, resulting in immediate and continuing harm to consumers.

The Complaint alleged that entry of new firms into the market or expansion of existing firms was unlikely to counteract the competitive harm caused by the formation and operation of Twin America. According to the Complaint, the primary barrier to entry was the difficulty of obtaining hop-on, hop-off bus stop authorizations from the New York City Department of Transportation (“NYCDOT”). Bus stop authorizations are required by NYCDOT for each location a tour operator wishes to load and unload passengers. Defendants obtained a robust portfolio of bus stop authorizations from NYCDOT several years ago, including authorizations at or very close to virtually all of Manhattan’s major tourist attractions. Recent entrants, by contrast, were consistently unable to obtain competitive bus stop authorizations from NYCDOT at top tourist attractions because NYCDOT allocated such authorizations on a “first come, first served” basis and most competitive bus stop locations were already at capacity or otherwise unavailable. As a result, more than five years after Twin America’s formation, the joint venture still dominated the market and Defendants had sustained their anticompetitive price increases.

The proposed Final Judgment addresses the harm alleged in the Complaint by requiring Twin America to divest all of City Sights’s bus stop authorizations in Manhattan to NYCDOT, the city agency charged with managing bus stop authorizations. The divestiture significantly eases the primary entry barrier alleged in the Complaint by increasing NYCDOT’s inventory of bus stops, including for the locations most sought by recent entrants. City Sights’s set of approximately 50 bus stops includes highly-coveted stops surrounding key tourist attractions such as Times Square, the Empire State Building, and Battery Park that are critical to operating a competitive hop-on, hop-off bus tour. The proposed Final Judgment also prohibits Defendants from applying for or obtaining any bus stop authorizations for hop-on, hop-off bus tours at the locations of the divested City Sights bus stop authorizations for five years, subject to limited exceptions. In compliance with the proposed Final Judgment, Defendants relinquished the City Sights bus stop authorizations to NYCDOT on April 30, 2015.

The proposed Final Judgment also requires Defendants to pay \$7.5 million in disgorgement to the United States and State of New York, which is on top

<sup>1</sup> In October 2014, this Court approved Defendants’ settlement of related class action lawsuits. See Order and Final Judgment Approving *In Re NYC Bus Tour Antitrust Litigation* Class Action Settlement, *In re NYC Bus Tour Antitrust Litigation*, No. 13-CV-0711 (ALC) (GWG) (S.D.N.Y. Oct. 21, 2014) (Dkt. No. 122).

of the payments made by Defendants to settle the class action.

### III. STANDARD OF JUDICIAL REVIEW UNDER THE TUNNEY ACT

The Tunney Act requires that proposed consent judgments in antitrust cases brought by the United States be subject to a 60-day public comment period, after which the court shall determine whether entry of the proposed Final Judgment “is in the public interest.” 15 U.S.C. 16(e)(1); *see also United States v. Apple, Inc.*, 889 F. Supp. 2d 623, 630 (S.D.N.Y. 2012); *United States v. Morgan Stanley*, 881 F. Supp. 2d 563, 566 (S.D.N.Y. 2012). In making that determination, the court, in accordance with the statute as amended in 2004, is required to consider:

(A) the competitive impact of such judgment, including termination of alleged violations, provisions for enforcement and modification, duration of relief sought, anticipated effects of alternative remedies actually considered, whether its terms are ambiguous, and any other competitive considerations bearing upon the adequacy of such judgment that the court deems necessary to a determination of whether the consent judgment is in the public interest; and

(B) the impact of entry of such judgment upon competition in the relevant market or markets, upon the public generally and individuals alleging specific injury from the violations set forth in the complaint including consideration of the public benefit, if any, to be derived from a determination of the issues at trial.

15 U.S.C. 16(e)(1); *see also Apple*, 889 F. Supp. 2d at 630–31; *Morgan Stanley*, 881 F. Supp. 2d at 566–67.

In considering these statutory factors, the court’s inquiry is necessarily a limited one. *Apple*, 889 F. Supp. 2d at 631; *Morgan Stanley*, 881 F. Supp. 2d at 567; *United States v. Keyspan Corp.*, 763 F. Supp. 2d 633, 637 (S.D.N.Y. 2011). A court should consider, among other things, the relationship between the remedy secured and the specific allegations set forth in the Complaint, whether the decree is sufficiently clear, whether the enforcement mechanisms are sufficient, and whether the decree may positively harm third parties. *Apple*, 889 F. Supp. 2d at 631; *United States v. Microsoft Corp.*, 56 F.3d 1448, 1458–62 (D.C. Cir. 1995). However, “[a] court must limit its review to the issues in the complaint and give ‘due respect to the [Government’s] perception of . . . its case[.]’” *Morgan Stanley*, 881 F. Supp. 2d at 567 (quoting *Microsoft*, 56 F.3d at 1461); *see also Keyspan*, 763 F. Supp. 2d at 638 (same); *Apple*, 889 F. Supp. 2d at 631 (“In most cases, the court is not permitted to reach beyond the complaint to evaluate claims that

the government did *not* make.”) (internal quotation omitted).

“The role of the court is not to determine whether the decree results in the array of rights and liabilities ‘that will *best* serve society, but only to ensure that the resulting settlement is within the *reaches* of the public interest.” *Apple*, 889 F. Supp. 2d at 631 (quoting *Keyspan*, 763 F. Supp. 2d at 637) (emphasis in original); *see also Morgan Stanley*, 881 F. Supp. 2d at 567; *Microsoft*, 56 F.3d at 1460; *United States v. BNS, Inc.*, 858 F.2d 456, 462 (9th Cir. 1988) (explaining court may not “engage in an unrestricted evaluation of what relief would best serve the public”); *United States v. Bechtel Corp.*, 648 F.2d 660, 666 (9th Cir. 1981) (noting that “court is required to determine not whether a particular decree is the one that will best serve society, but whether the settlement is within the reaches of the public interest”) (citations omitted).

In determining whether a proposed settlement is in the public interest, “the court should be ‘deferential to the government’s predictions as to the effect of the proposed remedies.’” *Apple*, 889 F. Supp. 2d at 631 (quoting *Microsoft*, 56 F.3d at 1461); *see also United States v. US Airways Grp., Inc.*, 38 F. Supp. 3d 69, 76 (D.D.C. 2014) (“must accord deference to the government’s predictions about the efficacy of its remedies”) (quoting *United States v. SBC Commc’ns, Inc.*, 489 F. Supp. 2d 1, 17 (D.D.C. 2007)); *United States v. Archer-Daniels-Midland Co.*, 272 F. Supp. 2d 1, 6 (D.D.C. 2003) (noting that the court should grant due respect to the United States’ “prediction as to the effect of proposed remedies, its perception of the market structure, and its view of the nature of the case”).

A court “is not permitted to reject the proposed remedies merely because the court believes other remedies are preferable.” *Keyspan*, 763 F. Supp. 2d at 637; *see also Apple*, 889 F. Supp. 2d at 631 (same); *United States v. Am. Tel. & Tel. Co.*, 552 F. Supp. 131, 151 (D.D.C. 1982) (stating that “proposed decree must be approved even if it falls short of the remedy the court would impose on its own, as long as it falls within the range of acceptability or is within the reaches of the public interest”) (citations and internal quotations omitted); *United States v. Alcan Aluminum Ltd.*, 605 F. Supp. 619, 622 (W.D. Ky. 1985) (approving consent decree even though the court would have imposed greater remedy).

The relevant inquiry “is whether the Government has established an ample ‘factual foundation for [its] decisions such that its conclusions regarding the proposed settlement are reasonable.’”

*Apple*, 889 F. Supp. 2d at 631 (quoting *Keyspan*, 763 F. Supp. 2d at 637–38); *see also Microsoft*, 56 F.3d at 1461 (assessing whether “the remedies [obtained in the decree are] so inconsonant with the allegations charged as to fall outside of the ‘reaches of the public interest.’”); *SBC Commc’ns*, 489 F. Supp. 2d at 17 (explaining that courts “may not require that the remedies perfectly match the alleged violations”). Accordingly, the United States “need only provide a factual basis for concluding that the settlements are reasonably adequate remedies for the alleged harms.” *SBC Commc’ns*, 489 F. Supp. 2d at 17; *see also Apple*, 889 F. Supp. 2d at 631.

In its 2004 amendments to the Tunney Act,<sup>2</sup> Congress made clear its intent to preserve the practical benefits of using consent decrees in antitrust enforcement, adding the unambiguous instruction that “[n]othing in this section shall be construed to require the court to conduct an evidentiary hearing or to require the court to permit anyone to intervene.” 15 U.S.C. 16(e)(2); *see also Apple*, 889 F. Supp. 2d at 631 (“The Tunney Act allows, but does not require, the court to conduct an evidentiary hearing and to permit third parties to intervene.”). The procedure for the public-interest determination is left to the discretion of the court, with the recognition that the court’s “scope of review remains sharply proscribed by precedent and the nature of Tunney Act proceedings.” *SBC Commc’ns*, 489 F. Supp. 2d at 11. “A court can make its public interest determination based on the competitive impact statement and response to public comments alone.” *US Airways*, 38 F. Supp. 3d at 76.

### IV. UNITED STATES’ RESPONSE TO PUBLIC COMMENT

The United States received one public comment, from Taxi Tours, Inc., doing business as BigBus (“Big Bus”). Big Bus entered the New York City hop-on, hop-off bus tour market in 2014 by acquiring an existing player, Big Taxi. The comment makes four principal points: (1) There should be additional remedies to facilitate competitors’ ticket sales; (2) there should be a more specific process governing the allocation of bus stop authorizations; (3) the judgment should apply to Defendants’ future affiliated

<sup>2</sup> The 2004 amendments substituted “shall” for “may” in directing relevant factors for courts to consider and amended the list of factors to focus on competitive considerations and to address potentially ambiguous judgment terms. *Compare* 15 U.S.C. 16(e) (2004), with 15 U.S.C. 16(e)(1) (2006); *see also SBC Commc’ns*, 489 F. Supp. 2d at 11 (concluding that the 2004 amendments “effected minimal changes” to Tunney Act review).



entities; and (4) there should be a process for third parties to report violations of the Final Judgment. The United States respectfully responds to each point below.

### 1. Divestiture of the City Sights bus stops is sufficient to remedy the harm alleged in the Complaint

Big Bus's comment asserts that Defendants prevent competitors from selling tickets for hop-on, hop-off bus tours at or near certain key tourist attractions and proposes that the settlement be amended to ensure equal access to vendors to market and sell tickets from Defendants' competitors. Big Bus also expresses concerns regarding the conduct of City Experts, an affiliate of Defendants that offers tourists a variety of tours and attractions from concierge desks it operates at certain New York City hotels. Big Bus contends that because City Experts sells Defendants' hop-on, hop-off bus tours as part of its bundled tourism packages but not the hop-on, hop-off bus tours of Defendants' competitors, it "prevents the Defendants' competitors from effectively competing at the hotel and retail level." Big Bus also complains that Twin America's employees prevent Big Bus staff from selling tickets by verbally and physically attacking them.

Pursuant to the Tunney Act, review of a proposed Final Judgment is limited to the relationship of the remedy to the violations alleged in the Complaint. *See Microsoft*, 56 F.3d at 1459–61; *Morgan Stanley*, 881 F. Supp. 2d at 567; *Keyspan*, 763 F. Supp. 2d at 637–38; *Apple*, 889 F. Supp. 2d at 631. As described above, the Complaint alleged that the formation and operation of Twin America substantially lessened competition in the hop-on, hop-off bus tour market in New York City and identified potential entrants' inability to obtain bus stop authorizations at or sufficiently near top tourist attractions as the primary entry barrier. The proposed settlement addresses this entry barrier by requiring Twin America to divest all of the approximately 50 City Sights bus stop authorizations in Manhattan, including highly desirable stops at or near key tourist attractions that rivals have been consistently unable to obtain. By relinquishing all of the City Sights bus stops to NYCDOT, the proposed Final Judgment increases the available inventory of bus stops for which rivals can obtain the authorizations needed to effectively compete with Twin America.

The Complaint did not allege that the conduct of Defendants' street sellers, its City Experts affiliate, or Defendants' sales practices otherwise served as a

meaningful barrier to competition in the hop-on, hop-off bus tour market. Nor did the Complaint allege that the formation of the joint venture had an impact on these practices. Thus, the suggested additional provisions are unnecessary to address the competitive harm set forth in the Complaint.

### 2. NYCDOT administers bus stop authorizations

Big Bus argues that the proposed settlement should establish certain rules and processes related to the allocation and use of hop-on, hop-off bus stops. First, Big Bus asserts that the Final Judgment "should define a fair and monitored process of reassignment/reallocation of the divested [City Sights bus stop] authorizations to ensure that all competitors in the relevant market have an equal opportunity to apply for the divested stop authorizations." Big Bus also claims that the Final Judgment should address how hop-on, hop-off bus stop authorizations would be handled in the event that Defendants acquired an existing hop-on, hop-off bus tour business.

Procedures relating to the assignment and allocation of bus stop authorizations are within the jurisdiction of NYCDOT, the New York City agency charged with regulating and managing bus stops. *See, e.g., NYC Charter § 2903* (giving NYCDOT control of and responsibility for "all those functions and operations of the city relating to transportation"); *NYC Charter § 2903(a)(14)* (empowering NYCDOT to enforce rules and regulations regarding vehicular traffic and the parking, standing, or stopping of vehicles on the city's streets); *34 RCNY § 4–10* (governing the operations of buses in the city and providing that bus operators, subject to certain exceptions, cannot "pick up or discharge passengers on a street except at a bus stop designated by the Commissioner [of NYCDOT] in writing."). Pursuant to this authority, NYCDOT is best positioned to determine how to distribute the City Sights bus stops that have been relinquished pursuant to the proposed Final Judgment, taking into account the relevant factors just as it does with respect to bus stop allocations and authorizations generally.

Given the established NYCDOT role in bus stop authorizations and allocations, the United States concluded that the facts of this case did not call for the proposed Final Judgment to establish any additional regulations or processes relating to the assignment or allocation of bus stop authorizations.

### 3. The proposed settlement already covers affiliated entities

Big Bus's comment raises a concern that two provisions of the proposed Final Judgment—having to do with notification to the government of certain transactions (Section X) and "reacquisition" of stops (Section XII)—would not apply to affiliated entities that Defendants might form after entry of the Final Judgment. Big Bus is incorrect. The proposed Final Judgment applies to Defendant entities as well as their "successors and assigns, and any subsidiaries, divisions, groups, affiliates, partnerships and joint ventures under their control, and their directors, officers, managers, agents, and employees" (emphasis added). Therefore, any entities that Defendants form or acquire after entry of the Final Judgment will also be subject to it.

### 4. Third parties may report violations of the Final Judgment to the United States or State of New York

Finally, Big Bus argues that Section XIII of the proposed Final Judgment, which provides that the Court retains jurisdiction for ten years to monitor and enforce the terms of the Final Judgment, should also set forth "a process whereby third parties may directly report violations of the Final Judgment by the Defendants." The United States does not believe this is necessary. Third parties can already report such violations to the Antitrust Division of the Department of Justice or the Antitrust Bureau of the New York Attorney General's Office. Plaintiffs will take the appropriate steps to respond to any reported violations, including by applying to the Court to enforce compliance or punish violations pursuant to Section XIII of the proposed Final Judgment.

## V. CONCLUSION

After carefully reviewing the public comment submitted by Big Bus, the United States has determined that the proposed Final Judgment, as drafted, provides an effective and appropriate remedy for the antitrust violation alleged in the Complaint and is therefore in the public interest. The United States will move this Court to enter the proposed Final Judgment after the public comment and this Response have been published in the **Federal Register**.

Dated: July 28, 2015

Respectfully submitted,

/s/

Sarah Oldfield  
David E. Altschuler

U.S. Department of Justice, Antitrust  
Division, Transportation, Energy &

*Agriculture Section, 450 Fifth Street NW.,  
Suite 8000, Washington, DC 20530,  
Telephone: (202) 305-8915,  
Sarah.Oldfield@usdoj.gov,  
David.Altshuler@usdoj.gov.*

*Benjamin Sirota  
U.S. Department of Justice, Antitrust  
Division, New York Office, 26 Federal Plaza,  
Room 3630, New York, NY 10278,*

*Telephone: (212) 335-8056,  
Benjamin.Sirota@usdoj.gov.  
Attorneys for Plaintiff United States*

May 22, 2015

U.S. Department of Justice

Attn.: William H. Stallings, Chief, Transportation, Energy and Agriculture Section, Antitrust Division

450 5th Street, N.W., Suite 8000

Washington, D.C. 20530

**RE: United States and State of New York v. Twin America, LLC, Coach USA, Inc., International Bus Services, Inc., Citysights LLC, City Sights Twin, LLC  
United States District Court for the Southern District of New York, 1:12-cv-08989-ALC-GWG**

Dear Mr. Stallings:

On behalf of Taxi Tours, Inc., dba BigBus ("Big Bus"), we offer the following comments pursuant to 15 U.S.C. § 16(d) with regard to the Proposed Final Judgment (the "PFJ") in the above-captioned matter.

**A. Background On Big Bus And Its Interest In This Matter**

Big Bus offers "hop-on, hop-off" services in New York City. Big Bus is a competitor of Twin America, LLC, Coach USA, Inc., International Bus Services, Inc., Citysights LLC, and City Sights Twin, LLC (collectively, the "Defendants"), in the relevant market. As such, BigBus has a direct, vested interest in that market and in the efficacy of the PFJ.

**B. The PFJ should ensure that equal access is given to ticket vendors in strategic areas to market and sell tickets for competitors of the Defendants.**

The PFJ focuses almost exclusively on the divested bus stop authorizations. However, the Defendants relinquishing the CitySights bus stop authorizations in Manhattan will not remedy the monopoly illegally maintained by the Defendants.

The Defendants exercise their monopoly also by means of preventing competitors from selling their tourist services in certain key areas in Manhattan, such as in the vicinity of landmark buildings, which are strategic for the sale of tourist services. For instance, the street vendors

around the Empire State Building market and sell exclusively the Defendants' tickets and prevent competitors from doing the same.

Even after the Defendants relinquish the CitySights bus stop authorizations in Manhattan to the New York City Department of Transportation ("NYCDOT"), they will still enjoy an unfair competitive advantage over their competitors in the relevant market due to the strategic barrier to entry which creates a monopoly in the ticket distribution in key tourist sites. The PFJ should ensure that equal access is given to ticket vendors in strategic areas to market and sell tickets for competitors of the Defendants.

Furthermore, in the relevant market the Defendants operate with affiliates, including, but not limited to, City Experts, LLC ("City Experts"), a company offering tourist services such as selling tickets to Broadway shows, transportation services through Manhattan and to New York's major airports, dining cruises, and, most importantly, sightseeing bus tours.

Through City Experts, the Defendants conduct a bundling practice by selling combinations of products offered by the Defendants and affiliate entities to consumers through a single point of sale, which has a tendency to restrain competitive access.

Big Bus offers its services by advertising sightseeing tours, among others, in hotels and retail stores in strategic areas in New York City. City Experts serves as an outsourced concierge desk for mid-market hotels. City Experts' representatives target those businesses, outbid competition by overpaying for the licenses, and lock them into exclusive contracts with City Experts.

Obtaining exclusive licenses to serve as a concierge service creates the exclusive advantage of offering the Defendants' products and services before any competitor can reach the consumers. City Experts monopolizes the local agent trade network and with its business conduct it deters entry.

As far as "hop-on, hop-off" tours are concerned, City Experts offers tickets for tours provided by Gray Line New York, which is another affiliate of Twin America, LLC. This behavior prevents the Defendants' competitors from effectively competing at the hotel and retail level, and more in general it constitutes a barrier to entry into the relevant market for the Defendants' competitors.

Finally, Twin America is attempting to establish a monopoly in Manhattan by allowing its personnel to attack its competitors' street staff verbally and physically and to damage and subtract private property. The frequency and seriousness of these attacks made it necessary for Big Bus to file police reports against Twin America's staff.

### **C. Significant Ambiguities In The PFJ Must Be Cured To Avoid Further Litigation**

The PFJ does not specifically address the compliance procedures after the PFJ becomes final, nor does it specify a clear process whereby the Defendants' competitors may apply for the divested bus stops. These deficiencies create ambiguity and pose the risk of further litigation.

(i) Application Process: Under the terms of the PFJ, once the CitySights bus stop authorizations are relinquished, they will be available to be assigned to other operators applying with the NYCDOT. However, the PFJ does not define the process of reassignment or reallocation of the divested authorizations to allow other operators to apply for and obtain such divested authorizations. §6.D of the PFJ should define a fair and monitored process of reassignment/reallocation of the divested authorizations to ensure that all competitors in the relevant market have an equal opportunity to apply for the divested stop authorizations.

(ii) Notification Obligations for Affiliates: The PFJ provides that the Defendants will have ongoing reporting obligations and will be required to provide the Government with advance notice, pursuant to the provisions of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, as amended, 15 U.S.C. § 18a, of any future acquisitions in the New York City hop-on hop-off bus tour services that would otherwise not be reportable by law. However, the PFJ does not specify what happens if Defendants purchase another ongoing "hop-on hop-off" business with its own stop authorizations. The PFJ should specify whether the purchased operation could be transferred with or without its previously obtained bus stop authorizations, and what regulatory oversight the transfer would be subject to.

(iii) Shared Stops: §VI of the PFJ requires that the Defendants relinquish the entire CitySights Bus Stop Authorizations in Manhattan. However, the Defendants share some of the divested stops with related entities currently lacking proper authorizations to operate a "hop-on, hop-off" business. The PFJ should contain a cease-and-desist provision, preventing the Defendants' related entities without authorization from any current or future unauthorized "hop-on, hop-off" operation.

### **D. Affiliate Entities Created After Entry of the PFJ Should Be Subject To The Same Provisions Applying To The Defendants and Their Current Affiliates.**

(i) Reassignment/Reallocation of CitySights Bus Stop Authorizations: The PFJ provides that, for a period of five years after entry of the Final Judgment, the Defendants may not apply for or obtain any bus stop authorizations for hop-on, hop-off bus tours at the locations of the divested CitySights bus stop authorizations. However, the PFJ is silent as to third-party entities related to the Defendants. The PFJ should specify that any related entities formed or acquired after entry of the Final Judgment are also prevented from applying for the divested stop authorizations for the same period of time.

(ii) Reporting Obligations: The PFJ includes, in the definition of each Defendant, their respective successors and assigns, and any subsidiaries, divisions, groups, affiliates, partnerships and joint ventures under its control, and their directors, officers, managers, agents, and employees, presumably at the time of the entry of the Final Judgment. However, the PFJ should specify that any new entities associated with any of the Defendants, even those which were formed or acquired after entry of the PFJ, should be subject to the same reporting obligations in case of acquisitions of "hop-on hop off" businesses in New York. The risk is, in fact, that the Defendants will form new entities to bypass their reporting obligations pursuant to the PFJ.

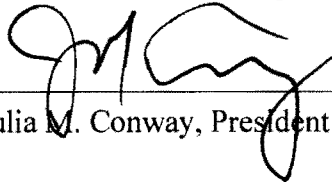
## E. Retention of Jurisdiction

Section XIII of the PFJ provides that "[t]his Court retains jurisdiction to enable any party to this Final Judgment to apply to this Court at any time for further orders and directions as may be necessary or appropriate to carry out or construe this Final Judgment, to modify any of its provisions, to enforce compliance, and to punish violations of its provisions."

However, this Section should also indicate a process whereby third parties may directly report violations of the Final Judgment by the Defendants.

Very truly yours,

Taxi Tours, Inc. dba Big Bus Tours New York



Julia M. Conway, President

[FR Doc. 2015-19495 Filed 8-6-15; 8:45 am]

BILLING CODE P

### DEPARTMENT OF LABOR

#### Employment and Training Administration

#### Workforce Information Advisory Council

**AGENCY:** Employment and Training Administration, Labor.

**ACTION:** Notice of Establishment of the Workforce Information Advisory Council and Solicitation of Nominations for Membership.

**SUMMARY:** The Department of Labor (Department) announces the establishment of the Workforce Information Advisory Council (WIAC), invites interested parties to submit nominations for individuals to serve on the WIAC, and announces the procedures for those nominations.

**DATES:** Nominations for individuals to serve on the WIAC must be submitted (postmarked, if sending by mail; submitted electronically; or received, if hand delivered) by October 6, 2015.

**ADDRESSES:** You may submit nominations and supporting materials described in this **Federal Register** Notice by any one of the following methods:

*Electronically:* Submit nominations, including attachments, by email using the following address: [WIAC@dol.gov](mailto:WIAC@dol.gov) (use subject line "Nomination—Workforce Information Advisory Council").

*Mail, express delivery, hand delivery, messenger, or courier service:* Submit one copy of the nominations and supporting materials to the following address: Workforce Information Advisory Council Nominations, Office of Workforce Investment, U.S. Department of Labor, 200 Constitution Ave. NW., Room C-4526, Washington, DC 20210. Deliveries by hand, express

mail, messenger, and courier service are accepted by the Office of Workforce Investment during the hours of 9:00 a.m.–5:00 p.m., Eastern Daylight Time, Monday through Friday. Due to security-related procedures, submissions by regular mail may experience significant delays.

*Facsimile:* The Department will not accept nominations submitted by fax.

**FOR FURTHER INFORMATION CONTACT:** Kimberly Vitelli, Division of National Programs, Tools, and Technical Assistance, Office of Workforce Investment (address above); (202) 693-3045; or use email address for the WIAC, [WIAC@dol.gov](mailto:WIAC@dol.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Background and Authority

Section 15 of the Wagner-Peyser Act, 29 U.S.C. 491-2, as amended by section 308 of the Workforce Innovation and Opportunity Act of 2014 (WIOA), Public Law #113-128 requires the Secretary of Labor (Secretary) to establish the WIAC.

The statute, as amended, requires the Secretary, acting through the Commissioner of Labor Statistics and the Assistant Secretary for Employment and Training, to formally consult at least twice annually with the WIAC to address: (1) Evaluation and improvement of the nationwide workforce and labor market information system established by the Wagner-Peyser Act, and of the statewide systems that comprise the nationwide system, and (2) how the Department and the States will cooperate in the management of those systems. The Secretary, acting through the Bureau of Labor Statistics (BLS) and the Employment and Training Administration (ETA), and in consultation with the WIAC and appropriate Federal agencies, must also develop a 2-year plan for management of the system, with subsequent updates every two years thereafter. The statute generally prescribes how the plan is to be developed and implemented, outlines the contents of the plan, and requires the Secretary to submit the plan to designated authorizing committees in the House and Senate.

By law, the Secretary must “seek, review, and evaluate” recommendations from the WIAC, and respond to the recommendations in writing to the WIAC. The WIAC must make written recommendations to the Secretary on the evaluation and improvement of the workforce and labor market information system, including recommendations for the 2-year plan. The 2-year plan, in turn, must describe WIAC recommendations and the extent to which the plan incorporates them.

The Department anticipates that the WIAC will accomplish its objectives by, for example: (1) Studying workforce and labor market information issues; (2) seeking and sharing information on innovative approaches, new technologies, and data to inform employment, skills training, and workforce and economic development decision making and policy; and (3) advising the Secretary on how the workforce and labor market information system can best support workforce development, planning, and program development.

## II. Structure

The Wagner-Peyser Act at section 15(d)(2)(B), requires the WIAC to have representative 14 members, appointed by the Secretary, consisting of:

(i) Four members who are representatives of lead State agencies with responsibility for workforce investment activities, or State agencies described in Wagner-Peyser Act section 4 (agency designated or authorized by

Governor to cooperate with the Secretary), who have been nominated by such agencies or by a national organization that represents such agencies;

(ii) Four members who are representatives of the State workforce and labor market information directors affiliated with the State agencies responsible for the management and oversight of the workforce and labor market information system as described in Wagner-Peyser Act section 15(e)(2), who have been nominated by the directors;

(iii) One member who is a representative of providers of training services under WIOA section 122 (Identification of Eligible Providers of Training Services);

(iv) One member who is a representative of economic development entities;

(v) One member who is a representative of businesses, who has been nominated by national business organizations or trade associations;

(vi) One member who is a representative of labor organizations, who has been nominated by a national labor federation;

(vii) One member who is a representative of local workforce development boards, who has been nominated by a national organization representing such boards; and

(viii) One member who is a representative of research entities that use workforce and labor market information.

The Secretary must ensure that the membership of the WIAC is geographically diverse, and that no two members appointed under clauses (i), (ii), and (vii), above, represent the same State. Each member will be appointed for a term of three years, except that the initial terms for members may be one, two, or three years in order to establish a rotation in which one-third of the members are selected each year. The Secretary will not appoint a member for any more than two consecutive terms. Any member whom the Secretary appoints to fill a vacancy occurring before the expiration of the predecessor’s term will be appointed only for the remainder of that term. Members of the WIAC will serve on a voluntary and generally uncompensated basis, but will be reimbursed for travel expenses to attend WIAC meetings, including per diem in lieu of subsistence, as authorized by the Federal travel regulations.

## III. Nominations Process

Of the seven types of members listed above and at section 15(d)(2), the

Secretary may consider all nominations for three types, but for the other four, the Secretary may only appoint individuals nominated by particular organizations. Type (i) requires nomination from “lead State agencies with responsibility for workforce investment activities” and type (ii) requires nomination from “State workforce and labor market information directors.” Type (v) requires nomination by national business organizations or trade associations and type (vi) requires nomination by a national labor federation. But for types (iii), (iv), and (vii), any interested person or organization may nominate one or more qualified individuals for membership. If you would like to nominate an individual or yourself for appointment to the WIAC, please submit, to one of the addresses listed below, the following information:

- A copy of the nominee’s biographical information and resume;
- A cover letter that provides your reason(s) for nominating the individual, the constituency area that they represent (as outlined above in the WIAC membership identification discussion), and their particular expertise for contributing to the national policy discussion on: (1) The evaluation and improvement of the nationwide workforce and labor market information system and statewide systems that comprise the nationwide system, and (2) how the Department and the States will cooperate in the management of those systems, including programs that produce employment-related statistics and State and local workforce and labor market information; and
- Contact information for the nominee (name, title, business address, business phone, fax number, and business email address).

In addition, the cover letter must state that the nomination is being made in response to this **Federal Register** Notice and that the nominee (if nominating someone other than oneself) has agreed to be nominated and is willing to serve on the WIAC.

**Authority:** Pursuant to the Wagner-Peyser Act of 1933, as amended, 29 U.S.C. 49 *et seq.*; Workforce Innovation and Opportunity Act, Pub. L. 113–128; Federal Advisory Committee Act, as amended, 5 U.S.C. App.

**Portia Wu,**

*Assistant Secretary, Employment and Training Administration.*

[FR Doc. 2015–19385 Filed 8–6–15; 8:45 am]

**BILLING CODE 4510-FN-P**

**DEPARTMENT OF LABOR****Office of the Secretary****Agency Information Collection Activities; Submission for OMB Review; Comment Request; Statement of Recovery Forms****ACTION:** Notice.

**SUMMARY:** The Department of Labor (DOL) is submitting the Office of Workers' Compensation Programs (OWCP) sponsored information collection request (ICR) revision titled, "Statement of Recovery Forms," to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 *et seq.*). Public comments on the ICR are invited.

**DATES:** The OMB will consider all written comments that agency receives on or before September 8, 2015.

**ADDRESSES:** A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at [http://www.reginfo.gov/public/do/PRAViewICR?ref\\_nbr=201504-1240-001](http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201504-1240-001) (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202-693-4129, TTY 202-693-8064, (these are not toll-free numbers) or sending an email to [DOL\\_PRA\\_PUBLIC@dol.gov](mailto:DOL_PRA_PUBLIC@dol.gov).

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL-OWCP, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202-395-5806 (this is not a toll-free number); or by email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov). Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor—OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: [DOL\\_PRA\\_PUBLIC@dol.gov](mailto:DOL_PRA_PUBLIC@dol.gov).

**For Further Information:** Contact Michel Smyth by telephone at 202-693-4129, TTY 202-693-8064, (these are not toll-free numbers) or sending an email to [DOL\\_PRA\\_PUBLIC@dol.gov](mailto:DOL_PRA_PUBLIC@dol.gov).

**Authority:** 44 U.S.C. 3507(a)(1)(D).

**SUPPLEMENTARY INFORMATION:** This ICR seeks approval under the PRA for revisions to the Statement of Recovery Forms information collection (Forms CA-1108 and CA-1122). The forms are used to obtain information about amounts received from a final judgment in litigation, or a settlement of the litigation, brought against a third party who is liable for damages due to a Federal employee comprehensive work-related injury. A Federal employee can sustain a work-related injury, for which he or she is eligible for compensation under the Federal Employees' Compensation Act (FECA), under circumstances that also create a legal liability for some third party to pay damages for the same injury. When this occurs, the FECA authorizes the Secretary of Labor either to require the employee to assign his or her right of action to the United States or to prosecute the action. *See* 5 U.S.C. 8131. An employee receiving a judgment or a settlement of the action must reimburse the United States (U.S.) for past compensation payments; if there are surplus future compensation payments, the FECA provides that the employee must refund to the U.S. the amount of compensation paid by the U.S. and credit any surplus on future payments of compensation. *See* 5 U.S.C. 8132. This information collection has been classified as a revision, because the OWCP has updated Form CA-1108 so that it automatically calculates attorney fee and court cost information, provides information about the employee's net entitlement, clarifies the instructions, and includes the case file number; Form CA-1122 has been changed to include the case file number and employee's name. The FECA authorizes this information collection. *See* 5 U.S.C. 8121, 8132, 8149

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1240-0001. The current approval is scheduled to expire on August 31, 2015; however, the DOL notes that existing information

collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. New requirements would only take effect upon OMB approval. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on May 11, 2015 (80 FR 26955).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1240-0001. The OMB is particularly interested in comments that:

- 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;
- Enhance the quality, utility, and clarity of the information to be collected; 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 technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

*Agency:* DOL-OWCP.

*Title of Collection:* Statement of Recovery Forms.

*OMB Control Number:* 1240-0001.

*Affected Public:* Individuals or Households and Private Sector—businesses or other for-profits.

*Total Estimated Number of Respondents:* 842.

*Total Estimated Number of Responses:* 842.

*Total Estimated Annual Time Burden:* 419.

*Total Estimated Annual Other Costs Burden:* \$219.

Dated: August 3, 2015.

**Michel Smyth,**

*Departmental Clearance Officer.*

[FR Doc. 2015-19457 Filed 8-6-15; 8:45 am]

**BILLING CODE 4510-CH-P**



## NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

### National Endowment for the Arts

#### Arts Advisory Panel Meetings

**AGENCY:** National Endowment for the Arts, National Foundation on the Arts and Humanities.

**ACTION:** Notice of meetings.

**SUMMARY:** Pursuant to the Federal Advisory Committee Act, as amended, notice is hereby given that one meeting of the Arts Advisory Panel to the National Council on the Arts will be held by teleconference.

**DATES:** All meetings are Eastern time and ending times are approximate:

*Literature* (review of applications): This meeting will be closed.

*Date and time:* September 16, 2015; 3:00 p.m. to 5:00 p.m.

**ADDRESSES:** National Endowment for the Arts, Constitution Center, 400 7th St. SW., Washington, DC 20506.

#### FOR FURTHER INFORMATION CONTACT:

Further information with reference to these meetings can be obtained from Ms. Kathy Plowitz-Worden, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, DC 20506; [plowitzk@arts.gov](mailto:plowitzk@arts.gov), or call 202/682-5691.

**SUPPLEMENTARY INFORMATION:** The closed portions of meetings are for the purpose of Panel review, discussion, evaluation, and recommendations on financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency. In accordance with the determination of the Chairman of February 15, 2012, these sessions will be closed to the public pursuant to subsection (c)(6) of section 552b of title 5, United States Code.

Dated: August 4, 2015.

**Kathy Plowitz-Worden,**

*Panel Coordinator, National Endowment for the Arts.*

[FR Doc. 2015-19426 Filed 8-6-15; 8:45 am]

**BILLING CODE 7537-01-P**

## NATIONAL SCIENCE FOUNDATION

### Sunshine Act Meetings; National Science Board

The National Science Board, pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended (42 U.S.C. 1862n-5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice of the

scheduling of meetings for the transaction of National Science Board business, as follows:

**DATE AND TIME:** August 12, 2015 from 8:00 a.m. to 4:45 p.m. and August 13, 2015 from 8:00 a.m. to 2:00 p.m. (EDT).

**PLACE:** These meetings will be held at the National Science Foundation, 4201 Wilson Blvd., Room 1235, Arlington, VA 22230. All visitors must contact the Board Office (call 703-292-7000 or send an email message to [nationalsciencebrd@nsf.gov](mailto:nationalsciencebrd@nsf.gov)) at least 24 hours prior to the meeting and provide name and organizational affiliation. Visitors must report to the NSF visitor desk located in the lobby at the 9th and N. Stuart Streets entrance to receive a visitor's badge.

**WEBCAST INFORMATION:** Public meetings and public portions of meetings will be webcast. To view the meetings, go to [www.tvworldwide.com/events/nsf/150812](http://www.tvworldwide.com/events/nsf/150812) and follow the instructions.

**UPDATES:** Please refer to the National Science Board Web site for additional information. Meeting information and schedule updates (time, place, subject matter or status of meeting) may be found at <http://www.nsf.gov/nsb/meetings/notices.jsp>.

**AGENCY CONTACT:** Ron Campbell, [jrcampbe@nsf.gov](mailto:jrcampbe@nsf.gov), (703) 292-7000.

**PUBLIC AFFAIRS CONTACT:** Nadine Lynn, [nlymn@nsf.gov](mailto:nlymn@nsf.gov), (703) 292-2490.

**STATUS:** Portions open; portions closed.

#### Open Sessions

*August 12, 2015*

8:00-8:35 a.m. (Plenary introduction, Chair and Director Reports)

8:35-9:40 a.m. (SEI)

9:40-10:00 a.m. (CSB)

10:00-10:20 a.m. (CPP)

1:00-1:30 p.m. (AO)

1:30-3:00 (CEH)

*August 13, 2015*

8:00-8:45 a.m. (AB)

1:30-2:00 p.m. (Plenary)

#### Closed Sessions

*August 12, 2015*

10:35-11:45 a.m. (AO)

11:45 a.m.-12:00 p.m. (Plenary executive)

3:13-4:45 p.m. (CPP)

*August 13, 2015*

8:45-9:50 a.m. (CSB)

10:20 a.m.-12:30 p.m. (Plenary)

#### MATTERS TO BE DISCUSSED:

**Tuesday, August 12, 2015**

*Plenary Board Meeting*

Open Session: 8:00-8:35 a.m.

- Introduction and NSB Chair's Report

- NSF Director's Report

*Committee on Science & Engineering Indicators (SEI)*

Open Session: 8:35-9:40 a.m.

- Committee Chair's introduction
- Approval of the May 2015 meeting minutes
- Discussion of the Science and Engineering Indicators 2016 'Orange Book' and the remaining steps of the review process
- Update on Digest and Overview
- Update on 'Digital Indicators'
- Discussion of 'Vignettes'
- Chair's closing remarks

*Committee on Strategy and Budget (CSB)*

Open Session: 9:40-10:00 a.m.

- Committee Chair's remarks
- Approval of CSB open minutes for the May 2015 meeting
- NSF FY 2016 budget update

*Committee on Programs and Plans (CPP)*

Open Session: 10:00-10:20 a.m.

- Approval of open minutes of the August 2015 meeting
- Committee Chair's remarks
  - CY 2015 schedule of planned action and information items; update for the August 2015 meeting
  - Update on IceCube Neutrino Observatory's M&O award
  - Information Item: National Center for Atmospheric Research/ University Corporation for Atmospheric Research (NCAR/UCAR) strategic planning process
  - Information Item: Gemini Observatory

*Audit and Oversight Committee*

Closed Session: 10:35-11:45 a.m.

- Approval of minutes of May 2015 closed meeting and August 5, 2015 closed teleconference
- Committee Chair's opening remarks, including status report regarding the National Academy of Public Administration (NAPA) study
- Office of the Inspector General FY 2017 budget request
- Update and discussion of two-month salary support compensation policy

*Plenary Board Meeting*

Executive Closed Session: 11:45 a.m.-12:00 p.m.

- NSB Chair's opening remarks
- Approval of executive closed session minutes, May 2015
- Update from Nominations Committee
- Board member proposal
- Chair's closing remarks

*Committee on Audit & Oversight (AO)*

Open Session: 1:00–1:30 p.m.

- Approval of May 2015 open meeting minutes
- Committee Chair's opening remarks
- Inspector General's update
- Chief Financial Officer's update

*Committee on Education and Human Resources (CEH)*

Open Session: 1:30–3:00 p.m.

- Committee Chair's opening remarks
- Approval of CEH open minutes for the February 2015 meeting
- Discussion: Grand challenges in STEM education

*Committee on Programs and Plans (CPP)*

Closed Session: 3:15–4:45 p.m.

- Approval of closed CPP minutes for May 2015 meeting
- Committee Chair's remarks
- Information Item: Risks to Antarctic Programs
- Information Item: CERN Agreement
- Information Item: Update on National Ecological Observatory Network (NEON)
- Discussion: Recompensation Policy
- Committee Chair's closing remarks

**Wednesday, August 13, 2015***Working Group on Administrative Burdens (AB)*

Open Session: 8:00–8:45 a.m.

- Working Group Chair's opening remarks
- Approval of prior minutes
- NSF implementation of NSB recommendations

*Committee on Strategy and Budget (CSB)*

Closed Session: 8:45–9:50 a.m.

- Committee Chair's remarks
- Approval of CSB closed minutes for the May 2015 meeting and July 2015 teleconference
- FY 2017 comprehensive budget approval

*Plenary Board Meeting*

Closed Session: 10:20 a.m.–12:30 p.m.

- NSB Chair's opening remarks
- NSF Director's remarks
- Approval of closed session minutes, May 2015
- Discussion of risks to NSF
- Closed committee reports
- Action on CSB recommendation regarding comprehensive NSF FY 2017 budget
- NSB Chair's remarks

*Plenary Board Meeting*

Open Session: 1:30–2:00 p.m.

- NSB Chair's opening remarks
- NSF Director's remarks
- Approval of open session minutes, May 2015
- Approval of NSB meeting dates for CY 2016
- Open committee reports
- Chairman's closing remarks, including discussion of and recommendations for structural changes to the *ad hoc* Honorary Awards Committee

**MEETING ADJOURNS: 2:00 p.m.****Kyscha Slater-Williams,***Program Specialist, National Science Board.*

[FR Doc. 2015–19583 Filed 8–5–15; 4:15 pm]

**BILLING CODE 7555-01-P****NATIONAL TRANSPORTATION SAFETY BOARD****Sunshine Act Meeting****TIME AND DATE:** 9:30 a.m., Tuesday, August 11, 2015.**PLACE:** NTSB Conference Center, 429 L'Enfant Plaza SW., Washington, DC 20594.**STATUS:** The one item is open to the public.**MATTER TO BE CONSIDERED:** 8717—Highway Accident Report: Multivehicle Work Zone Crash on Interstate 95, Cranbury, New Jersey, June 7, 2014.**NEWS MEDIA CONTACT:** Telephone: (202) 314–6100.

The press and public may enter the NTSB Conference Center one hour prior to the meeting for set up and seating.

Individuals requesting specific accommodations should contact Rochelle Hall at (202) 314–6305 or by email at [Rochelle.Hall@ntsb.gov](mailto:Rochelle.Hall@ntsb.gov) by Friday, August 7, 2015.The public may view the meeting via a live or archived webcast by accessing a link under "News & Events" on the NTSB home page at [www.nts.gov](http://www.nts.gov).Schedule updates, including weather-related cancellations, are also available at [www.nts.gov](http://www.nts.gov).**FOR FURTHER INFORMATION CONTACT:**Candi Bing at (202) 314–6403 or by email at [bingc@ntsb.gov](mailto:bingc@ntsb.gov).**FOR MEDIA INFORMATION CONTACT:** Keith Holloway (202) 314–6100 or by email at [keith.holloway@ntsb.gov](mailto:keith.holloway@ntsb.gov).

Dated: Tuesday, August 4, 2015.

**Candi R. Bing,***Federal Register Liaison Officer.*

[FR Doc. 2015–19502 Filed 8–5–15; 11:15 am]

**BILLING CODE 7533-01-P****NUCLEAR REGULATORY COMMISSION****[Docket No. 50–289; NRC–2015–0185]****Exelon Generation Company, LLC; Three Mile Island Nuclear Station, Unit 1****AGENCY:** Nuclear Regulatory Commission.**ACTION:** License amendment application; opportunity to comment, request a hearing, and petition for leave to intervene.**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is considering issuance of an amendment to Renewed Facility Operating License No. DPR–50, issued to Exelon Generation Company, LLC, for operation of the Three Mile Island Nuclear Station, Unit 1 (TMI or the licensee). The proposed amendment would modify the technical specifications to allow for the temporary connection of the borated water storage tank (BWST) to non-seismic piping for cleanup and recirculation to support activities associated with the TMI–1 fall 2015 Refueling Outage and Fuel Cycle 21 operation.**DATES:** Submit comments by September 8, 2015. Requests for a hearing or petition for leave to intervene must be filed by October 6, 2015.**ADDRESSES:** You may submit comments by any of the following methods (unless this document describes a different method for submitting comments on a specific subject):

- *Federal Rulemaking Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC–2015–0185. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: [Carol.Gallagher@nrc.gov](mailto:Carol.Gallagher@nrc.gov). For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *Mail comments to:* Cindy Bladey, Office of Administration, Mail Stop: OWFN–12–H08, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

For additional direction on obtaining information and submitting comments, see "Obtaining Information and Submitting Comments" in the **SUPPLEMENTARY INFORMATION** section of this document.**FOR FURTHER INFORMATION CONTACT:**Robert L. Gladney, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555–0001; telephone: 301–415–1022, email: [Robert.Gladney@nrc.gov](mailto:Robert.Gladney@nrc.gov).**SUPPLEMENTARY INFORMATION:**

## I. Obtaining Information and Submitting Comments

### A. Obtaining Information

Please refer to Docket ID NRC–2015–0185 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- *Federal Rulemaking Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC–2015–0185.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). The ADAMS accession number for each document referenced (if it is available in ADAMS) is provided the first time that it is mentioned in the **SUPPLEMENTARY INFORMATION** section.

- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

### B. Submitting Comments

Please include Docket ID NRC–2015–0185 in your comment submission.

The NRC cautions you not to include identifying or contact information that you do not want to be publicly disclosed in your comment submission. The NRC posts all comment submissions at <http://www.regulations.gov> as well as entering the comment submissions into ADAMS. The NRC does not routinely edit comment submissions to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the NRC, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that the NRC does not routinely edit comment submissions to remove such information before making the comment submissions available to the public or entering the comment submissions into ADAMS.

## II. Introduction

The NRC is considering issuance of an amendment to Renewed Facility Operating License No. DPR–50, issued to TMI, for operation of Unit 1, located in Dauphin County, Pennsylvania.

This amendment proposes changes to the technical specifications to allow for the temporary connection of the BWST to non-seismic piping for cleanup and recirculation to support activities associated with the TMI–1 Fall 2015 Refueling Outage and Fuel Cycle 21 operation.

Before any issuance of the proposed license amendment, the NRC will need to make the findings required by the Atomic Energy Act of 1954, as amended (the Act), and NRC's regulations.

The NRC has made a proposed determination that the license amendment request (LAR) involves no significant hazards consideration. Under the NRC's regulations in § 50.92 of Title 10 of the *Code of Federal Regulations* (10 CFR), this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed amendment involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The use of the Liquid Waste Disposal System (WDL) and the Spent Fuel Pool Cooling System (SF) to re-circulate and cleanup the BWST contents does not involve any physical changes or modifications to the plant, or create any new interfaces with the reactor coolant system. Therefore, the connection of the WDL and SF to the BWST would not affect the probability of Large and Small Break Loss of Coolant Accidents occurring. The WDL and the applicable components of the SF are not credited for safe shutdown of the plant or accident mitigation. A technical evaluation was performed to validate the seismic adequacy of the WDL piping to withstand a Safe Shutdown Earthquake (SSE). The evaluation determined sufficient margin exists in the installed piping and supports such that during an SSE, the WDL system and piping would not lose pressure boundary integrity. In addition, as additional defense-in-depth measure, administrative controls ensure that the BWST can be isolated from seismic Class II WDL piping following an SSE. Since the BWST will continue to perform its safety

functions and overall system performance is not affected, the consequences of an accident are not increased.

Therefore, the proposed change does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed amendment create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The design of the BWST, WDL and SF systems to allow recirculation and filtration/demineralization has not been altered. No new procedures are required to start or end BWST Cleanup or Recirculation operation. Proposed changes to the existing operating procedures will provide a higher priority and quicker response to isolate the BWST from seismic Class II piping paths, if operating in Cleanup or Recirculation modes, as an additional defense-in-depth administrative control during a seismic event. Since the seismic adequacy of the interconnected WDL system and piping has been evaluated for an SSE and validated by calculations to maintain pressure boundary integrity, the BWST safety functions are not affected.

Therefore, the proposed changes do not create the possibility of a new or different kind of accident from any accident previously evaluated.

3. Does the proposed amendment involve a significant reduction in a margin of safety?

Response: No.

The WDL and applicable components of the SF are not credited for safe shutdown of the plant or accident mitigation. The seismic adequacy of the BWST is maintained. The seismic evaluation determined that sufficient margin exists in the installed piping and supports such that during an SSE, the seismic Class II WDL system and piping would not lose pressure boundary integrity. Maximum piping and piping support stresses are below their respective allowables, are acceptable, and no pipe leakage will occur.

Therefore, the proposed changes do not involve a significant reduction in a margin of safety.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the LAR involves no significant hazards consideration.

The NRC is seeking public comments on this proposed determination that the LAR involves no significant hazards consideration. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of 60 days after the date of publication of this notice. The Commission may issue the license amendment before expiration of the 60-

day notice period if the Commission concludes the amendment involves no significant hazards consideration. In addition, the Commission may issue the amendment prior to the expiration of the 30-day comment period should circumstances change during the 30-day comment period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility. Should the Commission take action prior to the expiration of either the comment period or the notice period, it will publish in the **Federal Register** a notice of issuance. Should the Commission make a final No Significant Hazards Consideration Determination, any hearing will take place after issuance. The Commission expects that the need to take this action will occur very infrequently.

### III. Opportunity To Request a Hearing and Petition for Leave To Intervene

Within 60 days after the date of publication of this **Federal Register** notice, any person whose interest may be affected by this proceeding and who desires to participate as a party in the proceeding must file a written request for hearing or a petition for leave to intervene specifying the contentions which the person seeks to have litigated in the hearing with respect to the LAR. Requests for hearing and petitions for leave to intervene shall be filed in accordance with the NRC's "Agency Rules of Practice and Procedure" in 10 CFR part 2. Interested person(s) should consult a current copy of 10 CFR 2.309, which is available at the NRC's PDR. The NRC's regulations are accessible electronically from the NRC Library on the NRC's Web site at <http://www.nrc.gov/reading-rm/doc-collections/cfr/>.

As required by 10 CFR 2.309, a request for hearing or petition for leave to intervene must set forth with particularity the interest of the petitioner in the proceeding and how that interest may be affected by the results of the proceeding. The hearing request or petition must specifically explain the reasons why intervention should be permitted, with particular reference to the following general requirements: (1) The name, address, and telephone number of the requestor or petitioner; (2) the nature of the requestor's/petitioner's right under the Act to be made a party to the proceeding; (3) the nature and extent of the requestor's/petitioner's property, financial, or other interest in the proceeding; and (4) the possible effect of any decision or order which may be entered in the proceeding on the requestor's/petitioner's interest. The

hearing request or petition must also include the specific contentions that the requestor/petitioner seeks to have litigated at the proceeding.

For each contention, the requestor/petitioner must provide a specific statement of the issue of law or fact to be raised or controverted, as well as a brief explanation of the basis for the contention. Additionally, the requestor/petitioner must demonstrate that the issue raised by each contention is within the scope of the proceeding and is material to the findings that the NRC must make to support the granting of a license amendment in response to the application. The hearing request or petition must also include a concise statement of the alleged facts or expert opinion that support the contention and on which the requestor/petitioner intends to rely at the hearing, together with references to those specific sources and documents. The hearing request or petition must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact, including references to specific portions of the application for amendment that the petitioner disputes and the supporting reasons for each dispute. If the requestor/petitioner believes that the application for amendment fails to contain information on a relevant matter as required by law, the requestor/petitioner must identify each failure and the supporting reasons for the requestor's/petitioner's belief. Each contention must be one which, if proven, would entitle the requestor/petitioner to relief. A requestor/petitioner who does not satisfy these requirements for at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing with respect to resolution of that person's admitted contentions, including the opportunity to present evidence and to submit a cross-examination plan for cross-examination of witnesses, consistent with NRC regulations, policies, and procedures. The Atomic Safety and Licensing Board will set the time and place for any prehearing conferences and evidentiary hearings, and the appropriate notices will be provided.

Hearing requests or petitions for leave to intervene must be filed no later than 60 days from the date of publication of this notice. Requests for hearing, petitions for leave to intervene, and motions for leave to file new or

amended contentions that are filed after the 60-day deadline will not be entertained absent a determination by the presiding officer that the filing demonstrates good cause by satisfying the three factors in 10 CFR 2.309(c)(1)(i)-(iii).

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held. If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment. If the final determination is that the amendment request involves a significant hazards consideration, then any hearing held would take place before the issuance of any amendment unless the Commission finds an imminent danger to the health or safety of the public, in which case it will issue an appropriate order or rule under 10 CFR part 2.

### IV. Electronic Submissions (E-Filing)

All documents filed in NRC adjudicatory proceedings, including a request for hearing, a petition for leave to intervene, any motion or other document filed in the proceeding prior to the submission of a request for hearing or petition to intervene, and documents filed by interested governmental entities participating under 10 CFR 2.315(c), must be filed in accordance with the NRC's E-Filing rule (72 FR 49139; August 28, 2007). The E-Filing process requires participants to submit and serve all adjudicatory documents over the internet, or in some cases to mail copies on electronic storage media. Participants may not submit paper copies of their filings unless they seek an exemption in accordance with the procedures described below.

To comply with the procedural requirements of E-Filing, at least ten 10 days prior to the filing deadline, the participant should contact the Office of the Secretary by email at [hearing.docket@nrc.gov](mailto:hearing.docket@nrc.gov), or by telephone at 301-415-1677, to request (1) a digital identification (ID) certificate, which allows the participant (or its counsel or representative) to digitally sign documents and access the E-Submittal server for any proceeding in which it is participating; and (2) advise the Secretary that the participant will be submitting a request or petition for hearing (even in instances in which the

participant, or its counsel or representative, already holds an NRC-issued digital ID certificate). Based upon this information, the Secretary will establish an electronic docket for the hearing in this proceeding if the Secretary has not already established an electronic docket.

Information about applying for a digital ID certificate is available on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals/getting-started.html>. System requirements for accessing the E-Submittal server are detailed in the NRC's "Guidance for Electronic Submission," which is available on the agency's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>.

Participants may attempt to use other software not listed on the Web site, but should note that the NRC's E-Filing system does not support unlisted software, and the NRC Meta System Help Desk will not be able to offer assistance in using unlisted software.

If a participant is electronically submitting a document to the NRC in accordance with the E-Filing rule, the participant must file the document using the NRC's online, Web-based submission form. In order to serve documents through the Electronic Information Exchange System, users will be required to install a Web browser plug-in from the NRC's Web site. Further information on the Web-based submission form, including the installation of the Web browser plug-in, is available on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>.

Once a participant has obtained a digital ID certificate and a docket has been created, the participant can then submit a request for hearing or petition for leave to intervene. Submissions should be in Portable Document Format (PDF) in accordance with NRC guidance available on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>. A filing is considered complete at the time the documents are submitted through the NRC's E-Filing system. To be timely, an electronic filing must be submitted to the E-Filing system no later than 11:59 p.m. Eastern Time on the due date. Upon receipt of a transmission, the E-Filing system time-stamps the document and sends the submitter an email notice confirming receipt of the document. The E-Filing system also distributes an email notice that provides access to the document to the NRC's Office of the General Counsel and any others who have advised the Office of the Secretary that they wish to participate in the

proceeding, so that the filer need not serve the documents on those participants separately. Therefore, applicants and other participants (or their counsel or representative) must apply for and receive a digital ID certificate before a hearing request/petition to intervene is filed so that they can obtain access to the document via the E-Filing system.

A person filing electronically using the NRC's adjudicatory E-Filing system may seek assistance by contacting the NRC Meta System Help Desk through the "Contact Us" link located on the NRC's public Web site at <http://www.nrc.gov/site-help/e-submittals.html>, by email to [MSHD.Resource@nrc.gov](mailto:MSHD.Resource@nrc.gov), or by a toll-free call at 1-866-672-7640. The NRC Meta System Help Desk is available between 8 a.m. and 8 p.m., Eastern Time, Monday through Friday, excluding government holidays.

Participants who believe that they have a good cause for not submitting documents electronically must file an exemption request, in accordance with 10 CFR 2.302(g), with their initial paper filing requesting authorization to continue to submit documents in paper format. Such filings must be submitted by: (1) First class mail addressed to the Office of the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001, Attention: Rulemaking and Adjudications Staff; or (2) courier, express mail, or expedited delivery service to the Office of the Secretary, Sixteenth Floor, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852, Attention: Rulemaking and Adjudications Staff. Participants filing a document in this manner are responsible for serving the document on all other participants. Filing is considered complete by first-class mail as of the time of deposit in the mail, or by courier, express mail, or expedited delivery service upon depositing the document with the provider of the service. A presiding officer, having granted an exemption request from using E-Filing, may require a participant or party to use E-Filing if the presiding officer subsequently determines that the reason for granting the exemption from use of E-Filing no longer exists.

Documents submitted in adjudicatory proceedings will appear in the NRC's electronic hearing docket which is available to the public at <http://ehd1.nrc.gov/ehd/>, unless excluded pursuant to an order of the Commission, or the presiding officer. Participants are requested not to include personal privacy information, such as social security numbers, home addresses, or

home phone numbers in their filings, unless an NRC regulation or other law requires submission of such information. However, in some instances, a request to intervene will require including information on local residence in order to demonstrate a proximity assertion of interest in the proceeding. With respect to copyrighted works, except for limited excerpts that serve the purpose of the adjudicatory filings and would constitute a Fair Use application, participants are requested not to include copyrighted materials in their submission.

For further details with respect to this action, see the application for license amendment dated July 23, 2015 (ADAMS Accession No. ML15204A843), as supplemented by letter dated July 28, 2015 (ADAMS Accession No. ML15209A960).

*Attorney for licensee:* J. Bradley Fewell, Assistant General Counsel, Exelon Generation Company, LLC, 200 Exelon Way, Kennett Square, PA 19348.  
*NRC Branch Chief:* Douglas A. Broaddus.

Dated at Rockville, Maryland, this 30th day of July, 2015.

For the Nuclear Regulatory Commission.

**Robert L. Gladney,**

*Project Manager, Plant Licensing Branch I-2, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.*

[FR Doc. 2015-19409 Filed 8-6-15; 8:45 am]

**BILLING CODE 7590-01-P**

## NUCLEAR REGULATORY COMMISSION

[Docket Nos. 50-361 and 50-362; NRC-2013-0083]

### Southern California Edison; San Onofre Nuclear Generating Station, Units 2 and 3

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Director's decision under 10 CFR 2.206; issuance.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) has issued a final director's decision with regard to a petition dated June 18, 2012, filed by Mr. Richard Ayres, Counsel for Friends of the Earth (the petitioner), requesting that the NRC take action with regard to Southern California Edison (SCE or the licensee) at the San Onofre Nuclear Generating Station (SONGS). The petitioner's requests and the final director's decision are included in the **SUPPLEMENTARY INFORMATION** section of this document.

**ADDRESSES:** Please refer to Docket ID NRC-2013-0083 when contacting the

NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC-2013-0083. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; email: [Carol.Gallagher@nrc.gov](mailto:Carol.Gallagher@nrc.gov). For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). The ADAMS accession number for each document referenced (if that document is available in ADAMS) is provided the first time that a document is referenced.

- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

**FOR FURTHER INFORMATION CONTACT:** Thomas Wengert, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001; telephone: 301-415-4037, email: [Thomas.Wengert@nrc.gov](mailto:Thomas.Wengert@nrc.gov).

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that the Director, Office of Nuclear Reactor Regulation, has issued a director's decision (ADAMS Accession No. ML15183A164) on a petition filed by the petitioner on June 18, 2012 (ADAMS Accession No. ML12171A409). The petition was supplemented on November 16, 2012, January 16, 2013, and February 6, 2013 (ADAMS Accession Nos. ML12325A748, ML13029A643, and ML13109A075, respectively).

The petitioner requested that the NRC order SCE to submit a license amendment application for the design and installation of the SONGS, Units 2 and 3, replacement steam generators.

As the basis of the request, the petitioner asserted that the licensee violated section 50.59 of Title 10 of the *Code of Federal Regulations* (10 CFR), "Changes, Tests, and Experiments," when the steam generators for SONGS,

Units 2 and 3, were replaced in 2010 and 2011, without a license amendment request.

On January 16, 2013, the petitioner met with the NRC's Petition Review Board (PRB). The meeting provided the petitioner and the licensee an opportunity to provide additional information and to clarify issues cited in the petition. During the PRB meeting, the petitioner further requested that the NRC suspend SCE's licenses until they are amended. The transcript for that meeting was treated as a supplement to the petition and is available in ADAMS under Accession No. ML13029A643.

The NRC sent a copy of the proposed director's decision to the petitioner and the licensee for comment on February 27, 2015 (ADAMS Accession Nos. ML15020A121 and ML15020A165, respectively). The petitioner and the licensee were asked to provide comments within 30 days on any part of the proposed director's decision that was considered to be erroneous or any issues in the petition that were not addressed. Comments were received from the petitioner and are addressed in an attachment to the final director's decision. The licensee had no comments on the proposed director's decision; however, the licensee did provide a response to the petitioner's comments. The NRC staff reviewed the response from the licensee and determined that, because the licensee's comments are direct rebuttals to the petitioner's comments and raised no concerns with the director's decision, no changes to the director's decision are required as a result of these comments.

The Director of the Office of Nuclear Reactor Regulation has determined that the requests for the NRC to order the licensee to submit a license amendment application for the design and installation of the SONGS, Units 2 and 3, replacement steam generators and to suspend SCE's licenses until they are amended be denied. The reasons for this decision are explained in the director's decision (DD-15-07) pursuant to 10 CFR 2.206, "Requests for action under this subpart," of the Commission's regulations.

The NRC will file a copy of the director's decision with the Secretary of the Commission for the Commission's review in accordance with 10 CFR 2.206. As provided by this regulation, the director's decision will constitute the final action of the Commission 25 days after the date of the decision unless the Commission, on its own motion, institutes a review of the director's decision in that time.

Dated at Rockville, Maryland, this 28 day of July 2015.

For the Nuclear Regulatory Commission.

**William M. Dean,**  
*Director, Office of Nuclear Reactor Regulation.*

[FR Doc. 2015-19407 Filed 8-6-15; 8:45 am]

**BILLING CODE 7590-01-P**

## NUCLEAR REGULATORY COMMISSION

[Docket No. 50-443; NRC-2010-0206]

**NextEra Energy Seabrook, LLC;  
Seabrook Station, Unit 1**

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Supplemental environmental impact statement; issuance.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is issuing a final plant-specific supplement, Supplement 46, to NUREG-1437, "Generic Environmental Impact Statement for License Renewal of Nuclear Plants" (GEIS), regarding the renewal of NextEra Energy Seabrook, LLC (NextEra) operating license NPF-86 for an additional 20 years of operation for Seabrook Station, Unit 1 (Seabrook).

**DATES:** The final Supplement 46 to the GEIS is available as of August 7, 2015.

**ADDRESSES:** Please refer to Docket ID NRC-2010-0206 when contacting the NRC about the availability of information regarding this document. You may obtain publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC-2010-0206. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; email: [Carol.Gallagher@nrc.gov](mailto:Carol.Gallagher@nrc.gov). For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). The final Supplement 46 to the GEIS is in ADAMS under Accession No.

ML15209A575 (Volume 1) and ML15209A270 (Volume 2).

- *NRC's PDR*: You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

**FOR FURTHER INFORMATION CONTACT:** Lois James, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-3306; email: [Lois.James@nrc.gov](mailto:Lois.James@nrc.gov).

**SUPPLEMENTARY INFORMATION:**

**I. Background**

In accordance with § 51.118 of Title 10 of the *Code of Federal Regulations*, the NRC is making available final Supplement 46 to the GEIS regarding the renewal of NextEra operating license NPF-86 for an additional 20 years of operation for Seabrook. Draft Supplement 46 to the GEIS was noticed by the NRC in the **Federal Register** on August 5, 2011 (76 FR 47612), and noticed by the Environmental Protection Agency on August 12, 2011 (76 FR 50214). The public comment period on draft Supplement 46 to the GEIS ended on October 26, 2011. In April 2013, a supplement to draft Supplement 46 was published. The supplement to draft Supplement 46 was noticed by the Environmental Protection Agency on May 3, 2013 (78 FR 26027). The end of the comment period for the supplement to draft Supplement 46 was on June 30, 2013. The comments received on the draft Supplement 46 published in 2011 and supplement to the draft Supplement 46 to the GEIS. Final Supplement 46 to the GEIS is available as indicated in the **ADDRESSES** section of this document.

**II. Discussion**

As discussed in Section 9.4 of the final Supplement 46 to the GEIS, the NRC determined that the adverse environmental impacts of license renewal for Seabrook are not so great that preserving the option of license renewal for energy-planning decisionmakers would be unreasonable. This recommendation is based on: (1) the analysis and findings in the GEIS; (2) information provided in the environmental report and other documents submitted by NextEra; (3) consultation with Federal, State, local, and Tribal agencies; (4) the NRC staff's independent environmental review; and (5) consideration of public comments received during the scoping process and on the draft Supplemental Environmental Impact Statement.

Dated at Rockville, Maryland, this 30th day of July 2015.

For the Nuclear Regulatory Commission.

**James G. Danna,**  
*Chief, Projects Branch 2, Division of License Renewal, Office of Nuclear Reactor Regulation.*

[FR Doc. 2015-19408 Filed 8-6-15; 8:45 am]

**BILLING CODE 7590-01-P**

**NUCLEAR REGULATORY COMMISSION**

[NRC-2014-0062]

**Special Nuclear Material Doorway Monitors**

**AGENCY:** Nuclear Regulatory Commission.

**ACTION:** Regulatory guide; issuance.

**SUMMARY:** The U.S. Nuclear Regulatory Commission (NRC) is issuing a revised regulatory guide, (RG) 5.27, Revision 1, "Special Nuclear Material Doorway Monitors." This guidance addresses NRC requirements that individuals must be searched as they leave a material access area (MAA) for facilities that contain special nuclear material (SNM) of a type and quantity that require an MAA.

**ADDRESSES:** Please refer to Docket ID NRC-2014-0062 when contacting the NRC about the availability of information regarding this document. You may access information related to this document, which the NRC possesses and is publicly available, using the following methods:

- *Federal Rulemaking Web site:* Go to <http://www.regulations.gov> and search for Docket ID NRC-2014-0062. Address questions about NRC dockets to Carol Gallagher; telephone: 301-287-3422; email: [Carol.Gallagher@nrc.gov](mailto:Carol.Gallagher@nrc.gov).

- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may access publicly available documents online in the ADAMS Public Documents collection at <http://www.nrc.gov/reading-rm/adams.html>. To begin the search, select "ADAMS Public Documents" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1-800-397-4209, 301-415-4737, or by email to [pdr.resource@nrc.gov](mailto:pdr.resource@nrc.gov). The ADAMS accession number for each document referenced in this notice (if that document is available in ADAMS) is provided the first time that a document is referenced. Revision 1 of Regulatory Guide 5.27 is available in ADAMS under Accession No.

ML14290A268. The regulatory analysis may be found in ADAMS under Accession No. ML12237A124.

- *NRC's PDR*: You may examine and purchase copies of public documents at the NRC's PDR, Room O1-F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

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**FOR FURTHER INFORMATION CONTACT:** Al Tardiff, Office of Nuclear Security and Incident Response, telephone: 301-415-7015, email: [Al.Tardiff@nrc.gov](mailto:Al.Tardiff@nrc.gov) or, Richard Jervey, Office of Nuclear Regulatory Research, telephone: 301-251-7404, email: [Richard.Jervey@nrc.gov](mailto:Richard.Jervey@nrc.gov); U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

**SUPPLEMENTARY INFORMATION:**

**I. Introduction**

The NRC is issuing a new guide in the NRC's "Regulatory Guide" series. This series was developed to describe and make available to the public information such as methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff needs in its review of applications for permits and licenses.

Regulatory Guide 5.27, Revision 1 was issued for comment as Draft Regulatory Guide (DG) 5038. The NRC developed this regulatory guide to describe a method that the NRC staff considers acceptable to implement the search requirement for concealed SNM applied to personnel exiting a material access area MAA. For holders of a reactor license under part 50 of title 10 of the *Code of Federal Regulations* (10 CFR) (Ref. 1), "Domestic Licensing of Production and Utilization Facilities," a combined license under 10 CFR part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," or a fuel cycle facility license under 10 CFR part 76, "Certification of Gaseous Diffusion Plants," having the need to possess or use SNM within their facility, the NRC typically has included in their license a condition granting a general license to use SNM under 10 CFR part 70, "Domestic Licensing of Special Nuclear Material." The RG applies to facilities that contain SNM of a type and quantity to require an MAA. An MAA is any location which contains special nuclear material, within a vault or a building, the roof, walls, and floor of which each constitute a physical barrier.

This RG is being revised because it was out-of-date with current, related

guidance and references in the CFR. Related specifications and standards for SNM monitors and metal detectors have been updated or developed since the previous revision was issued in 1974. This revision has been developed to provide detection practices and criteria that licensees may use to meet NRC regulations in 10 CFR part 73 and to augment programmatic information within the general reference, NUREG-1964, "Access Control Systems: Technical Information for NRC Licensees," issued in April of 2011. NUREG-1964 may be found in ADAMS under Accession No. ML1115A078.

## II. Additional Information

DG-5038 was published in the **Federal Register** on March 26, 2014, (79 FR 16832) for a 30 day public comment period. The public comment period closed on April 25, 2014. Public comments on DG-5038 and the staff responses to the public comments are available at ADAMS Accession Number ML14288A653.

## III. Congressional Review Act

This regulatory guide is a rule as defined in the Congressional Review Act (5 U.S.C. 801-808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

## IV. Backfitting and Issue Finality

This RG applies to applicants for, and current and future holders of special nuclear material licenses under 10 CFR part 70, and operating licenses under part 50, combined licenses under part 52, and certificates of compliance or approvals of a compliance plan for gaseous diffusion plants under part 76 if they are also applicants for, or holders of, special nuclear material licenses under part 70. Issuance of this RG does not constitute backfitting under 10 CFR parts 50, 70, or 76, and is not otherwise inconsistent with the issue finality provisions in 10 CFR part 52. As discussed in the "Implementation" section of the RG, the NRC has no current intention to impose this RG on holders of part 50 operating licenses, part 52 combined licenses, part 70 licensees, or part 76 certificates of compliance. Moreover, the guidance in the RG addresses security issues, which are matters separate from the technical requirements to operate a facility covered by backfitting and issue finality provisions.

The NRC has determined that the backfit provisions in § 50.109 do not apply to non-power reactor licensees because the rulemaking record for

§ 50.109 indicates that the Commission likely intended to apply this provision to only power reactors, and NRC practice has been consistent with this rulemaking record. The part 52 issue finality provisions do not apply to non-power reactors because part 52 does not apply to non-power reactors.

This RG could be applied to applications for part 50 operating licenses, part 52 combined licenses, part 70 licenses, and part 76 certificates of compliance docketed by the NRC as of the date of issuance of the RG, as well as future such applications submitted after the issuance of the RG. Such action would not constitute backfitting as defined in 10 CFR 50.109, 70.76, or 76.76, or be otherwise inconsistent with the applicable issue finality provision in 10 CFR part 52, inasmuch as such applicants or potential applicants are not within the scope of entities protected by 10 CFR 50.109, 70.76, and 76.76, or the relevant issue finality provisions in part 52. Backfitting restrictions were not intended to apply to every NRC action that substantially changes settled expectations, and applicants have no reasonable expectation that future requirements may change, *see* 54 FR 15372 (April 18, 1989), at 15385-86. Although the issue finality provisions in part 52 are intended to provide regulatory stability and issue finality, the matters addressed in this RG (concerning certain security requirements in part 73) are not within the scope of issues that may be resolved for design certification, design approval or a manufacturing license, and therefore are not subject to issue finality protections in part 52.

Dated at Rockville, Maryland, this 23rd day of July 2015.

For the Nuclear Regulatory Commission.

**Thomas H. Boyce,**

*Chief, Regulatory Guidance and Generic Issues Branch, Division of Engineering, Office of Nuclear Regulatory Research.*

[FR Doc. 2015-19445 Filed 8-6-15; 8:45 am]

**BILLING CODE 7590-01-P**

## OFFICE OF PERSONNEL MANAGEMENT

### Federal Employees' Group Life Insurance Program; Premium Changes and Open Season

**AGENCY:** U.S. Office of Personnel Management.

**ACTION:** Notice.

**SUMMARY:** The Office of Personnel Management (OPM) is announcing an upcoming FEGLI Open Season and changes in premium rates for certain

Federal Employees' Group Life Insurance (FEGLI) categories in accordance with sections 870.401(a)(2) and 870.402(a)(3) of title 5 of the Code of Federal Regulations. These include changes to premium rates for Option A (most age bands), Option B (most age bands), Option C (most age bands), and Post-Retirement Basic Insurance. These rates will be effective the first pay period beginning on or after January 1, 2016. The FEGLI Open Season will be held from September 1, 2016 through September 30, 2016.

**DATES:** These rates will be effective the first pay period beginning on or after January 1, 2016.

**FOR FURTHER INFORMATION CONTACT:** Delon Pinto, *Delon.Pinto@opm.gov*, (202) 606-0004.

**SUPPLEMENTARY INFORMATION:** This notice announces an upcoming FEGLI Open Season between September 1, 2016 and September 30, 2016 and also announces changes to FEGLI Option A (most age bands), Option B (most age bands), Option C (most age bands), and Post-Retirement Basic Insurance.

Open Seasons are one method by which healthy individuals can be attracted to join and reduce the risk profile of the program. Some less healthy individuals may elect coverage during Open Seasons. To mitigate this risk, the effective date for employees in active pay status who make an Open Season election would be delayed one full year to October 1, 2017, subject to FEGLI law and regulation, including applicable pay and duty status requirements.

FEGLI premium rates are assessed based on Program experience in accordance with FEGLI statutes at 8711(b), 8714a(e), 8714b(e), and 8714c(e), and OPM's Annual FEGLI Rate Review Process. The premium rates in the FEGLI program represent estimates of premium income necessary to pay future expected benefits costs. The rates for all coverage categories are specific to the experience of the FEGLI group and are not based on mortality rates within the general population. Actuarial analysis of changing mortality rates makes periodic premium adjustments necessary.

OPM has completed a study of funding and claims experience within the FEGLI Program. Based on this updated actuarial analysis of actual claims experience, OPM has determined that changes are required to Option A, Option B, Option C and Post-Retirement Basic Insurance premiums. These changes reflect updated mortality and claims rates from actual program experience within each FEGLI category.



The legislative structure of the FEGLI Program assumes that we set premium rates for each age band independently of the other bands so that each age band is financially self-supporting.

We will issue guidance to all agencies for the purpose of counseling employees and we will notify affected annuitants directly via OPM's Office of Retirement Services. The FEGLI premium rates will

be maintained on the FEGLI Web site [www.opm.gov/insure/life](http://www.opm.gov/insure/life).

The new FEGLI premium rates for Option A, Option B, Option C and the Post-Retirement Basic Option are as follows:

**OPTION A (FOR \$10,000 OF INSURANCE)**

[The premiums for compensationers who are paid every four weeks are two times the biweekly premium]

Age band	Bi-Weekly	Monthly
< 35	\$0.20	\$0.43
35-39	0.30	0.65
40-44	0.40	0.87
45-49	0.70	1.52
50-54	1.10	2.38
55-59	2.00	4.33
60 +	6.00	13.00

**OPTION B (PER \$1,000 OF INSURANCE)**

[The premiums for compensationers who are paid every four weeks are two times the biweekly premium]

Age band	Bi-Weekly	Monthly
< 35	\$0.02	\$0.043
35-39	0.03	0.065
40-44	0.04	0.087
45-49	0.07	0.152
50-54	0.11	0.238
55-59	0.20	0.433
60-64	0.44	0.953
65-69	0.54	1.170
70-74	0.96	2.080
75-79	1.80	3.900
80 +	2.64	5.720

**OPTION C (PER MULTIPLE OF INSURANCE)**

[The premiums for compensationers who are paid every four weeks are two times the biweekly premium]

Age band	Bi-Weekly	Monthly
< 35	\$0.22	\$0.48
35-39	0.27	0.59
40-44	0.41	0.89
45-49	0.59	1.28
50-54	0.92	1.99
55-59	1.48	3.21
60-64	2.70	5.85
65-69	3.14	6.80
70-74	3.83	8.30
75-79	5.26	11.40
80 +	7.20	15.60

**POST-RETIREMENT BASIC INSURANCE FOR ANNUITANTS**

[Monthly rate per \$1,000 of insurance]

	Before age 65	After age 65
75% Reduction	\$0.3250	No cost.
50% Reduction	1.0350	\$0.71.
No Reduction	2.4550	\$2.13.

**POST-RETIREMENT BASIC INSURANCE FOR COMPENSATIONERS**

[Withholding every four weeks per \$1,000 of insurance]

	Before Age 65	After Age 65
75% Reduction	\$0.30	No cost.
50% Reduction	0.96	\$0.66.

## POST-RETIREMENT BASIC INSURANCE FOR COMPENSATIONERS—Continued

[Withholding every four weeks per \$1,000 of insurance]

	Before Age 65	After Age 65
No Reduction .....	2.27	\$1.97.

Premium rates for Basic Employee insurance will not change at this time. These rates will be effective the first pay period beginning on or after January 1, 2016.

U.S. Office of Personnel Management.

**Beth F. Cobert,**  
Acting Director.

[FR Doc. 2015-19398 Filed 8-6-15; 8:45 am]

**BILLING CODE 6325-38-P**

## POSTAL REGULATORY COMMISSION

[Docket No. CP2015-119; Order No. 2630]

### New Postal Product

**AGENCY:** Postal Regulatory Commission.  
**ACTION:** Notice.

**SUMMARY:** The Commission is noticing a recent Postal Service filing concerning an additional Global Expedited Package Services 3 negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

**DATES:** *Comments are due:* August 10, 2015.

**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
- II. Notice of Commission Action
- III. Ordering Paragraphs

#### I. Introduction

On July 31, 2015, the Postal Service filed notice that it has entered into an additional Global Expedited Package Services 3 (GEPS 3) negotiated service agreement (Agreement).<sup>1</sup>

<sup>1</sup> Notice of United States Postal Service of Filing a Functionally Equivalent Global Expedited Package Services 3 Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal, July 31, 2015 (Notice).

To support its Notice, the Postal Service filed a copy of the Agreement, a copy of the Governors' Decision authorizing the product, 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 No. CP2015-119 for consideration of matters raised by the Notice.

The Commission invites comments on whether the Postal Service's filing is consistent with 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 August 10, 2015. The public portions of the filing can be accessed via the Commission's Web site (<http://www.prc.gov>).

The Commission appoints Kenneth R. Moeller to serve as an officer of the Commission to represent the interests of the general public in this proceeding (Public Representative).

#### III. Ordering Paragraphs

*It is ordered:*

1. The Commission establishes Docket No. CP2015-119 for consideration of the matters raised by the Postal Service's Notice.

2. Pursuant to 39 U.S.C. 505, Kenneth R. Moeller is appointed as the Public Representative in this proceeding.

3. Comments are due no later than August 10, 2015.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

**Ruth Ann Abrams,**

Acting Secretary.

[FR Doc. 2015-19388 Filed 8-6-15; 8:45 am]

**BILLING CODE 7710-FW-P**

## POSTAL REGULATORY COMMISSION

[Docket Nos. MC2015-76 and CP2015-120; Order No. 2628]

### 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 139 negotiated service agreement 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:* August 10, 2015.

**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:

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- I. Introduction
- II. Notice of Commission Action
- III. Ordering Paragraphs

#### I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.*, the Postal Service filed a formal request and associated supporting information to add Priority Mail Contract 139 to the competitive product list.<sup>1</sup>

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. *Id.* 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. MC2015-76 and CP2015-120 to consider the Request pertaining to the

<sup>1</sup> Request of the United States Postal Service to Add Priority Mail Contract 139 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, July 31, 2015 (Request).

proposed Priority Mail Contract 139 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 August 10, 2015. The public portions of these filings can be accessed via the Commission's Web site (<http://www.prc.gov>).

The Commission appoints Katalin K. Clendenin to serve as Public Representative in these dockets.

### III. Ordering Paragraphs

It is ordered:

1. The Commission establishes Docket Nos. MC2015-76 and CP2015-120 to consider the matters raised in each docket.

2. Pursuant to 39 U.S.C. 505, Katalin K. Clendenin 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 August 10, 2015.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

**Ruth Ann Abrams,**  
*Acting Secretary.*

[FR Doc. 2015-19432 Filed 8-6-15; 8:45 am]

**BILLING CODE 7710-FW-P**

## POSTAL REGULATORY COMMISSION

[Docket No. CP2015-122; Order No. 2631]

### New Postal Product

**AGENCY:** Postal Regulatory Commission.

**ACTION:** Notice.

**SUMMARY:** The Commission is noticing a recent Postal Service filing concerning an additional Global Expedited Package Services 3 negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

**DATES:** *Comments are due:* August 10, 2015.

**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:

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- I. Introduction
- II. Notice of Commission Action
- III. Ordering Paragraphs

#### I. Introduction

On July 31, 2015, the Postal Service filed notice that it has entered into an additional Global Expedited Package Services 3 (GEPS 3) negotiated service agreement (Agreement).<sup>1</sup>

To support its Notice, the Postal Service filed a copy of the Agreement, a copy of the Governors' Decision authorizing the product, 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 No. CP2015-122 for consideration of matters raised by the Notice.

The Commission invites comments on whether the Postal Service's filing is consistent with 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 August 10, 2015. The public portions of the filing can be accessed via the Commission's Web site (<http://www.prc.gov>).

The Commission appoints JP Klingenberg to serve as Public Representative in this docket.

#### III. Ordering Paragraphs

*It is ordered:*

1. The Commission establishes Docket No. CP2015-122 for consideration of the matters raised by the Postal Service's Notice.

2. Pursuant to 39 U.S.C. 505, JP Klingenberg is appointed to serve as an officer of the Commission to represent the interests of the general public in this proceeding (Public Representative).

3. Comments are due no later than August 10, 2015.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

**Ruth Ann Abrams,**  
*Acting Secretary.*

[FR Doc. 2015-19389 Filed 8-6-15; 8:45 am]

**BILLING CODE 7710-FW-P**

<sup>1</sup> Notice of United States Postal Service of Filing a Functionally Equivalent Global Expedited Package Services 3 Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal, July 31, 2015 (Notice).

## POSTAL REGULATORY COMMISSION

[Docket No. CP2014-56; Order No. 2629]

### New Postal Product

**AGENCY:** Postal Regulatory Commission.

**ACTION:** Notice.

**SUMMARY:** The Commission is noticing a recent Postal Service filing concerning an amendment to the existing Priority Mail Contract 83 negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

**DATES:** *Comments are due:* August 10, 2015.

**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
- II. Notice of Commission Action
- III. Ordering Paragraphs

#### I. Introduction

On July 31, 2015, the Postal Service filed notice that it has agreed to an Amendment to the existing Priority Mail Contract 83 negotiated service agreement approved in this docket.<sup>1</sup> In support of its Notice, the Postal Service includes a redacted copy of the Amendment.

The Postal Service also filed the unredacted Amendment under seal. The Postal Service seeks to incorporate by reference the Application for Non-Public Treatment originally filed in this docket for the protection of information that it has filed under seal. *Id.* at 1.

The Amendment changes the volume commitment provision in Section I.E of the contract.

The Postal Service intends for the Amendment to become effective one business day after the date that the Commission completes its review of the Notice. *Id.* The Postal Service asserts that the Amendment will not materially affect the cost coverage of Priority Mail Contract 83. *Id.*

<sup>1</sup> Notice of United States Postal Service of Amendment to Priority Mail Contract 83, with Portions Filed Under Seal, July 31, 2015 (Notice).

## II. Notice of Filings

The Commission invites comments on whether the changes presented in the Postal Service's Notice are consistent with the policies of 39 U.S.C. 3632, 3633, or 3642, 39 CFR 3015.5, and 39 CFR part 3020, subpart B. Comments are due no later than August 10, 2015. The public portions of these filings can be accessed via the Commission's Web site (<http://www.prc.gov>).

The Commission appoints JP Klingenberg to represent the interests of the general public (Public Representative) in this docket.

## III. Ordering Paragraphs

It is ordered:

1. The Commission reopens Docket No. CP2014-56 for consideration of matters raised by the Postal Service's Notice.

2. Pursuant to 39 U.S.C. 505, the Commission appoints JP Klingenberg to serve as an officer of the Commission (Public Representative) to represent the interests of the general public in this proceeding.

3. Comments are due no later than August 10, 2015.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

**Ruth Ann Abrams,**

*Acting Secretary.*

[FR Doc. 2015-19433 Filed 8-6-15; 8:45 am]

**BILLING CODE 7710-FW-P**

## POSTAL REGULATORY COMMISSION

[Docket Nos. MC2015-77 and CP2015-121; Order No. 2634]

### 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 Express Contract 26 negotiated service agreement 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:* August 12, 2015.

**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:

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- I. Introduction
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#### I. Introduction

In accordance with 39 U.S.C. 3642 and 39 CFR 3020.30 *et seq.*, the Postal Service filed a formal request and associated supporting information to add Priority Mail Express Contract 26 to the competitive product list.<sup>1</sup>

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. *Id.* 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. MC2015-77 and CP2015-121 to consider the Request pertaining to the proposed Priority Mail Express Contract 26 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 August 12, 2015. 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. MC2015-77 and CP2015-121 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

<sup>1</sup> Request of the United States Postal Service to Add Priority Mail Express Contract 26 to Competitive Product List and Notice of Filing (Under Seal) of Unredacted Governors' Decision, Contract, and Supporting Data, July 31, 2015 (Request).

of the Commission to represent the interests of the general public in these proceedings (Public Representative).

3. Comments are due no later than August 12, 2015.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

**Ruth Ann Abrams,**

*Acting Secretary.*

[FR Doc. 2015-19435 Filed 8-6-15; 8:45 am]

**BILLING CODE 7710-FW-P**

## POSTAL REGULATORY COMMISSION

[Docket No. CP2015-118; Order No. 2633]

### New Postal Product

**AGENCY:** Postal Regulatory Commission.

**ACTION:** Notice.

**SUMMARY:** The Commission is noticing a recent Postal Service filing concerning an additional Global Expedited Package Services 3 negotiated service agreement. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

**DATES:** *Comments are due:* August 10, 2015.

**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:

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- I. Introduction
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#### I. Introduction

On July 31, 2015, the Postal Service filed notice that it has entered into an additional Global Expedited Package Services 3 (GEPS 3) negotiated service agreement (Agreement).<sup>1</sup>

To support its Notice, the Postal Service filed a copy of the Agreement, a copy of the Governors' Decision authorizing the product, a certification of compliance with 39 U.S.C. 3633(a),

<sup>1</sup> Notice of United States Postal Service of Filing a Functionally Equivalent Global Expedited Package Services 3 Negotiated Service Agreement and Application for Non-Public Treatment of Materials Filed Under Seal, July 31, 2015 (Notice).

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 No. CP2015–118 for consideration of matters raised by the Notice.

The Commission invites comments on whether the Postal Service's filing is consistent with 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 August 10, 2015. The public portions of the filing 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 this docket.

## III. Ordering Paragraphs

*It is ordered:*

1. The Commission establishes Docket No. CP2015–118 for consideration of the matters raised by the Postal Service's Notice.

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 this proceeding (Public Representative).

3. Comments are due no later than August 10, 2015.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

**Ruth Ann Abrams,**

*Acting Secretary.*

[FR Doc. 2015–19390 Filed 8–6–15; 8:45 am]

BILLING CODE 7710–FW–P

## POSTAL REGULATORY COMMISSION

[Docket No. CP2015–117; Order No. 2632]

### Change in Postal Rates

**AGENCY:** Postal Regulatory Commission.

**ACTION:** Notice.

**SUMMARY:** The Commission is noticing a recent Postal Service filing concerning change in rates not of general applicability for Inbound EMS 2. This notice informs the public of the filing, invites public comment, and takes other administrative steps.

**DATES:** *Comments are due:* August 10, 2015.

**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:

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- III. Ordering Paragraphs

#### I. Introduction

*Notice of filing.* On July 31, 2015, the Postal Service filed notice pursuant to 39 CFR 3015.5, announcing its intention to change rates not of general applicability for Inbound EMS 2 effective January 1, 2016.<sup>1</sup> The timing of the filing comports with a requirement that notice of this type of change be submitted at least 15 days before the effective date. *See* 39 CFR 3015.5.

#### II. Contents of Filing

To accompany its Notice, the Postal Service filed the following attachments:

- Attachment 1—an application for non-public treatment of materials filed under seal;
- Attachment 2A—a redacted copy of Governors' Decision No. 08–20;
- Attachment 2B—a redacted copy of Governors' Decision No. 11–6;
- Attachment 3—a redacted copy of the new rates;
- Attachment 4—a copy of the certification required under 39 CFR 3015.5(c)(2); and
- Attachment 5—the most recent annual EMS Pay-for-Performance Plan available, the most recent annual Report Card, and all available quarterly Report Cards for the calendar year preceding the effective date of the Inbound EMS 2 rates that are the subject of the filing.

Notice at 2–3.

The material filed under seal consists of unredacted copies of Governors' Decision Nos. 08–20 and 11–6, the new rates, and related financial information. *Id.* The Postal Service notes that it reserves the right to impose Inbound EMS rates reciprocally when another country's inbound EMS rates for U.S.-origin EMS shipments exceed the Postal Service's announced rates. *Id.* at 3. The Postal Service represents that it will file notice of such reciprocal rates with the Quarter 3, FY 2016 quarterly filing, once all such rates have been established. *Id.*

*Explanation of Classification and Rates.* The Notice incorporates the explanations for Inbound EMS 2

<sup>1</sup> Notice of the United States Postal Service of Filing Changes in Rates Not of General Applicability for Inbound EMS 2, July 31, 2015 (Notice).

contained in its 2009 Request, as well as other materials filed in Docket No. CP2009–57. *Id.* at 4. The Postal Service represents that those filings explain that the two-tiered rate structure for Inbound EMS 2 exists as a result of the EMS Cooperative's expectation that all of its members will participate in the Pay-for-Performance Plan. *Id.*

Further, in Docket No. CP2013–77, the Postal Service notified the Commission of a pricing separation of Tier 1 for Pay-for-Performance members into Tiers 1a and 1b. *Id.* The Postal Service states that Docket No. CP2013–77 explains that Tier 1a prices are available to EMS Cooperative members that participate in the Cooperative's Pay-for-Performance Plan, while Tier 1b offers a range of discounts from Tier 1a prices to any EMS Cooperative member that participates in the Pay-for-Performance Plan and agrees to grant a reciprocal discount from the charges for delivery of U.S.-origin EMS items in the territory served by such a member. *Id.* The Postal Service asserts that its proposal to notify the Commission of any new reciprocally discounted rates for Tier 1b as part of the routine quarterly reporting process remains consistent with the process permitted by the Commission's prior order in Docket No. CP2013–77.<sup>2</sup>

#### III. Commission Action

The Commission establishes Docket No. CP2015–117 for consideration of matters raised by the Notice.

The Commission invites comments on whether the Postal Service's filing is consistent with 39 U.S.C. 3632, or 3633, and 39 CFR part 3015. Comments are due no later than August 10, 2015. The public portions of the filing can be accessed via the Commission's Web site (<http://www.prc.gov>).

The Commission appoints Katalin K. Clendenin to serve as Public Representative in this docket.

#### IV. Ordering Paragraphs

*It is ordered:*

1. The Commission establishes Docket No. CP2015–117 for consideration of the matters raised by the Postal Service's Notice.

2. Pursuant to 39 U.S.C. 505, Katalin K. Clendenin is appointed to serve as an officer of the Commission to represent the interests of the general public in this proceeding (Public Representative).

3. Comments are due no later than August 10, 2015.

<sup>2</sup> *Id.* at 5, n.8 citing Order No. 1865, Order Granting Motion for Reconsideration of Order No. 1822, October 30, 2013.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

**Ruth Ann Abrams**,  
*Acting Secretary.*

[FR Doc. 2015-19434 Filed 8-6-15; 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:* August 7, 2015.

**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 July 31, 2015, it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Contract 139 to Competitive Product List*. Documents are available at [www.prc.gov](http://www.prc.gov), Docket Nos. MC2015-76, CP2015-120.

**Stanley F. Mires**,  
*Attorney, Federal Compliance.*

[FR Doc. 2015-19397 Filed 8-6-15; 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:* August 7, 2015.

**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 July 31, 2015,

it filed with the Postal Regulatory Commission a *Request of the United States Postal Service to Add Priority Mail Express Contract 26 to Competitive Product List*. Documents are available at [www.prc.gov](http://www.prc.gov), Docket Nos. MC2015-77, CP2015-121.

**Stanley F. Mires**,  
*Attorney, Federal Compliance.*

[FR Doc. 2015-19399 Filed 8-6-15; 8:45 am]

BILLING CODE 7710-12-P

## SECURITIES AND EXCHANGE COMMISSION

[File No. 500-1]

### In the Matter of PDK Energy, Inc.; Order of Suspension of Trading

August 5, 2015.

PDK Energy, Inc. (CIK No. 0001497126) is a Mississippi corporation located in Ann Arbor, Michigan with a class of securities registered with the Securities and Exchange Commission ("Commission") pursuant to Section 12(g) of the Securities Exchange Act of 1934 ("Exchange Act"). PDK Energy, Inc. is delinquent in its periodic filings with the Commission, having not filed any periodic reports since it filed a Form 10-Q for the period ended April 30, 2013. On January 26, 2015, the Division of Corporation Finance sent PDK Energy, Inc. a delinquency letter requesting compliance with its periodic filing obligations, but the letter was returned because of PDK Energy, Inc.'s failure to maintain a valid address on file with the Commission. As of June 16, 2015, the company's stock (symbol "PDKI") was quoted on OTC Link (previously, "Pink Sheets") operated by OTC Markets Group, Inc., had two market makers, and was eligible for the "piggyback" exception of Exchange Act Rule 15c2-11(f)(3).

It appears to the Commission that there is a lack of current and accurate information concerning the securities of PDK Energy, Inc. because it has not filed any periodic reports since its Form 10-Q for the period ended April 30, 2013. The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of PDK Energy, Inc.

Therefore, it is ordered, pursuant to Section 12(k) of the Exchange Act, that trading in the securities of PDK Energy, Inc. is suspended for the period from 9:30 a.m. EDT on August 5, 2015, through 11:59 p.m. EDT on August 18, 2015.

By the Commission.

**Brent J. Fields**,  
*Secretary.*

[FR Doc. 2015-19569 Filed 8-5-15; 11:15 am]

BILLING CODE 8011-01-P

## SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-75589; File No. SR-CFE-2015-005]

### Self-Regulatory Organizations; CBOE Futures Exchange, LLC; Notice of Proposed Rule Change Regarding Disruptive Trading Practices

August 3, 2015.

Pursuant to Section 19(b)(7) of the Securities Exchange Act of 1934 ("Act"),<sup>1</sup> notice is hereby given that on July 16, 2015 CBOE Futures Exchange, LLC ("CFE" or "Exchange") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change described in Items I, II, and III below, which Items have been prepared by CFE. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons. CFE also has filed this proposed rule change with the Commodity Futures Trading Commission ("CFTC"). CFE filed a written certification with the CFTC under Section 5c(c) of the Commodity Exchange Act ("CEA")<sup>2</sup> on July 16, 2015.

#### I. Self-Regulatory Organization's Description of the Proposed Rule Change

The Exchange proposes to amend its rules related to disruptive trading practices. The scope of this filing is limited solely to the application of the rule amendments to security futures that are permitted for trading on CFE. The only security futures that previously traded on CFE were traded under Chapter 16 of CFE's Rulebook, which is applicable to Individual Stock Based and Exchange-Traded Fund Based Volatility Index security futures. No security futures are currently listed for trading on CFE. The text of the proposed rule change is attached as Exhibit 4 to the filing but is not attached to the publication of this notice.

#### II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, CFE included statements concerning the

<sup>1</sup> 15 U.S.C. 78s(b)(7).

<sup>2</sup> 7 U.S.C. 7a-2(c).

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. CFE 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 proposed CFE rule amendments included as part of this rule change is to amend CFE Rule 620 (Disruptive Practices) and add CFE Policy and Procedure XVIII (Disruptive Trading Practices (Rule 620)) to provide further guidance on prohibited disruptive trading practices. The rule amendments included as part of this rule change are to apply to all products traded on CFE. As previously noted, no security futures are currently listed for trading on the Exchange.

CFE Rule 620 currently prohibits the disruptive practices enumerated in Section 4c(a)(5) of the CEA,<sup>3</sup> which were added to the CEA by Section 747 of the Dodd-Frank Act.<sup>4</sup> Specifically, Section 4c(a)(5) and Rule 620 prohibit any trading, practice, or conduct that "(A) violates bids or offers; (B) demonstrates intentional or reckless disregard for the orderly execution of transactions during the closing period; or (C) is, is of the character of, or is commonly known to the trade as, 'spoofing' (bidding or offering with the intent to cancel the bid or offer before execution)." Additionally, on May 28, 2013, the CFTC made effective an interpretive guidance and policy statement regarding the scope and application of these prohibitions.<sup>5</sup> The amendments amend CFE Rule 620 and add CFE Policy and Procedure XVIII to the Policies and Procedures section of the CFE Rulebook to provide greater detail regarding the type of activity that is prohibited under Rule 620.

Amendments to CFE Rule 620

The amendments add new paragraph (b) to Rule 620, which sets forth particular types of disruptive order entry and trading practices that CFE considers to be abusive to the orderly

conduct of trading or the fair execution of transactions. Specifically, the amendments add the following language as new subsection (b) to Rule 620:

(b) All Orders must be entered for the purpose of executing bona fide transactions. Additionally, all non-actionable messages must be entered in good faith for legitimate purposes.

(i) No Person shall enter or cause to be entered an Order or quote with the intent, at the time of entry, to cancel the Order or quote before execution or to modify the Order or quote to avoid execution;

(ii) No Person shall enter or cause to be entered an actionable or non-actionable message or messages with intent to mislead other market participants;

(iii) No Person shall enter or cause to be entered an actionable or non-actionable message or messages with intent to overload, delay, or disrupt the systems of the Exchange or other market participants; and

(iv) No Person shall enter or cause to be entered an actionable or non-actionable message with intent to disrupt, or with reckless disregard for the adverse impact on, the orderly conduct of trading or the fair execution of transactions.

The provisions of this Rule apply to all market states, including the pre-opening period, the closing period, and all trading sessions.

These amendments are consistent with similar rules and guidance established and provided by other designated contract markets ("DCMs") regarding disruptive practices.<sup>6</sup>

New CFE Policy and Procedure XVIII

The amendments add new CFE Policy and Procedure XVIII, which lists various factors that the Exchange may consider in assessing whether conduct violates

<sup>6</sup> These DCMs are the Chicago Mercantile Exchange, Inc. and its affiliated DCMs ("CME"), ICE Futures U.S., Inc. ("ICE") and NASDAQ Futures, Inc. ("NFX"), which each submitted self-certification rule filings to the CFTC pursuant to CFTC Regulation § 40.6(a) to effectuate their respective changes. Copies of these filings (*CME Submission No. 14-367* (August 28, 2014); *ICE Submission No. 14-144* (December 29, 2014); and *NFX Submission No. 15-16* (April 6, 2015)) may be accessed at the CFTC's Web site. CME amended its filing and submitted *CME Submission No. 14-367R* on September 12, 2014. That filing may be accessed at the CME's Web site.

The Exchange understands that there is a desire by many market participants for uniformity and consistency among DCMs to have similar rules and interpretations regarding disruptive trading practices. CFE states that this current filing closely tracks the provisions adopted by CME, ICE and NFX and deviates as needed when issues or topics addressed by the other DCMs do not apply to CFE, e.g., CFE does not have all of the same order types as some of the other DCMs.

CFE Rule 620 and provides a non-exhaustive list of examples of activity considered by CFE to be in violation of Rule 620. Specifically, the amendments provide the following as new Policy and Procedure XVIII:

Rule 620 prohibits disruptive trading practices as described by the Rule. The following are a non-exclusive list of factors that the Exchange may consider in assessing whether conduct violates Rule 620.

A. Factors the Exchange May Consider in Assessing Whether Conduct Violates Rule 620

The Exchange may consider a variety of factors in assessing whether conduct violates Rule 620, including, but not limited to:

- Whether the market participant's intent was to induce others to trade when they otherwise would not;
- whether the market participant's intent was to affect a price rather than to change the market participant's position;
- whether the market participant's intent was to create misleading market conditions;
- market conditions in the impacted market(s) and related markets;
- the effect on other market participants;
- the market participant's historical pattern of activity;
- the market participant's Order<sup>7</sup> entry and cancellation activity;
- the size of the Order(s) relative to market conditions at the time the Order(s) was placed;
- the size of the Order(s) relative to the market participant's position and/or capitalization;
- the number of Orders;
- the ability of the market participant to manage the risk associated with the Order(s) if fully executed;
- the duration for which the Order(s) is exposed to the market;
- the duration between, and frequency of, non-actionable messages;
- the queue position or priority of the Order in the order book;
- the prices of preceding and succeeding bids, offers, and trades;
- the change in the best offer price, best bid price, last sale price, or other price (such as the Expected Opening Price ("EOP")) that results from the entry of the Order; and
- the market participant's activity in related markets.

<sup>7</sup> For purposes of this Policy and Procedure, all references to Orders include Orders and quotes.

<sup>3</sup> 7 U.S.C. 6c(a)(5).

<sup>4</sup> Dodd-Frank Wall Street Reform and Consumer Protection Act, Public Law 111-203, 124 Stat. 1376, 1739, Sec. 747 (2010).

<sup>5</sup> Antidistruptive Practices Authority, 78 FR 31890 (May 28, 2013), available at <http://www.cftc.gov/ucm/groups/public/@lrfederalregister/documents/file/2013-12365a.pdf>.

#### B. Meaning of the Term “Misleading” in the Context of Rule 620(b)(ii)

The language is intended to be a more specific statement of the general requirement that market participants are not permitted to act in violation of just and equitable principles of trade. This section of the Rule prohibits a market participant from entering Orders or messages with the intent of creating the false impression of market depth or market interest. The Exchange generally will find the requisite intent where the purpose of the participant’s conduct was, for example, to induce another market participant to engage in market activity.

#### C. Specific Amount of Time an Order Should Be Exposed to the Market

Although the amount of time an Order is exposed to the market may be a factor that is considered when determining whether the Order constituted a disruptive trading practice, there is no prescribed safe harbor. The Exchange will consider a variety of factors, including exposure time, to determine whether an Order or Orders constitute a disruptive practice.

#### D. Modification or Cancellation of an Order Once it has Been Entered

An Order, entered with the intent to execute a bona fide transaction, that is subsequently modified or cancelled due to a perceived change in circumstances does not constitute a violation of Rule 620.

#### E. Orders Entered by Mistake

An unintentional, accidental, or “fat-finger” Order will not constitute a violation of Rule 620, but such activity may be a violation of other Exchange rules, including, but not limited to, Rule 608 (Acts Detrimental to the Exchange; Acts Inconsistent with Just and Equitable Principles of Trade; Abusive Practices). Market participants are expected to take steps to mitigate the occurrence of errors, and their impact on the market. This is particularly true for entities that run algorithmic trading applications, or otherwise submit large numbers of automated Orders to the market.

#### F. Partial Fill of an Order

While execution of an Order, in part or in full, may be one indication that an Order was entered in good faith, an execution does not automatically cause the Order to be considered compliant with Rule 620. Orders must be entered in an attempt to consummate a trade. A variety of factors may lead to a violative Order ultimately achieving an execution. The Exchange will consider

a multitude of factors in assessing whether Rule 620 has been violated.

#### G. Making a Two-Sided Market With Unequal Quantities (e.g., 100 Bid at 10 Offered)

Market participants are not precluded from making unequal markets as long as the Orders are entered for the purpose of executing bona fide transactions. If either (or both) Order(s) are entered with prohibited intent, including recklessness, such activity will constitute a violation of Rule 620.

#### H. Stop Limit Orders Entered for Purposes of Protecting a Position

Market participants may enter Stop Limit Orders as a means of minimizing potential losses with the hope that the Order will not be triggered. However, it must be the intent of the market participant that the Order will be executed if the specified condition is met. Such an order entry is not prohibited by this Rule.

#### I. Entering Order(s) at Various Price Levels Throughout the Order Book in Order to Gain Queue Position and Subsequently Canceling Those Orders as the Market Changes

It is understood that market participants may want to achieve queue position at certain price levels, and given changing market conditions may wish to modify or cancel those Orders. In the absence of other indicia that the Orders were entered for disruptive purposes, they would not constitute a violation of Rule 620.

#### J. “Actionable” and “non-actionable” messages in relation to rule 620(b)(ii), (iii), and (iv)

Actionable messages are messages that can be accepted by another party or otherwise lead to the execution of a trade. An example of an actionable message is an Order message. Non-actionable messages are those messages submitted to the Exchange that relate to a non-actionable event. An example of a non-actionable message is a Request for Quote.

#### K. The Exchange’s Definition of “orderly conduct of trading or the fair execution of transactions”

Whether a market participant intends to disrupt the orderly conduct of trading or the fair execution of transactions or demonstrates a reckless disregard for the orderly conduct of trading or the fair execution of transactions may be evaluated only in the context of the specific instrument, market conditions, and other circumstances present at the time in question. Some of the factors

that may be considered in determining whether there was orderly conduct or the fair execution of transactions were described by the Commission as follows: “[A]n orderly market may be characterized by, among other things, parameters such as a rational relationship between consecutive prices, a strong correlation between price changes and the volume of trades, levels of volatility that do not dramatically reduce liquidity, accurate relationships between the price of a derivative and the underlying such as a physical commodity or financial instrument, and reasonable spreads between contracts for near months and for remote months.” Antidistruptive Practices Authority, 78 FR at 31,895–96. Volatility alone, however, will not be presumptively interpreted as disorderly or disruptive as market volatility can be consistent with markets performing their price discovery function.

#### L. Entering Orders That May Be Considered Large for a Particular Market, and Thus May Have a Potential Impact on the Market

The size of an Order or cumulative Orders may be deemed to violate Rule 620 if the entry results in disorderliness in the markets, including, but not limited to, price or volume aberrations. Market participants should further be aware that the size of an Order may be deemed to violate Rule 620 if that Order distorts the integrity of the settlement prices. Accordingly, market participants should be cognizant of the market characteristics of the products they trade and ensure that their Order entry activity does not result in market disruptions. Exigent circumstances may be considered in determining whether a violation of Rule 620 has occurred and, if so, what the appropriate sanction should be for such violation.

#### M. Meaning of the “closing period” in Rule 620

“Closing period” typically refers to the period during which transactions, bids, and offers are reviewed for purposes of informing settlement price determinations.

#### N. Factors the Exchange Will Consider in Determining if an Act Was Done With the Prohibited Intent or Reckless Disregard of the Consequences

Proof of intent is not limited to instances in which a market participant admits the market participant’s state of mind. Where the conduct was such that it more likely than not was intended to produce a prohibited disruptive consequence, intent may be found. Claims of ignorance, or lack of



knowledge, are not acceptable defenses to intentional or reckless conduct. Recklessness has been commonly defined as conduct that “departs so far from the standards of ordinary care that it is very difficult to believe the actor was not aware of what he or she was doing.” See *Drexel Burnham Lambert, Inc. v. CFTC*, 850 F.2d 742, 748 (D.C. Cir. 1988).

#### O. Orders Entered for the Purpose of Ignoring Momentum in the Market

A “momentum ignition” strategy occurs when a market participant initiates a series of Orders or trades in an attempt to ignite a price movement in that market or a related market.

This conduct may be deemed to violate Rule 620 if it is determined the intent was to disrupt the orderly conduct of trading or the fair execution of transactions, if the conduct was reckless, or if the conduct distorted the integrity of the determination of settlement prices. Further, this activity may violate Rule 620(b)(i) if the momentum igniting Orders were intended to be canceled before execution, or if the Orders were intended to mislead others. If the conduct was intended to create artificially high or low prices, this may also constitute a violation of Rule 603 (Market Manipulation).

#### P. “Flipping” Orders

Flipping is defined as the entry of Orders or trades for the purpose of causing turns of the market and the creation of volatility and/or instability.

A “flip” Order typically has two main characteristics. First, it is an aggressor Order (*i.e.*, an Order that takes liquidity). Second, shortly before the entry of the Order, the market participant cancels an Order(s) on the opposite side of the market, typically at the same price as the aggressor Order. The market participant, for example, has flipped from offering to bidding at the same price. The Exchange recognizes there are many variables that can cause a market participant to change that market participant’s perspective of the market. This Rule, therefore, does not prohibit a market participant from changing that market participant’s bias from short (long) to long (short).

Flipping activity may, however, be disruptive to the marketplace. For example, repeated instances of a market participant entering flipping Orders that are each large enough to turn the market (*i.e.*, being of a sufficient quantity to sweep the entire quantity on the book at the particular price level and create a new best bid or best offer price with any remaining quantity from the aggressor

flipping Order) can be disruptive to the orderly conduct of trading or the fair execution of transactions. In considering whether this conduct violates Rule 620, the Exchange would consider, among other factors:

- The impact on other market participants;
- price fluctuations;
- market conditions in the impacted market(s) and related markets;
- the participant’s activity in related markets;
- whether the flip involved the cancellation of a large sized Order(s) relative to the existing bid or offer depth; and
- whether repeated flipping turns the market back and forth (*e.g.*, the first flip turns the market in favor of the offer (bid) and the second flip turns the market in favor of the bid (offer)).

#### Q. Cancelling an Order Via the Exchange’s Self-Trade Prevention Functionality or Other Self-Match Prevention Technology

The means by which an Order is cancelled, in and of itself, is not an indicator of whether an Order violates Rule 620. The use of self-trade prevention functionality in a manner that causes a disruption to the market may constitute a violation of Rule 620. Further, if the resting Order that was cancelled was non-bona fide *ab initio*, it would be considered to have been entered in violation of Rule 620.

#### R. Type of Pre-Open Activity Prohibited by Rule 620

Orders entered during the pre-opening period and opening rotation period must be entered for the purpose of executing bona fide transactions upon the opening of the market.

The entry and cancellation of Orders during the pre-opening period and opening rotation period for the purpose of either manipulating the EOP or attempting to identify the depth of the order book at different price levels is prohibited and may be deemed a violation of Rule 620 or other rules.

Other activity related to the pre-opening period may also be considered disruptive, including but not limited to the entry of orders prior to the commencement of the pre-opening period in an attempt to “time” the price-time priority queue for Trade at Settlement (“TAS”) transactions, or other similar purposes.

#### S. Orders Entered Into the CBOE System for the Purpose of Testing, Such as To Verify a Connection to the CBOE System or a Data Feed From the CBOE System

The entering of an Order(s) without the intent to execute a bona fide transaction, including for the purpose of verifying connectivity or checking a data feed, is not permissible. CFE provides a testing environment and test symbols in CBOE Command for TPHs to use for the purpose of testing.

#### T. Creation or Execution of User-Defined Spreads for the Purposes of Deceiving or Disadvantaging Other Market Participants

Trading Privilege Holders are not permitted to attempt to create any user-defined spreads (*i.e.*, spreads created by Trading Privilege Holders on their own) in the CBOE System. If a Trading Privilege Holder would like a type of CFE spread to be created that is not already available in the CBOE System, the Trading Privilege Holder should contact the Help Desk to request creation of the spread.

Market participants are reminded that knowingly creating and/or trading spreads in a manner intended to deceive or unfairly disadvantage other market participants is considered a violation of Rule 620.

#### U. Examples of Prohibited Activity

The following is a non-exhaustive list of various examples of conduct that may be found to violate Rule 620.

- A market participant enters one or more Orders to generate selling or buying interest in a specific contract. By entering the Orders, often in substantial size relative to the contract’s overall pending order volume, the market participant creates a misleading and artificial appearance of buy- or sell-side pressure. The market participant places these large Orders at or near the best bid and offer prevailing in the market at the time. The market participant benefits from the market’s reaction by either receiving an execution on an already resting Order on the opposite side of the book from the larger Order(s) or by obtaining an execution by entering an opposing side Order subsequent to the market’s reaction. Once the smaller Orders are filled, the market participant cancels the large Orders that had been designed to create the false appearance of market activity. Placing a bona fide Order on one side of the market while entering Order(s) on the other side of the market without intention to trade those Orders violates Rule 620.
- A market participant places buy (or sell) Orders that the market participant

intends to have executed, and then immediately enters numerous sell (or buy) Orders for the purpose of attracting interest to the resting Orders. The market participant placed these subsequent Orders to induce or trick other market participants to execute against the initial Order. Immediately after the execution against the resting Order, the market participant cancels the open Orders.

- A market participant enters one or more Orders in a particular market (Market A) to identify algorithmic activity in a related market (Market B). Knowing how the algorithm will react to order activity in Market A, the participant first enters an Order or Orders in Market B that the market participant anticipates would be filled opposite the algorithm when ignited. The participant then enters an Order or Orders in Market A for the purpose of igniting the algorithm and creating momentum in Market B. This results in the market participant's Order(s) in Market B being filled opposite the algorithm. This conduct violates Rule 620(b)(i), as the Orders in Market A were not intended to be executed, and Rule 620(b)(ii), as the Orders in Market A were intended to mislead participants in related markets. If the conduct resulted in a disruption to the orderly execution of transactions, it may also violate Rule 620(b)(iv).

- A market participant enters a large aggressor buy (sell) Order at the best offer (bid) price, trading opposite the resting sell (buy) Orders in the book, which results in the remainder of the original aggressor Order resting first in the queue at the new best bid (offer). As the market participant anticipated and intended, other participants join the market participant's best bid (offer) behind the market participant in the queue. The market participant then enters a large aggressor sell (buy) Order into the market participant's now resting buy (sell) Order at the top of the book. The market participant's use of CFE's Self-Trade Prevention functionality or other wash blocking functionality cancels the market participant's resting buy (sell) Order, such that market participant's aggressor sell (buy) Order then trades opposite the Orders that joined and were behind the market participant's best bid (offer) in the book.

- A market participant places large quantity Orders during the pre-opening period in an effort to artificially increase or decrease the EOP with the intent to attract other market participants. Once others join the market participant's bid or offer, the market participant cancels

the market participant's Orders shortly before the opening.

- During the pre-opening period, a market participant enters a large Order priced at a bid higher than the existing best bid or at an offer lower than the existing best offer, and continues to systematically enter successive Orders priced further through the book until it causes a movement in the best bid or best offer. These Orders are subsequently cancelled. The market participant continues to employ this strategy on both sides of the market for the purpose of determining the depth of support at a specific price level for the product before the market opens.

- A market participant enters a large number of messages for the purpose of overloading the quotation systems of other market participants with excessive market data messages to create "information arbitrage."

- A market participant enters messages for the purpose of creating latencies in the market or in information dissemination by the Exchange for the purpose of disrupting the orderly functioning of the market.

As with the amendments to CFE Rule 620, these amendments are consistent with similar rules and guidance established and provided by other DCMs regarding disruptive practices.<sup>8</sup>

## 2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,<sup>9</sup> in general, and furthers the objectives of Sections 6(b)(5)<sup>10</sup> and 6(b)(7)<sup>11</sup> in particular in that it is designed:

- To prevent fraudulent and manipulative acts and practices,
- to promote just and equitable principles of trade,
- to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and
- to remove impediments to and perfect the mechanism of a free and open market and a national market system, and in general, to protect investors and the public interest.

The Exchange believes that the proposed rule change would strengthen its ability to carry out its responsibilities as a self-regulatory organization by providing further guidance regarding the type of activity that is prohibited under CFE Rule 620. CFE Rule 620 currently prohibits the disruptive trading practices that were added to the

CEA by the Dodd-Frank Act and are codified under Section 4c(a)(5) of the CEA. The proposed rule change sets forth particular types of disruptive order entry and trading practices that are prohibited under Rule 620, lists various factors that the Exchange may consider in assessing whether conduct violates Rule 620, and provides a non-exhaustive list of examples of activity considered by CFE to be in violation of Rule 620. By providing this further guidance, the proposed rule change not only will provide greater clarity to market participants regarding prohibited disruptive trading practices but also will strengthen the Exchange's disciplinary program for these types of violative behavior. As a result, the Exchange believes that the proposed rule change is equitable and not unfairly discriminatory because the amendments regarding disruptive trading practices will apply equally to all market participants. In addition, the proposed rule change will promote consistency in guidance for market participants regarding disruptive trading practices by paralleling similar guidance provided by other DCMs.

### *B. Self-Regulatory Organization's Statement on Burden on Competition*

CFE does not believe that the proposed rule change will impose any burden on competition not necessary or appropriate in furtherance of the purposes of the Act, in that the rule change will enhance CFE's ability to carry out its responsibilities as a self-regulatory organization. The proposed rule change is not designed to address any aspect of competition, whether between the Exchange and its competitors, or among market participants. Instead, the proposed rule change is designed to make CFE's disruptive trading practice rules consistent with the existing rules and guidance published by other DCMs.

### *C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

No written comments were solicited or received with respect to the proposed rule change.

## **III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action**

The proposed rule change will become effective on July 30, 2015. At any time within 60 days of the date of effectiveness of the proposed rule change, the Commission, after consultation with the CFTC, may summarily abrogate the proposed rule

<sup>8</sup> See *supra* note 6.

<sup>9</sup> 15 U.S.C. 78f(b).

<sup>10</sup> 15 U.S.C. 78f(b)(5).

<sup>11</sup> 15 U.S.C. 78f(b)(7).

change and require that the proposed rule change be refiled in accordance with the provisions of Section 19(b)(1) of the Act.<sup>12</sup>

**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](mailto:rule-comments@sec.gov). Please include File Number SR-CFE-2015-005 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-CFE-2015-005. 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-CFE-2015-005, and should be submitted on or before August 28, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>13</sup>

**Robert W. Errett,**

*Deputy Secretary.*

[FR Doc. 2015-19382 Filed 8-6-15; 8:45 am]

**BILLING CODE 8011-01-P**

**SECURITIES AND EXCHANGE COMMISSION**

[File No. 500-1]

**In the Matter of Solar Acquisition Corp., Order of Suspension of Trading**

August 5, 2015.

Solar Acquisition Corp. (CIK No. 0001375495) is a Florida corporation located in Ann Arbor, Michigan with a class of securities registered with the Securities and Exchange Commission (“Commission”) pursuant to Section 12(g) of the Securities Exchange Act of 1934 (“Exchange Act”). Solar Acquisition Corp. is delinquent in its periodic filings with the Commission, having not filed any periodic reports since it filed a Form 10-K for the period ended December 31, 2012. On November 6, 2014, the Division of Corporation Finance sent Solar Acquisition Corp. a delinquency letter requesting compliance with its periodic filing obligations, but the letter was returned because of Solar Acquisition Corp.’s failure to maintain a valid address on file with the Commission. As of June 16, 2015, the company’s stock (symbol “SLRX”) was quoted on OTC Link (previously, “Pink Sheets”) operated by OTC Markets Group, Inc., had eight market makers, and was eligible for the “piggyback” exception of Exchange Act Rule 15c2-11(f)(3).

It appears to the Commission that there is a lack of current and accurate information concerning the securities of Solar Acquisition Corp. because it has not filed any periodic reports since its Form 10-K for the period ended December 31, 2012. The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of Solar Acquisition Corp.

Therefore, it is ordered, pursuant to Section 12(k) of the Exchange Act, that trading in the securities of Solar Acquisition Corp. is suspended for the period from 9:30 a.m. EDT on August 5, 2015, through 11:59 p.m. EDT on August 18, 2015.

By the Commission.

**Brent J. Fields,**

*Secretary.*

[FR Doc. 2015-19572 Filed 8-5-15; 4:15 pm]

**BILLING CODE 8011-01-P**

**SECURITIES AND EXCHANGE COMMISSION**

[Release No. 34-75588; File No. SR-FINRA-2015-026]

**Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of a Proposed Rule Change to Require an Indicator When a TRACE Report Does Not Reflect a Commission or Mark-Up/Mark-Down**

August 3, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act”) <sup>1</sup> and Rule 19b-4 thereunder, <sup>2</sup> notice is hereby given that on July 20, 2015, Financial Industry Regulatory Authority, Inc. (“FINRA”) 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 FINRA. 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**

FINRA is proposing to amend FINRA Rule 6730 (Transaction Reporting) to require an indicator when the TRACE report does not reflect a commission or mark-up/mark-down.

Below is the text of the proposed rule change. Proposed new language is in italics.<sup>3</sup>

\* \* \* \* \*

**6000. Quotation and Transaction Reporting Facilities**

\* \* \* \* \*

**6700. Trade Reporting and Compliance Engine (Trace)**

\* \* \* \* \*

**6730. Transaction Reporting**

- (a) through (b) No Change.
- (c) Transaction Information To Be Reported.

<sup>1</sup> 15 U.S.C. 78s(b)(1).

<sup>2</sup> 17 CFR 240.19b-4.

<sup>3</sup> The text of the proposed rule change reflects rule text approved by the SEC in SR-FINRA-2014-050, but which does not become effective until November 2, 2015. See Securities Exchange Act Release No. 74482 (March 11, 2015); 80 FR 13940 (March 17, 2015) (Order Approving File No. SR-FINRA-2014-050).

<sup>12</sup> 15 U.S.C. 78s(b)(1).

<sup>13</sup> 17 CFR 200.30-3(a)(73).

Each TRACE trade report shall contain the following information:

(1) through (10) No Change.

(11) The commission (total dollar amount), *if applicable*;

(12) through (13) No Change.

(d) Procedures for Reporting Price, Capacity, Volume.

(1) Price.

For principal transactions, report the price, which must include the mark-up or mark-down. (However, if a price field is not available, report the contract amount and, if applicable, the accrued interest.) For agency transactions, report the price, which must exclude the commission. (However, if a price field is not available, report the contract amount and, if applicable, the accrued interest.) Report the total dollar amount of the commission *if one is assessed on the transaction. Notwithstanding the foregoing, a member is not required to include a commission, mark-up or mark-down where one is not assessed on a trade-by-trade basis at the time of the transaction or where the amount is not known at the time the trade report is due. In all cases, a member must use the No Remuneration indicator as provided in paragraph (d)(4)(F) where a trade report does not reflect either a commission, mark-up or mark-down.*

(2) through (3) No Change.

(4) Modifiers; Indicators.

Members shall append the applicable trade report modifiers or indicators as specified by FINRA to all transaction reports.

(A) through (E) No Change.

(F) No Remuneration Indicator.

Where a trade report does not reflect either a commission, mark-up or mark-down, select the No Remuneration indicator.

(e) through (f) No Change.

• • • Supplementary Material:

.01 through .02 No Change.

\* \* \* \* \*

## II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA 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. FINRA 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

FINRA Rule 6730 (Transaction Reporting) sets forth the requirements applicable to members reporting transactions in TRACE-Eligible Securities,<sup>4</sup> and provides the specific items of information that must be included in a TRACE trade report. Among other things, Rules 6730(c) and (d) require that firms report the commission (total dollar amount) separately on the TRACE trade report for agency transactions. FINRA then combines the dollar amount that is reported as the commission with the amount that is reported in the price field, and disseminates to the market this aggregate amount as the transaction's price. For principal transactions, Rule 6730(d)(1) provides that firms must report a price that includes the mark-up/mark-down, and FINRA disseminates this price to the market. The goal of these reporting requirements is to enable FINRA to provide investors and market participants with pricing information that better reflects comparable prices for principal and agency trades in a TRACE-Eligible Security.

FINRA is proposing that firms identify those transactions for which a commission or mark-up/mark-down is not reflected in a TRACE trade report because the firm does not charge or does not know the amount of the commission or mark-up/mark-down at the time of TRACE reporting. For example, some firms may assess a charge that is not transaction-based, such as in the case of a "fee-based account" where remuneration is based upon assets under management (and individual commissions or mark-ups/mark-downs are not charged).<sup>5</sup> As a result, when the price of the transaction is publicly disseminated, there currently is no

indication to the public that the price is not inclusive of a commission or mark-up/mark-down.

By way of further example, some firms charge a commission or mark-up/mark-down, but may not know the exact amount of that commission or mark-up/mark-down at the time the TRACE transaction report is required to be submitted because of their remuneration structure (e.g., a firm may not calculate a mark-up for a transaction on a trade-by-trade basis, but will, nonetheless, ultimately assess transaction remuneration pursuant to a monthly volume-based schedule). As a result, the firm will not know the commission or mark-up/mark-down at the time of TRACE reporting.<sup>6</sup>

FINRA therefore proposes to require firms to identify such trades, and FINRA will flag these disseminated transactions as not being inclusive of remuneration.<sup>7</sup> As is the case now, the disseminated TRACE feed will not explicitly distinguish between agency and principal transactions, and the no-remuneration flag will apply to both principal and agency transactions. FINRA believes that pricing information disseminated today may be incomplete and, in some cases, misleading given that disseminated prices on transactions that do not include remuneration are not distinguished from transactions that do include a commission or mark-up/mark-down. FINRA believes that the proposal will provide more meaningful pricing transparency through TRACE by identifying those transactions where no commission or mark-up/mark-down was charged or known at the time of TRACE reporting, while not inhibiting possible firm remuneration arrangements, particularly if these arrangements benefit customers.

FINRA also believes that this proposal will enhance its regulatory audit trail

<sup>6</sup> As a practical matter, it is difficult for firms to comply with the current TRACE rules for these types of volume-based mark-up/mark-down arrangements, since firms are unable to report accurately all the required information related to the transaction on a timely basis and would need to submit a cancel and replace to update the pricing information. In some cases, this information may not be known until the end of the month. Under the proposal, members would not be required to reflect a mark-up/mark-down or commission in a TRACE trade report where the charge is not known at the time of the transaction, but would be required to report the proposed identifier.

<sup>7</sup> In addition, if a firm does not charge any remuneration associated with the trade (in any form), they would be required to identify the trade as one for which no remuneration was assessed to the transaction. FINRA notes that the MSRB has similarly proposed to require members to report an indicator that would be disseminated to identify transactions that do not include a dealer compensation component. See MSRB Regulatory Notice 2014-14 (August 13, 2014).

<sup>4</sup> Rule 6710 generally defines a "TRACE-Eligible Security" as: (1) A debt security that is U.S. dollar-denominated and issued by a U.S. or foreign private issuer (and, if a "restricted security" as defined in Securities Act Rule 144(a)(3), sold pursuant to Securities Act Rule 144A); or (2) a debt security that is U.S. dollar-denominated and issued or guaranteed by an "Agency" as defined in Rule 6710(k) or a "Government-Sponsored Enterprise" as defined in Rule 6710(n). Most transactions reported to TRACE are publicly disseminated immediately upon receipt of a transaction report.

<sup>5</sup> Another example of a fee structure that is not transaction-based is where an ATS charges subscribers a fixed fee for unlimited trading each month. The ATS could then execute trades either as principal, by acting as an intermediary in all subscriber trades, or on an agency basis, by providing the system through which subscribers' trades are executed.

and surveillance patterns. With this additional level of detail, surveillance patterns should yield fewer false positives regarding mark-up and best execution surveillance, reduce regulatory inquiries, and provide greater focus for FINRA's regulatory efforts. For example, without this designation, FINRA's surveillance patterns for best execution may generate an alert for transactions whose prices reflect a commission or a mark-up as being outliers compared to transactions whose prices do not reflect a charge.

FINRA discussed the proposal with advisory committees in developing its approach. These parties were supportive of the proposal, believing that it would improve the value of information for TRACE-Eligible Securities that is submitted to FINRA, and, by extension, to investors and market participants. With regards to effort involved in affecting the change, committee members did not express any particular concerns with respect to the operational impacts or costs of the proposal. However, as to facilitate planning and scheduling, firms specifically requested that sufficient lead-time be provided when determining the effective date of the rule. Further discussions with firms that would be directly impacted by the proposal also indicated that the proposal would be beneficial to market participants, and that the necessary technological changes would not be unduly burdensome given an adequate implementation timeframe.

If the Commission approves the proposed rule change, the proposed rule change shall be effective upon Commission approval. The implementation date will be May 23, 2016.

## 2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of Section 15A(b)(6) of the Act,<sup>8</sup> which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest, and Section 15A(b)(9) of the Act,<sup>9</sup> which requires that FINRA rules not impose any burden on competition that is not necessary or appropriate.

FINRA believes that this proposal is consistent with the Act because the additional identifier will enhance its regulatory audit trail and surveillance patterns. With this additional level of

detail, surveillance patterns should yield fewer false positives regarding mark-up and best execution surveillance, reduce regulatory inquiries, and provide greater focus for FINRA's regulatory efforts. For example, without this designation, FINRA's surveillance patterns for best execution may generate an alert for transactions whose prices reflect a commission or a mark-up as being outliers compared to transactions whose prices do not reflect a charge. FINRA also believes that the proposal will improve the information value of TRACE reports as investors and other market participants will receive additional information regarding pricing information for TRACE-Eligible Securities. Finally, FINRA believes that this proposal would permit firms additional flexibility in structuring their fee arrangements with investors, which may provide cost benefits to such investors.

### *B. Self-Regulatory Organization's Statement on Burden on Competition*

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. FINRA notes that the proposed rule change is designed to assist FINRA in meeting its regulatory obligations by enhancing its audit trail and surveillance patterns. While this proposal will require members to meet the proposed reporting obligation, ensure that they can properly ascertain transactions that require the new identifier, and update their compliance procedures and reporting protocols accordingly, FINRA notes that this proposal will apply uniformly to firms that report transactions in TRACE-Eligible Securities. FINRA also believes that this proposal will allow firms more flexibility in designing their fee structures.

As set forth above, FINRA has undertaken an economic impact assessment to further analyze, among other things, the need for the proposed rulemaking and the economic impacts of the proposed rulemaking. As discussed above, FINRA does not believe that the compliance costs associated with the proposal would be unduly burdensome given an adequate implementation timeframe.

### *Economic Impact Assessment*

FINRA has undertaken an economic impact assessment, as set forth below, to further analyze the need for the proposed rulemaking, the regulatory objective of the rulemaking, the economic baseline of analysis, and the economic impacts.

### (a) Need for the Rule

FINRA believes that pricing information disseminated today may be incomplete and, in some cases, misleading given that disseminated prices on transactions that do not include remuneration are not distinguished from transactions that do include a commission or mark-up/mark-down.

### (b) Regulatory Objective

FINRA believes that the proposal will provide more meaningful pricing transparency through TRACE by identifying those transactions where no commission or mark-up/mark-down was charged or known at the time of TRACE reporting, while not inhibiting possible firm fee remuneration arrangements, particularly if these fee arrangements benefit customers. FINRA also believes that the additional identifier will enhance its regulatory audit trail and surveillance patterns, because it will require the firm to affirmatively report this information related to the commission or mark-up/mark-down and will enable FINRA to more efficiently separate out no-remuneration trades for purposes of surveillance, analysis, and dissemination.

### (c) Economic Baseline

The staff analyzed corporate bond transactions reported to TRACE in Q3 2013.<sup>10</sup> Transactions where the broker-dealer acts in an agency capacity are reported to TRACE with a separate field for commission. FINRA can therefore accurately identify agency-capacity transactions reported without a commission.<sup>11</sup> In contrast, for transactions where the broker-dealer acts in a principal capacity, the mark-up or mark-down is included in the reported price. It was necessary for the staff to pair a broker-dealer's buy and

<sup>10</sup> For purposes of this analysis, FINRA used data reported to TRACE (not the TRACE-disseminated data). Although the TRACE-disseminated data includes a flag (Y or blank) that identifies whether a commission is included in the disseminated price, the data does not specify in what capacity the dealer acted in the transaction. As such, an agency transaction without a commission, e.g., the commission flag is blank, would look the same on the TRACE-disseminated data as a principal transaction with or without a mark-up/mark-down.

Corporate bond transactions represented approximately 73% of all transactions reported to TRACE in 2013.

<sup>11</sup> Although FINRA is currently able to accurately identify agency-capacity transactions that are reported without a commission, this process requires FINRA to match trades where the commission field is blank with trades where the dealer acted as agent. With the no-remuneration flag, the firm will be required to affirmatively report this information related to the commission or mark-up/mark-down, and FINRA will be able to more efficiently identify such trades.

<sup>8</sup> 15 U.S.C. 78o-3(b)(6).

<sup>9</sup> 15 U.S.C. 78o-3(b)(9).

sell principal-capacity transactions of equal sizes in a given security on a given day to estimate the mark-ups or mark-downs on the customer transactions.<sup>12</sup>

During Q3 2013, the daily average number of agency-capacity transactions in corporate bonds was 9,100.<sup>13</sup> Approximately 55% of agency-capacity transactions in corporate bonds were customer transactions. Based on the

data, the staff estimated that approximately 85% of Investment Grade corporate bond customer transactions where the broker-dealer acted in an agency capacity were reported without a commission. For Non-Investment Grade and unrated corporate bonds, the proportions were 74% and 92%, respectively. Such transactions may have been executed for fee-based accounts or other accounts where firm

remuneration was not determined on a per-transaction basis. For the agency-capacity customer transactions reported with commissions, the table below summarizes the average commission charged for agency-capacity customer buy and customer sell transactions in Investment Grade, Non-Investment Grade and Unrated securities over the quarter.

	Average commission (in basis points)		
	Investment grade	Non-Investment grade	Unrated
Customer Buy .....	18	21	21
Customer Sell .....	21	20	32

During Q3 2013, the daily average number of principal-capacity transactions in corporate bonds was just under 48,000.<sup>14</sup> Approximately 45% of principal-capacity transactions in corporate bonds were customer transactions. Using the previously

described pairing methodology, the staff estimated that 19% of these customer transactions were reported to have been executed without a mark-up or mark-down. For the principal-capacity customer transactions estimated to include mark-ups or mark-downs, the

table below summarizes the estimated average remuneration charged for principal-capacity customer buy and customer sell transactions in Investment Grade, Non-Investment Grade and Unrated securities in the quarter.

	Average mark-up/mark-down (in basis points)		
	Investment grade	Non-investment grade	Unrated
Customer Buy .....	75	66	73
Customer Sell .....	50	78	60

(d) Economic Impacts

FINRA believes that the proposal will enable market participants, including investors relying on TRACE for valuation information, to better understand the prevailing market prices by being able to distinguish between transactions that include remuneration and those that do not. As discussed above, FINRA further believes that the additional identifier will enhance its regulatory audit trail and surveillance patterns. With this additional level of detail, surveillance patterns should yield fewer false positives regarding mark-up and best execution surveillance, reduce regulatory inquiries, and provide greater focus for FINRA's regulatory efforts. For example, without this designation, FINRA's surveillance patterns for best execution may generate an alert for transactions whose prices reflect a commission or a mark-up as being outliers compared to

transactions whose prices do not reflect a charge.

The proposal will require member firms to meet the proposed reporting obligation, ensure that they can properly ascertain transactions that require the new identifier, and update their compliance procedures and reporting protocols accordingly. Member firms would also need to make technological changes to their systems to include the identifier. Based on discussions with advisory committees and member firms, FINRA does not believe that the compliance costs associated with the proposal would be unduly burdensome given an adequate implementation timeframe.

*C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others*

Written comments were neither solicited nor received.

**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.

<sup>12</sup> FINRA recognizes that any pairing methodology adopted requires assumptions as part of that methodology. Further, there is not a unique set of assumptions that reasonable parties might all choose to adopt if they were to go through a similar exercise. As a result, FINRA provides results of this

methodology as part of the baseline in order to inform the discussion of potential regulatory impacts.

<sup>13</sup> This excludes List or Fixed Offering Price Transactions, as defined in FINRA Rule 6710(q),

and Takedown Transactions as defined in FINRA Rule 6710(r).

<sup>14</sup> This excludes List or Fixed Offering Price Transactions, as defined in FINRA Rule 6710(q), and Takedown Transactions as defined in FINRA Rule 6710(r).

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](mailto:rule-comments@sec.gov). Please include File Number SR-FINRA-2015-026 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-FINRA-2015-026. 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 FINRA. 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-FINRA-2015-026 and should be submitted on or before August 28, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.<sup>15</sup>

**Robert W. Errett,**

*Deputy Secretary.*

[FR Doc. 2015-19381 Filed 8-6-15; 8:45 am]

**BILLING CODE 8011-01-P**

**SECURITIES AND EXCHANGE COMMISSION**

[Release No. IC-31732]

**Notice of Applications for Deregistration Under Section 8(f) of the Investment Company Act of 1940**

July 31, 2015.

The following is a notice of applications for deregistration under section 8(f) of the Investment Company Act of 1940 for the month of July 2015. A copy of each 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. An order granting each application will be issued unless the SEC orders a hearing. Interested persons may request a hearing on any application by writing to the SEC's Secretary at the address below and serving the relevant applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on August 25, 2015, 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:** The Commission: Brent J. Fields, Secretary, U.S. Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

**FOR FURTHER INFORMATION CONTACT:** Diane L. Titus at (202) 551-6810, SEC, Division of Investment Management, Chief Counsel's Office, 100 F Street NE., Washington, DC 20549-8010.

**Dow 30 Premium & Dividend Income Fund Inc. [File No. 811-21708]**

**Dow 30 Enhanced Premium & Income Fund Inc. [File No. 811-22029]**

*Summary:* Each applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicants transferred their assets to Nuveen Dow 30sm Dynamic Overwrite Fund, and on December 22, 2014, made distributions to their shareholders based on net asset value. Expenses of \$536,640 incurred in connection with the reorganization were paid by applicants.

*Filing Date:* The applications were filed on June 26, 2015.

*Applicants' Address:* 333 West Wacker Dr., Chicago, IL 60606.

**Encompass Funds [File No. 811-21885]**

*Summary:* Applicant seeks an order declaring that it has ceased to be an investment company. On May 29, 2015, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses of \$14,433 incurred in connection with the liquidation were paid by Brick Asset Management, Inc., applicant's investment adviser.

*Filing Date:* The application was filed on July 17, 2015.

*Applicant's Address:* 1700 California St., Ste. 335, San Francisco, CA 94109.

**KKR Series Trust [File No. 811-22720]**

*Summary:* Applicant seeks an order declaring that it has ceased to be an investment company. On March 31, 2014, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses in connection with the liquidation were paid by KKR Credit Advisors (US) LLC, applicant's investment adviser.

*Filing Date:* The application was filed on July 17, 2015.

*Applicant's Address:* 555 California St., 50th Floor, San Francisco, CA 94104.

**BlackRock MuniYield New Jersey Quality Fund, Inc. [File No. 811-7138]**

*Summary:* Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant transferred its assets to BlackRock MuniHoldings New Jersey Quality Fund, Inc. on July 13, 2015. Expenses of \$310,020 incurred in connection with the reorganization were paid by applicant and BlackRock Advisors, LLC, applicant's investment adviser.

*Filing Date:* The application was filed on July 9, 2015.

*Applicant's Address:* 100 Bellevue Parkway, Wilmington, DE 19809.

**John Hancock Tax-Exempt Series Fund [File No. 811-5079]**

*Summary:* Applicant seeks an order declaring that it has ceased to be an investment company. Applicant transferred its assets to John Hancock Tax-Free Bond Fund, a series of John Hancock Municipal Securities Trust, and on February 13, 2015, made distributions to its shareholders based on net asset value. Expenses of \$201,891 incurred in connection with the reorganization were paid by applicant and John Hancock Advisers, LLC, applicant's investment adviser.

<sup>15</sup> 17 CFR 200.30-3(a)(12).

*Filing Date:* The application was filed on July 7, 2015.

*Applicant's Address:* 601 Congress St., Boston, MA 02210-2805.

**ACP Strategic Opportunities Fund II LLC [File No. 811-21031]**

**ACP Funds Trust [File No. 811-21324]**

*Summary:* Each applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On May 21, 2015, applicants made their final liquidating distributions to their shareholders, based on net asset value. Applicants incurred no expenses in connection with the liquidations.

*Filing Date:* The applications were filed on July 17, 2015.

*Applicants' Address:* Ascendant Capital Partners LP, C/O Barlow Partners, 880 Third Ave., 3rd Floor, New York, NY 10022.

**Nuveen Massachusetts Dividend Advantage Municipal Fund [File No. 811-9451]**

**Nuveen Massachusetts AMT-Free Municipal Income Fund [File No. 811-21216]**

*Summary:* Each applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicants transferred their assets to Nuveen Massachusetts Premium Income Municipal Fund, and on June 9, 2014, made distributions to their shareholders based on net asset value. Expenses of approximately \$497,000 incurred in connection with reorganizations were paid by applicants and the acquiring fund.

*Filing Date:* The applications were filed on June 26, 2015.

*Applicants' Address:* 333 West Wacker Dr., Chicago, IL 60606.

**Nuveen Global Income Opportunities Fund [File No. 811-21893]**

**Nuveen Diversified Currency Opportunities Fund [File No. 811-22018]**

*Summary:* Each applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicants transferred their assets to Nuveen Global High Income Fund, and on November 24, 2014, made distributions to their shareholders based on net asset value. Expenses of \$763,852 incurred in connection with the reorganizations were paid by applicants.

*Filing Date:* The applications were filed on June 26, 2015.

*Applicants' Address:* 333 West Wacker Dr., Chicago, IL 60606.

**Nuveen Equity Premium Advantage Fund [File No. 811-21731]**

**NASDAQ Premium Income & Growth Fund Inc. [File No. 811-21983]**

*Summary:* Each applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicants transferred their assets to Nuveen NASDAQ 100 Dynamic Overwrite Fund, and on December 22, 2014, made distributions to their shareholders based on net asset value. Expenses of \$528,102 incurred in connection with the reorganizations were paid by applicants.

*Filing Date:* The applications were filed on June 26, 2015.

*Applicants' Address:* 333 West Wacker Dr., Chicago, IL 60606.

**Nuveen New Jersey Investment Quality Municipal Fund Inc. [File No. 811-6264]**

**Nuveen New Jersey Premium Income Municipal Fund Inc. [File No. 811-7118]**

**Nuveen New Jersey Dividend Advantage Municipal Fund 2 [File No. 811-10551]**

*Summary:* Each applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicants transferred their assets to Nuveen New Jersey Dividend Advantage Municipal Fund, and on November 10, 2014, made distributions to their shareholders based on net asset value. Expenses of approximately \$1,242,000 incurred in connection with the reorganizations were paid by applicants, the acquiring fund and Nuveen Fund Advisors, LLC, applicants' investment adviser.

*Filing Date:* The applications were filed on June 26, 2015.

*Applicants' Address:* 333 West Wacker Dr., Chicago, IL 60606.

**Nuveen Pennsylvania Premium Income Municipal Fund 2 [File No. 811-7482]**

**Nuveen Pennsylvania Dividend Advantage Municipal Fund [File No. 811-9457]**

**Nuveen Pennsylvania Dividend Advantage Municipal Fund 2 [File No. 811-10549]**

*Summary:* Each applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicants transferred their assets to Nuveen Pennsylvania Investment Quality Municipal Fund, and on February 10, 2014, transferred their assets to their shareholders based on net asset value. Expenses of approximately \$1,166,000

incurred in connection with the reorganization were paid by applicants and the acquiring fund.

*Filing Date:* The applications were filed on June 26, 2015.

*Applicants' Address:* 333 West Wacker Dr., Chicago, IL 60606.

**Nuveen California Performance Plus Municipal Fund Inc. [File No. 811-5930]**

**Nuveen California Municipal Market Opportunity Fund Inc. [File No. 811-6081]**

**Nuveen California Investment Quality Municipal Fund Inc. [File No. 811-6177]**

**Nuveen California Select Quality Municipal Fund Inc. [File No. 811-6294]**

**Nuveen California Quality Income Municipal Fund Inc. [File No. 811-6425]**

*Summary:* Each applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicants transferred their assets to Nuveen California Dividend Advantage Municipal Fund, and on June 9, 2014, made distributions to their shareholders based on net asset value. Expenses of \$1,931,348 incurred in connection with the reorganizations were paid by applicants and the acquiring fund.

*Filing Date:* The applications were filed on June 26, 2015.

*Applicant's Address:* 333 West Wacker Dr., Chicago, IL 60606.

**Putnam Limited Duration Government Income Fund [File No. 811-6257]**

*Summary:* Applicant seeks an order declaring that it has ceased to be an investment company. Applicant transferred its assets to Putnam U.S. Government Income Trust, and on November 12, 2007, made distributions to its shareholders based on net asset value. Expenses of approximately \$324,064 incurred in connection with the reorganization were paid by applicant and the acquiring fund.

*Filing Date:* The application was filed on July 22, 2015.

*Applicant's Address:* One Post Office Square, Boston, MA 02109.

**Cantor Opportunistic Alternatives Fund, LLC [File No. 811-21943]**

*Summary:* Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. On March 29, 2015, applicant made a liquidating distribution to its shareholders, based on net asset value. Expenses of \$2,625



incurred in connection with the liquidation were paid by Cantor Fitzgerald Investment Advisors, L.P., applicant's investment adviser.

*Filing Dates:* The application was filed on April 23, 2015, and amended on July 22, 2015.

*Applicant's Address:* 110 East 59th St., New York, NY 10022.

**Sentry Variable Account I [File No. 811-3901]**

*Summary:* Applicant, a unit investment trust, seeks an order declaring that it has ceased to be an investment company. On April 17, 2015, applicant made a final liquidating distribution to its unit holders, based on net asset value. Applicant incurred no expenses in connection with the liquidation.

*Filing Dates:* The application was filed on June 16, 2015, and amended on July 16, 2015.

*Applicant's Address:* 220 Salina Meadows Parkway, Suite 255, Syracuse, NY 13212.

**Nuveen California Premium Income Municipal Fund [File No. 811-7720]**

*Summary:* Applicant, a closed-end investment company, seeks an order declaring that it has ceased to be an investment company. Applicant transferred its assets to Nuveen California AMT-Free Municipal Income Fund, and on June 9, 2014, made a distribution to its shareholders based on net asset value. Expenses of \$589,639 incurred in connection with the reorganization were paid by applicant and the acquiring fund.

*Filing Date:* The application was filed on June 26, 2015.

*Applicant's Address:* 333 West Wacker Dr., Chicago, IL 60606.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

**Robert W. Errett,**  
*Deputy Secretary.*

[FR Doc. 2015-19383 Filed 8-6-15; 8:45 am]

**BILLING CODE 8011-01-P**

**SMALL BUSINESS ADMINISTRATION**

**[Disaster Declaration #14399 and #14400]**

**South Dakota Disaster #SD-00068**

**AGENCY:** U.S. Small Business Administration.

**ACTION:** Notice.

**SUMMARY:** This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of South Dakota (FEMA-4233-DR), dated 07/30/2015.

*Incident:* Severe storms, tornadoes, straight-line winds, and flooding.

*Incident Period:* 06/17/2015 through 06/24/2015.

*Effective Date:* 07/30/2015.

*Physical Loan Application Deadline Date:* 09/28/2015.

*Economic Injury (EIDL) Loan Application Deadline Date:* 05/02/2016.

**ADDRESSES:** Submit completed loan applications to: U.S. Small Business Administration Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

**FOR FURTHER INFORMATION CONTACT:**

A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that as a result of the President's major disaster declaration on 07/30/2015, Private Non-Profit organizations that provide essential services of governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

**Primary Counties:**

Brule, Buffalo, Fall River, Haakon, Hughes, Jackson, Jerauld, Jones, Lyman, Mccook, Oglala, Lakota, Stanley, Crow Creek Sioux Tribe, Lower Brule Sioux Tribe, Oglala Sioux Tribe Within Oglala Lokota County

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Non-Profit Organizations with Credit Available Elsewhere ...	2.625
Non-Profit Organizations without Credit Available Elsewhere .....	2.625
<i>For Economic Injury:</i>	
Non-Profit Organizations without Credit Available Elsewhere .....	2.625

The number assigned to this disaster for physical damage is 14399B and for economic injury is 14400B. (Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

**Joseph P Loddio,**

*Acting Associate Administrator for Disaster Assistance.*

[FR Doc. 2015-19424 Filed 8-6-15; 8:45 am]

**BILLING CODE 8025-01-P**

**SMALL BUSINESS ADMINISTRATION**

**[Disaster Declaration #14397 and #14398]**

**Vermont Disaster #VT-00016**

**AGENCY:** U.S. Small Business Administration.

**ACTION:** Notice.

**SUMMARY:** This is a Notice of the Presidential declaration of a major disaster for Public Assistance Only for the State of Vermont (FEMA-4232-DR), dated 07/29/2015.

*Incident:* Severe storm and flooding.

*Incident Period:* 06/09/2015.

**DATES:**

*Effective Date:* 07/29/2015.

*Physical Loan Application Deadline Date:* 09/28/2015.

*Economic Injury (EIDL) Loan Application Deadline Date:* 04/29/2016.

**ADDRESSES:** Submit completed loan applications to: U.S. Small Business Administration, Processing And Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

**FOR FURTHER INFORMATION CONTACT:** A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that as a result of the President's major disaster declaration on 07/29/2015, Private Non-Profit organizations that provide essential services of governmental nature may file disaster loan applications at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

*Primary Counties:* Addison, Chittenden.

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Non-Profit Organizations With Credit Available Elsewhere ...	2.625
Non-Profit Organizations Without Credit Available Elsewhere .....	2.625
<i>For Economic Injury:</i>	
Non-Profit Organizations without Credit Available Elsewhere .....	2.625

The number assigned to this disaster for physical damage is 14397B and for economic injury is 14398B.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

**James E. Rivera,**

*Associate Administrator for Disaster Assistance.*

[FR Doc. 2015-19412 Filed 8-6-15; 8:45 am]

**BILLING CODE 8025-01-P**

**SMALL BUSINESS ADMINISTRATION**

**National Women’s Business Council; Quarterly Public Meeting**

**AGENCY:** National Women’s Business Council.

**ACTION:** Notice of open Public Meeting.

**SUMMARY:** The U.S. Small Business Administration (SBA) announces the meeting of the National Women’s Business Council.

**DATES:** The meeting will be held on September 11th, 2015 from 2:00 p.m. to 4:00 p.m. EST.

**ADDRESSES:** The meeting will take place virtually via webconference.

**SUPPLEMENTARY INFORMATION:** Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C., Appendix 2), the U.S. Small Business Administration (SBA) announces the meeting of the National Women’s Business Council. The National Women’s Business Council is tasked with providing policy recommendations on issues of importance and impact to women entrepreneurs to the SBA, Congress, and the White House.

The business portion will include remarks from the Council Chair, Carla Harris; an update from each of the NWBC committees on recent activities and research on women business owners; and a preview of the policy recommendations that the Council will be making to the SBA, Congress, and the White House for improving the business climate for women entrepreneurs, as well as the new research portfolio. The second half of the program will include a panel discussion related to the Council’s Access to Capital body of work. The panel will feature women influencers discussing the lack of women in venture capital generally and the potential policy implications.

**FOR FURTHER INFORMATION CONTACT:** The meeting is open to the public however advance notice of attendance is requested. To RSVP and confirm attendance, the general public should email [info@nwbc.gov](mailto:info@nwbc.gov) with subject line—“RSVP-Public Meeting.” Anyone wishing to make a presentation to the NWBC at this meeting must either email their interest to [info@nwbc.gov](mailto:info@nwbc.gov) or call the main office number at 202-205-3850.

For more information, please visit the National Women’s Business Council Web site at [www.nwbc.gov](http://www.nwbc.gov).

**Miguel J. L’Heureux,**

*SBA Committee Management Officer.*

[FR Doc. 2015-19410 Filed 8-6-15; 8:45 am]

**BILLING CODE P**

**SMALL BUSINESS ADMINISTRATION**

**[Disaster Declaration #14391 and #14392]**

**Louisiana Disaster #LA-00054**

**AGENCY:** U.S. Small Business Administration.

**ACTION:** Notice.

**SUMMARY:** This is a notice of an Administrative declaration of a disaster for the State of Louisiana dated 07/29/2015.

*Incident:* Red River Flooding.  
*Incident Period:* 05/18/2015 through 06/20/2015.

**EFFECTIVE DATE:** 07/29/2015.

*Physical Loan Application Deadline Date:* 09/28/2015.

*Economic Injury (EIDL) Loan Application Deadline Date:* 04/29/2016.

**ADDRESSES:** Submit completed loan applications to: U.S. Small Business Administration, Processing and Disbursement Center, 14925 Kingsport Road, Fort Worth, TX 76155.

**FOR FURTHER INFORMATION CONTACT:** A. Escobar, Office of Disaster Assistance, U.S. Small Business Administration, 409 3rd Street SW., Suite 6050, Washington, DC 20416.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given that as a result of the Administrator’s disaster declaration, applications for disaster loans may be filed at the address listed above or other locally announced locations.

The following areas have been determined to be adversely affected by the disaster:

*Primary Counties:* Caddo.

*Contiguous Counties:*

Louisiana: Bossier, De Soto, Red River.

Arkansas: Lafayette, Miller.

Texas: Cass, Harrison, Marion, Panola.

The Interest Rates are:

	Percent
<i>For Physical Damage:</i>	
Homeowners With Credit Available Elsewhere .....	3.375
Homeowners Without Credit Available Elsewhere .....	1.688
Businesses With Credit Available Elsewhere .....	6.000
Businesses Without Credit Available Elsewhere .....	4.000

	Percent
Non-Profit Organizations With Credit Available Elsewhere ...	2.625
Non-Profit Organizations Without Credit Available Elsewhere .....	2.625
<i>For Economic Injury:</i>	
Businesses & Small Agricultural Cooperatives Without Credit Available Elsewhere .....	4.000
Non-Profit Organizations Without Credit Available Elsewhere .....	2.625

The number assigned to this disaster for physical damage is 14391 6 and for economic injury is 14392 0.

The States which received an EIDL Declaration # are Louisiana, Arkansas, Texas.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

Dated: July 29, 2015.

**Maria Contreras-Sweet,**  
*Administrator.*

[FR Doc. 2015-19411 Filed 8-6-15; 8:45 am]

**BILLING CODE 8025-01-P**

**SOCIAL SECURITY ADMINISTRATION**

**[Docket No. SSA-2015-0026]**

**Modifications to the Disability Determination Procedures; Extension of Testing of Some Disability Redesign Features**

**AGENCY:** Social Security Administration.

**ACTION:** Notice of the extension of tests involving modifications to the disability determination procedures.

**SUMMARY:** We are announcing the extension of tests involving modifications to disability determination procedures authorized by 20 CFR 404.906 and 416.1406. These rules authorize us to test several modifications to the disability determination procedures for adjudicating claims for disability insurance benefits under title II of the Social Security Act (Act) and for supplemental security income payments based on disability under title XVI of the Act.

**DATES:** We are extending our selection of cases to be included in these tests from September 25, 2015 until no later than September 23, 2016. If we decide to continue selection of cases for these tests beyond this date, we will publish another notice in the **Federal Register**.

**FOR FURTHER INFORMATION CONTACT:** Kenneth Williams, Office of Disability Policy, Social Security Administration, 6401 Security Boulevard, Baltimore, MD

21235–6401, (410) 965–0608, for information about this notice. For information on eligibility or filing for benefits, call our national toll-free number, 1–800–772–1213 or TTY 1–800–325–0778, or visit our Internet site, Social Security Online, at <http://www.socialsecurity.gov>.

**SUPPLEMENTARY INFORMATION:** Our current rules authorize us to test, individually or in any combination, certain modifications to the disability determination procedures. 20 CFR 404.906 and 416.1406. We conducted several tests under the authority of these rules. In the “single decisionmaker” test, a disability examiner may make the initial disability determination in most cases without obtaining the signature of a medical or psychological consultant.

We also conducted a separate test, which we call the “prototype,” in 10 States. 64 FR 47218. Currently, the prototype combines the single decisionmaker approach described above with the elimination of the reconsideration level of our administrative review process.

We extended the period for selecting claims for these tests several times. Most recently, we extended the time from September 26, 2014 to September 25, 2015. 79 FR 39453. We are extending case selection for the prototype and the single decisionmaker tests until September 23, 2016. If we decide to continue selection of cases for these tests beyond this date, we will publish another notice in the **Federal Register**.

**Virginia Reno,**

*Deputy Commissioner for Retirement and Disability Policy.*

[FR Doc. 2015–19460 Filed 8–6–15; 8:45 am]

**BILLING CODE 4191–02–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

[Summary Notice No. 2015–48]

#### Petition for Exemption; Summary of Petition Received; Insitu, Inc.

**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 August 27, 2015.

**ADDRESSES:** Send comments identified by docket number FAA–2015–2904 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:**

Thuy H. Cooper (202) 267–4715 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 August 4, 2015.

**Lirio Liu,**

*Director, Office of Rulemaking.*

#### Petition For Exemption

**Docket No.:** FAA–2015–2904

**Petitioner:** Insitu, Inc. (a subsidiary of The Boeing Company)

**Section(s) of 14 CFR Affected:** 91.215(a)

**Description of Relief Sought:** The petitioner seeks an exemption to use a Sagetech XPC transponder that does not possess a Technical Standard Order. Allowing the ScanEagle X200 aircraft to use the Sagetech XPC transponder will increase the operational safety of the proposed beyond visual-line-of-sight (BVLOS) flight operations in central, eastern New Mexico: an area bounded by Clovis, NM and Belin, NM.

[FR Doc. 2015–19413 Filed 8–6–15; 8:45 am]

**BILLING CODE 4910–13–P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### Notice of Intent To Release Certain Properties From all Terms, Conditions, Reservations and Restrictions of a Quitclaim Deed Agreement Between the City of Zephyrhills and the Federal Aviation Administration for the Zephyrhills Municipal Airport, Zephyrhills, FL

**AGENCY:** Federal Aviation Administration (FAA), DOT.

**ACTION:** Request for public comment.

**SUMMARY:** The FAA hereby provides notice of intent to release approximately 3.99 acres at the Zephyrhills Municipal Airport, Zephyrhills, FL from the conditions, reservations, and restrictions as contained in a Quitclaim Deed agreement between the FAA and the City of Zephyrhills, dated May 15, 1947. The release of property will allow the City of Zephyrhills to dispose of the property for other than aeronautical purposes. The property is located on the northeast corner of airport property at 39301 South Avenue, Zephyrhills, FL 33647. The parcel is currently designated as non-aeronautical use. The property will be released of its federal obligations for industrial purposes. The fair market value of this parcel has been determined to be \$200,000.

Documents reflecting the Sponsor’s request are available, by appointment only, for inspection at the Zephyrhills Municipal Airport and the FAA Airports District Office.

**DATES:** Comments are due on or before September 8, 2015.

**ADDRESSES:** Documents are available for review at the Zephyrhills Municipal Airport, and the FAA Airports District Office, 5950 Hazeltime National Drive, Suite 400, Orlando, FL 32822. Written comments on the Sponsor’s request must be delivered or mailed to: Marisol C. Elliott, Program Manager, Orlando Airports District Office, 5950 Hazeltime

National Drive, Suite 400, Orlando, FL 32822-5024.

**FOR FURTHER INFORMATION CONTACT:**

Marisol C. Elliott, Program Manager, Orlando Airports District Office, 5950 Hazeltine National Drive, Suite 400, Orlando, FL 32822-5024.

**SUPPLEMENTARY INFORMATION:** Section 125 of The Wendell H. Ford Aviation Investment and Reform Act for the 21st Century (AIR-21) requires the FAA to provide an opportunity for public notice and comment prior to the “waiver” or “modification” of a sponsor’s Federal obligation to use certain airport land for non-aeronautical purposes.

Issued in Orlando, Florida on July 31, 2015.

**Rebecca R. Henry,**

*Acting Manager, Orlando Airports District Office Southern Region.*

[FR Doc. 2015-19473 Filed 8-6-15; 8:45 a.m.]

**BILLING CODE 4910-13-P**

**DEPARTMENT OF TRANSPORTATION**

**National Highway Traffic Safety Administration**

**Reports, Forms, and Record Keeping Requirements Agency Information Collection Activity Under OMB Review**

**AGENCY:** National Highway Traffic Safety Administration (NHTSA), U.S. Department of Transportation (DOT).

**ACTION:** Notice

**SUMMARY:** In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), this notice announces that the Information Collection Request (ICR) abstracted below has been forwarded to the Office of Management and Budget (OMB) for review and comment. The ICR describes the nature of the information collection and its expected burden. The **Federal Register** Notice with a 60-day comment period soliciting public comments was published on March 25, 2015 (**Federal Register**/Vol. 80, No. 57/pp. 15866-15867).

**DATES:** Comments must be submitted on or before September 8, 2015.

**ADDRESSES:** Send comments, within 30 days, to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725-17th Street NW., Washington, DC 20503, Attention NHTSA Desk Officer.

**FOR FURTHER INFORMATION CONTACT:** Dr. Kathy Sifrit, 202-366-0868.

**SUPPLEMENTARY INFORMATION:**

*Title:* Older Drivers’ Self-Regulation and Exposure.

*Type of Request:* New information collection requirement.

*Abstract:* Research has shown that drivers 75 and over have a crash rate nearly double that of drivers between the ages of 25 and 65. In addition to increased crash rates, older drivers are also more likely to be killed in automobile crashes when compared to younger age groups. Some research showed that drivers aged 75 to 79 were 3.5 times more likely to be killed in an automobile crash than drivers 30 to 65 years of age. This ratio jumped to 9.5 after age 80. Factors such as declining cognitive and motor skills may help explain these older driver crash statistics. Some older drivers may attempt to offset any functional declines by adopting compensatory or self-regulatory behaviors (e.g., slowing down, braking earlier, limiting conditions or times of day in which they drive, and/or voluntarily giving up driving).

This research effort is focused on determining how much older drivers self-regulate their driving through changes in behaviors or by reducing exposure. The project involves an initial questionnaire collecting information from licensed drivers about their age, driver license status, driving habits, vehicle type and age, and the extent to which they self-limit their driving exposure. The project plans to recruit a total of 60 participants, 20 of whom are 60-69, 20 who are 70-79, and 20 who are 80+ years of age. Staff will attempt to recruit equal numbers of males and females in each age group and to distribute the ages across each interval. Qualifying participants will have a tracking device installed in the vehicle for approximately 30 days. The device will record all trips made by the participant. At the end of the 30-day tracking period, each participant will be asked to take a battery of standard clinical functional measures and complete an on-road driving assessment administered by a certified driving rehabilitation specialist. Researchers will examine the driving behaviors of participants based on age group and other covariates collected during the initial questionnaire and assessments.

The results of this project will assist NHTSA in determining the relative extent to which older drivers appear to be aware of their cognitive and motor skill deterioration, and whether their perception of declining ability was affecting driving behaviors and exposure.

*Affected Public:* Participants will include 60 licensed drivers who drive a minimum of 3 trips per week, 20 of

whom are 60-69, 20 who are 70-79, and 20 who are 80+ years of age.

*Estimated Total Annual Burden:* 120 hours maximum.

Comments are invited on the following:

(i) 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) the accuracy of the Department’s estimate of the burden of the proposed information collection;

(iii) ways to enhance the quality, utility and clarity of the information to be collected; and

(iv) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

A comment to OMB is most effective if OMB receives it within 30 days of publication of this notice.

**Authority:** 44 U.S.C. Section 3506(c)(2)(A).

Issued on: August 4, 2015.

**Jeff Michael,**

*Associate Administrator, Research and Program Development.*

[FR Doc. 2015-19453 Filed 8-6-15; 8:45 am]

**BILLING CODE 4910-59-P**

**DEPARTMENT OF TRANSPORTATION**

**National Highway Traffic Safety Administration**

[Docket No. NHTSA-2015-0022; Notice 1]

**Notice of Receipt of Petition for Decision That Nonconforming Model Year 2006 Ferrari 612 Scagletti Passenger Cars Manufactured Before September 1, 2006 Are Eligible for Importation**

**AGENCY:** National Highway Traffic Safety Administration, DOT.

**ACTION:** Receipt of petition.

**SUMMARY:** This document announces receipt by the National Highway Traffic Safety Administration (NHTSA) of a petition for a decision that nonconforming model year (MY) 2006 Ferrari 612 Scagletti passenger cars (PC) manufactured before September 1, 2006 that were not originally manufactured to comply with all applicable Federal motor vehicle safety standards (FMVSS), are eligible for importation into the United States because they are substantially similar to vehicles that were originally manufactured for sale in the United States and that were certified by their manufacturer as complying with the safety standards (the U.S.-

certified version of the MY 2006 Ferrari 612 Scagletti PC manufactured before September 1, 2006) and they are capable of being readily altered to conform to the standards.

**DATES:** The closing date for comments on the petition is September 8, 2015.

**ADDRESSES:** Comments should refer to the docket and notice numbers above and be submitted 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: U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12-140, Washington, DC 20590-0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays.
- *Fax:* 202-493-2251.

**Instructions:** 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 your comments 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. Please see the Privacy Act heading 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).

**How to Read Comments submitted to the Docket:** You may read the comments received by Docket Management at the address and times given above. You may also view the documents from the Internet at <http://www.regulations.gov>. Follow the online instructions for accessing the dockets. The docket ID number and title of this notice are shown at the heading of this document notice. 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 search the Docket for new material.

**FOR FURTHER INFORMATION CONTACT:** George Stevens, Office of Vehicle Safety Compliance, NHTSA (202-366-5308).

**SUPPLEMENTARY INFORMATION:**

**Background**

Under 49 U.S.C. 30141(a)(1)(A), a motor vehicle that was not originally manufactured to conform to all applicable FMVSS shall be refused admission into the United States unless NHTSA has decided that the motor vehicle is substantially similar to a motor vehicle originally manufactured for importation into and sale in the United States, certified under 49 U.S.C. 30115, and of the same model year as the model of the motor vehicle to be compared, and is capable of being readily altered to conform to all applicable FMVSS.

Petitions for eligibility decisions may be submitted by either manufacturers or importers who have registered with NHTSA pursuant to 49 CFR part 592. As specified in 49 CFR 593.7, NHTSA publishes notice in the **Federal Register** of each petition that it receives, and affords interested persons an opportunity to comment on the petition. At the close of the comment period, NHTSA decides, on the basis of the petition and any comments that it has received, whether the vehicle is eligible for importation. The agency then publishes this decision in the **Federal Register**.

Wallace Environmental Testing Laboratories ("WETL"), Inc. of Houston, Texas (Registered Importer R-90-005) has petitioned NHTSA to decide whether nonconforming MY 2006 Ferrari 612 Scagletti PC's manufactured before September 1, 2006 are eligible for importation into the United States. The vehicles which WETL believes are substantially similar are MY 2006 Ferrari 612 Scagletti PC's manufactured before September 1, 2006 for sale in the United States and certified by their manufacturer as conforming to all applicable FMVSS.

The petitioner claims that it compared non-U.S. certified MY 2006 Ferrari 612 Scagletti PC's manufactured before September 1, 2006 to their U.S.-certified counterparts, and found the vehicles to be substantially similar with respect to compliance with most FMVSS.

WETL submitted information with its petition intended to demonstrate that non-U.S. certified MY 2006 Ferrari 612 Scagletti PC's manufactured before September 1, 2006, as originally

manufactured, conform to many FMVSS in the same manner as their U.S.-certified counterparts, or are capable of being readily altered to conform to those standards. Specifically, the petitioner claims that the non-U.S. certified MY 2006 Ferrari 612 Scagletti PC's manufactured before September 1, 2006 are identical to their U.S.-certified counterparts with respect to compliance with Standard Nos. 102 *Transmission Shift Lever Sequence, Starter Interlock, and Transmission Braking Effect*, 103 *Windshield Defrosting and Defogging Systems*, 104 *Windshield Wiping and Washing Systems*, 106 *Brake Hoses*, 109 *New Pneumatic Tires*, 113 *Hood Latch System*, 116 *Motor Vehicle Brake Fluids*, 118 *Power-Operated Window, Partition, and Roof panel System*, 124 *Accelerator Control Systems*, 135 *Light Vehicle Brake Systems*, 201 *Occupant Protection in Interior Impact*, 202 *Head Restraints*, 204 *Steering Control Rearward Displacement*, 205 *Glazing Materials*, 206 *Door Locks and Door Retention Components*, 207 *Seating Systems*, 209 *Seat Belt Assemblies*, 210 *Seat Belt Assembly Anchorages*, 212 *Windshield Mounting*, 214 *Side Impact Protection*, 216 *Roof Crush Resistance*, 219 *Windshield Zone Intrusion*, and 302 *Flammability of Interior Materials*.

The petitioner also contends that the subject non-U.S. certified vehicles are capable of being readily altered to meet the following standards, in the manner indicated:

**Standard No. 101 Controls and Displays:** Replacement of the instrument cluster and associated software, or modification of the instrument cluster by replacing the speedometer faceplate and brake telltale and reprogramming of the instrument cluster. If, the instrument cluster is modified, the method of altering any software as part of the modification will be included as part of the statement of conformity and associated documents (referred to as a "conformity package") the RI must submit to NHTSA under 49 CFR 592.6(d) to obtain release of the DOT Conformance bond furnished at the time the vehicle is imported.

**Standard No. 108 Lamps, Reflective Devices and Associated Equipment:** Replacement of the front and rear side marker lamps with U.S.-model components.

**Standard No. 110 Tire Selection and Rims:** Installation of the required tire information placard.

**Standard No. 111 Rearview Mirrors:** Installation of the conforming U.S.-model passenger side mirror, or inscription of the required warning statement on the face of the passenger mirror.

Standard No. 114 *Theft Protection*: Reprogramming of the instrument cluster. A description of the reprogramming will accompany the vehicle conformity package.

Standard No. 225 *Child Restraint Anchorage Systems*: Installation of U.S.-model child restraint anchorage system components including lateral rear window plates and brackets for belt coupler with covers.

Standard No. 301 *Fuel System Integrity*: The inspected vehicle was found to be equipped with conforming components, however each vehicle must be inspected for the presence of U.S.-model multifunction valve and tank ventilation valve. Vehicles without these U.S.-model valves must have them installed.

Standard No. 401 *Interior Trunk Release*: Installation of trunk release system components to ensure that the system, as modified, is identical to the U.S.-model system.

The petitioner additionally states that a vehicle identification plate must be affixed to the vehicle near the left windshield pillar to meet the requirements of 49 CFR part 565.

All comments received before the close of business on the closing date indicated above will be considered, and will be available for examination in the docket at the above addresses both before and after that date. To the extent possible, comments filed after the closing date will also be considered. Notice of final action on the petition will be published in the **Federal Register** pursuant to the authority indicated below.

**Authority:** 49 U.S.C. 30141(a)(1)(A), (a)(1)(B), and (b)(1); 49 CFR 593.7; delegation of authority at 49 CFR 1.95 and 501.8.

Issued on: July 31, 2015.

**Coleman R. Sachs,**  
*Acting Director, Office of Vehicle Safety Compliance.*

[FR Doc. 2015-19470 Filed 8-6-15; 8:45 am]

**BILLING CODE 4910-59-P**

## DEPARTMENT OF TRANSPORTATION

### Surface Transportation Board

[Docket No. FD 35945]

#### **Regional Rail Holdings, LLC— Acquisition of Control Exemption— Regional Rail, LLC**

Regional Rail Holdings, LLC (Regional Holdings), a noncarrier, has filed a verified notice of exemption under 49 CFR 1180.2(d)(2) to acquire control of Regional Rail, LLC (Regional Rail), a holding company for three Class III rail

carriers, East Penn Railroad, LLC, Middletown & New Jersey Railroad, LLC, and Tyburn Railroad LLC.

The transaction is expected to be consummated on or after August 22, 2015, the effective date of the exemption.<sup>1</sup>

Applicants state that: (i) The railroads will not connect with each other or any railroad in their corporate family; (ii) the subject acquisition of control is not part of a series of anticipated transactions that would connect the railroads with each other or any railroad in their corporate family; and (iii) the transaction does not involve a Class I 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 sections 11324 and 11325 that involve only Class III rail carriers. Because this transaction involves Class III rail carriers only, the Board, under the statute, may not impose labor protective conditions for this transaction.

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 no later than August 15, 2015 (at least seven days before the exemption becomes effective).

An original and 10 copies of all pleadings referring to Docket No. FD 35945, 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 Mary Anne Mason, Crowell & Moring LLP, 1001 Pennsylvania Ave. NW., Washington, DC 20004.

Board decisions and notices are available on our Web site at [WWW.STB.DOT.GOV](http://WWW.STB.DOT.GOV).

<sup>1</sup> In its verified notice, Regional Holdings requests expedited consideration to minimize potential disruption to its business as a result of the change in majority ownership due to its acquisition of Regional Rail. However, to permit the exemption to become effective before the scheduled 30-day consummation date, a party must file a separate petition for partial waiver of 49 CFR 1150.32(b), including its supporting rationale, which would be decided by the entire Board. See *The Great Lake Port Corp. d/b/a Grand River Ry.—Acquis. & Operation Exemption—CSX Transp., Inc.*, FD 35888 (STB served Dec. 24, 2014).

Decided: August 4, 2015.

By the Board, Rachel D. Campbell,  
Director, Office of Proceedings.

**Kenyatta Clay,**  
*Clearance Clerk.*

[FR Doc. 2015-19492 Filed 8-6-15; 8:45 am]

**BILLING CODE 4915-01-P**

## DEPARTMENT OF TRANSPORTATION

### Surface Transportation Board

[Docket No. AB 1032X]

#### **Nebraska, Kansas & Colorado Railway, L.L.C.—Abandonment Exemption—in Decatur, Norton, and Phillips Counties, Kan., and Harlan County, Neb.**

Nebraska, Kansas & Colorado Railway, L.L.C. (NKCR) has filed a verified notice of exemption under 49 CFR pt. 1152 subpart F—*Exempt Abandonments* to abandon 57.31 miles of rail line between (1) milepost 3.35 near Orleans, Neb., and milepost 29.84 at Alma, Kan.; (2) milepost 47.23 at Reager, Kan., and milepost 78.05 at Oberlin, Kan.; and (3) the Norton Spur in Norton, Kan.<sup>1</sup> NKCR also seeks to discontinue overhead trackage rights over a 17.7-mile line of railroad owned by Kyle Railroad between milepost 29.6 at Alma and milepost 47.3 at Oronoque Junction, Kan. NKCR acquired the trackage rights by assignment from Burlington Northern Railroad Company. *Neb., Kan. & Colo. Railnet—Acquis. & Operation Exemption—Lines of Burlington N. R.R.*, FD 33314, slip op. at 2 (STB served Dec. 24, 1996). The lines traverse United States Postal Service Zip Codes 68966, 67622, 67647, 67654, 67749 and 67653.

NKCR has certified that: (1) No local traffic has moved over the lines for at least two years; (2) any overhead traffic could be rerouted over other lines; (3) no formal complaint filed by a user of rail service on the lines (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the lines either is pending with the Surface Transportation Board (Board) or with any U.S. District Court or has been decided in favor of complainant within the two-year period; and (4) the requirements at 49 CFR

<sup>1</sup> The notice was originally filed on June 12, 2015, and was supplemented on June 23 and 29, 2015. In the June 29, 2015 supplement, NKCR certifies that an Environmental Report and a transmittal letter were mailed, on June 29, 2015, to the National Geodetic Survey (NGS), as required by 49 CFR 1105.7 and 1105.11. Because those documents were required to be served on NGS at least 20 days prior to filing the notice of exemption, see 49 CFR 1105.7(b)(1), service and publication of this notice has been delayed to account for the 20 days of advanced notice that NGS should have received, and deadlines have been adjusted accordingly.

1105.7(c) (environmental report), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho*, 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on September 8, 2015, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,<sup>2</sup> formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),<sup>3</sup> and trail use/rail banking requests under 49 CFR 1152.29 must be filed by August 17, 2015. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by August 27, 2015, with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to NKCR's representative: Karl Morell, Karl Morell & Associates, 655 Fifteenth Street NW., Suite 225, Washington, DC 20005.

If the verified notice contains false or misleading information, the exemption is void *ab initio*.

NKCR has filed environmental and historic reports that address the effects, if any, of the abandonment on the environment and historic resources. OEA will issue an environmental assessment (EA) by August 14, 2015. Interested persons may obtain a copy of the EA by writing to OEA (Room 1100, Surface Transportation Board, Washington, DC 20423–0001) or by calling OEA at (202) 245–0305. Assistance for the hearing impaired is available through the Federal Information Relay Service at (800) 877–

<sup>2</sup> The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Office of Environmental Analysis (OEA) in its independent investigation) cannot be made before the exemption's effective date. See *Exemption of Out-of-Serv. Rail Lines*, 5 I.C.C. 2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

<sup>3</sup> Each OFA must be accompanied by the filing fee, which is currently set at \$1,600. See 49 CFR 1002.2(f)(25).

8339. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), NKCR shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the lines. If consummation has not been effected by NKCR's filing of a notice of consummation by August 7, 2016, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

Board decisions and notices are available on our Web site at "[WWW.STB.DOT.GOV](http://WWW.STB.DOT.GOV)."

Decided: August 4, 2015.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

**Brendetta S. Jones**,  
Clearance Clerk.

[FR Doc. 2015–19449 Filed 8–6–15; 8:45 am]

**BILLING CODE 4915–01–P**

## DEPARTMENT OF THE TREASURY

### Alcohol and Tobacco Tax and Trade Bureau

[Docket No. TTB–2015–0012; Notice No. 156]

#### Importation of Distilled Spirits, Wine, Beer, Tobacco Products, Processed Tobacco, and Cigarette Papers and Tubes; Availability of Pilot Program and Filing Instructions To Test the Collection of Import Data for Implementation of the International Trade Data System

**AGENCY:** Alcohol and Tobacco Tax and Trade Bureau, Treasury.

**ACTION:** Notice of availability and request for comments.

**SUMMARY:** The Alcohol and Tobacco Tax and Trade Bureau (TTB) is announcing a pilot program in which importers, Customs and Border Protection (CBP), and TTB will test, as part of the International Trade Data System (ITDS) project, the electronic collection of import data required by TTB and the transfer of that data through CBP to TTB. TTB is also announcing the availability of and requesting comment on a draft set of instructions that describes how importers of distilled spirits, wine, beer, tobacco products, processed tobacco, or cigarette papers and tubes may file information

electronically to meet TTB requirements at the importation of those commodities. The information gathered through the comments on the draft instructions and pilot program and through an evaluation of the pilot program will allow TTB and CBP to refine their implementation of ITDS.

**DATES:** Comments on the draft Filing Instructions must be received by October 6, 2015.

The pilot program will commence no earlier than August 19, 2015, and will continue until concluded by publication of a notice in the **Federal Register** ending the test. Pilot program participants should consult the following Web site to determine which ports are or will be operational for the test: <http://www.cbp.gov/document/guidance/list-aceitds-pga-message-set-pilot-ports>. Comments on the pilot will be accepted through the duration of the pilot.

**ADDRESSES:** Please send your comments on the draft Automated Commercial Environment Filing Instructions for TTB-Regulated Commodities and on the pilot program to one of the following addresses:

- <http://www.regulations.gov> (via the online comment form for this document as posted within Docket No. TTB–2015–0012 at Regulations.gov, the Federal e-rulemaking portal);

- *U.S. Mail:* Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005; or

- *Hand delivery/courier in lieu of mail:* Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Suite 400, Washington, DC 20005.

See the Public Participation section of this document for specific instructions and requirements for submitting comments.

**FOR FURTHER INFORMATION CONTACT:** For information about the filing instructions or the pilot program, contact John Kyranos, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005; telephone (202) 453–1039, extension 001; or email [regulations@ttb.gov](mailto:regulations@ttb.gov).

For technical questions related to the Automated Commercial Environment (ACE) or Automated Broker Interface (ABI) transmissions, contact Steven Zaccaro at [steven.j.zaccaro@cbp.dhs.gov](mailto:steven.j.zaccaro@cbp.dhs.gov).

#### SUPPLEMENTARY INFORMATION:

##### TTB Authority

The Alcohol and Tobacco Tax and Trade Bureau (TTB) of the Department

of the Treasury regulates, among other things, the importation of distilled spirits, wine, and malt beverages pursuant to the Federal Alcohol Administration Act (FAA Act). TTB also administers the provisions of the Internal Revenue Code of 1986, as amended (IRC), with respect to the taxation of distilled spirits, wine, beer, tobacco products, processed tobacco, and cigarette papers and tubes. These statutory provisions are the basis of TTB regulations that require importers to submit certain information to U.S. Customs and Border Protection (CBP) upon importation.

Section 103(a) of the FAA Act (27 U.S.C. 203(a)) requires that a person obtain a permit before engaging in certain activities related to distilled spirits, wine, and malt beverages, including importation. This section of the FAA Act states that it shall be unlawful, except pursuant to a "basic permit" issued by the Secretary of the Treasury (the Secretary), to engage in the business of importing into the United States distilled spirits, wine, or malt beverages. Section 103(a) of the FAA Act also states that it is unlawful, except pursuant to a basic permit, for any person so engaged to sell, offer or deliver for sale, contract to sell, or ship, in interstate or foreign commerce, directly or indirectly or through an affiliate, distilled spirits, wine, or malt beverages so imported. The terms "distilled spirits" and "wine," when used in the context of the FAA Act, apply only to distilled spirits and wine for nonindustrial use.

Additionally, section 105(e) of the FAA Act (27 U.S.C. 205(e)) authorizes the Secretary to prescribe regulations relating to the labeling of distilled spirits, wine, and malt beverages. With regard to imported commodities, the FAA Act provides that no person shall remove from customs custody, in bottles, for sale or any other commercial purpose, distilled spirits, wine, or malt beverages, without having obtained a certificate of label approval and being in possession of that certificate.

Chapter 51 of the IRC pertains to the taxation and regulation of distilled spirits (including spirits used for both beverage and nonbeverage purposes), wines, and beer (see 26 U.S.C. chapter 51). The IRC imposes a Federal excise tax on all distilled spirits, wine, and beer manufactured in or imported into the United States. See, respectively, 26 U.S.C. 5001, 5041, and 5051. In general, the tax on imported distilled spirits, wine, and beer is collected by CBP, along with any import duties. The IRC at 26 U.S.C. 5232, 5364, and 5418 provides for limited circumstances

under which products may be withdrawn from customs custody without payment of tax for transfer to the bonded premises of an industry member regulated by TTB. These provisions cover distilled spirits imported in bulk and released from customs custody for transfer to a distilled spirits plant, natural wine (as defined in 26 U.S.C. 5381) imported in bulk and released from customs custody for transfer to a bonded wine cellar, and beer imported in bulk and released from customs custody for transfer to a brewery. Under these circumstances, the proprietor of the bonded premises becomes liable for the tax on the product withdrawn from customs custody upon its release from customs custody, and the applicable tax is collected by TTB when the product is removed from the distilled spirits plant, bonded wine cellar, or brewery, respectively. The IRC also contains provisions under which imported distilled spirits may be entered free of tax by the United States or any governmental agency of the United States for nonbeverage purposes. See 26 U.S.C. 5313. Furthermore, industrial alcohol may under certain circumstances be imported free of tax from the Virgin Islands to qualified industrial alcohol users. See 26 U.S.C. 5314(b).

Chapter 52 of the IRC contains excise tax and related provisions pertaining to tobacco products and cigarette papers and tubes. Section 5701 of the IRC (26 U.S.C. 5701) imposes Federal excise tax on such commodities manufactured in or imported into the United States. In general, the tax on imported tobacco products and cigarette papers and tubes is collected by CBP, along with any import duties. Under 26 U.S.C. 5704, tobacco products and cigarette papers and tubes may be released from customs custody under certain conditions without payment of tax for delivery to the proprietor of an export warehouse or a manufacturer of tobacco products or cigarette papers and tubes. Upon removal from the manufacturer's premises, the tax on such products is collected by TTB.

Chapter 52 of the IRC also contains provisions pertaining to the manufacture and importation of processed tobacco, which is not subject to tax. Section 5712 of the IRC (26 U.S.C. 5712) requires that importers of tobacco products or processed tobacco, before engaging in such business, apply for and obtain a permit.

TTB administers the FAA Act and chapters 51 and 52 of the IRC pursuant to section 1111(d) of the Homeland Security Act of 2002, as codified at 6

U.S.C. 531(d). The Secretary has delegated various authorities through Treasury Department Order 120-01, dated December 10, 2013, to the TTB Administrator to perform the functions and duties in the administration and enforcement of these provisions. Responsibility for collecting, accounting for, and depositing as internal revenue the excise taxes due incident to the importation of alcohol and tobacco products is vested by statute with the Secretary of the Treasury (see 6 U.S.C. 212), but has been delegated to the Secretary of Homeland Security and CBP. See Treasury Department Order 100-16, 68 FR 28322 (May 23, 2003), and 6 U.S.C. 212 and 215(1).

The TTB regulations at 27 CFR parts 1, 4, 5, and 7 set forth requirements related to certain FAA Act provisions. Section 1.20 (27 CFR 1.20) repeats the FAA Act basic permit requirement for importers of distilled spirits, wine, and malt beverages. Parts 4, 5, and 7 require that, in order for an imported distilled spirit, wine, or malt beverage to be released from customs custody, a certificate of label approval must be "deposited with the appropriate Customs officer at the port of entry." See 27 CFR 4.40, 5.51, and 7.31, respectively, regarding wine, distilled spirits, and malt beverages. Parts 4 and 5 also include several requirements related to certification of the origin and, in some cases, method of production of certain alcohol beverages by a foreign government. In general, certificates relating to origin or method of production are required to "accompany" the imported commodities. See 27 CFR 4.27, 4.45, and 5.52.

The TTB regulations at 27 CFR part 27 set forth requirements related to the IRC provisions that apply to importations of distilled spirits, wine, and beer. One example of a requirement for which records must be filed with CBP is the importation of distilled spirits in bulk without payment of tax, which is subject to the requirements in subparts H and I of part 27. For such releases, the person importing the spirits must prepare a record of information that is given to the customs officer upon release of the spirits from customs custody. Part 27 also includes requirements to submit information for transfers of distilled spirits without payment of tax from customs custody to a distilled spirits plant (27 CFR 27.172) and for imports of distilled spirits free of tax for use of a government agency (27 CFR 27.183).

The TTB regulations at 27 CFR part 26 address distilled spirits, wine, and beer brought into the United States from



Puerto Rico or the Virgin Islands and contain provisions similar to those in part 27, as well as requirements associated with tax-free shipments to industrial alcohol users (27 CFR 26.292). (**Note:** As provided in 19 CFR 101.1, Puerto Rico is within the customs territory of the United States; the Virgin Islands is not. As described below, this notice addresses a document and pilot program related to the electronic filing of import information with CBP. Because shipments into the United States from Puerto Rico are not treated as imports by CBP, such shipments are not covered by this initiative.)

The TTB regulations at 27 CFR part 41 address the importation of tobacco products, processed tobacco, and cigarette papers and tubes. In that part, § 41.81 requires certain information to be submitted to CBP regarding imported tobacco products or cigarette papers or tubes, and § 41.86 requires information to be submitted using a specified form in order for tobacco products or cigarette papers and tubes imported and released without payment of tax to be delivered to a specified TTB-permitted manufacturer or export warehouse proprietor.

#### *Electronic Submission of TTB-Required Information to CBP*

On March 27, 2014, TTB published in the **Federal Register** (79 FR 17029) a direct final rule, T.D. TTB-119, that among other amendments added a new section to 27 CFR part 73. Part 73 addresses the electronic submission of forms and electronic signatures. The new section, 27 CFR 73.40, provides that a regulated entity may satisfy any requirement in the TTB regulations to submit a form to another agency by submitting the form to the agency by electronic means, as long as the agency provides for, and authorizes, the electronic submission of the form and any registration and other requirements to use the electronic submission functionality are met. In part 73, the term “form” includes all documents required to be submitted.

#### **The International Trade Data System**

The International Trade Data System (ITDS) is an interagency program to establish a single electronic access point (or “single window”) through which importers and exporters may submit the data required by Federal government agencies for international trade transactions. The Security and Accountability for Every Port Act of 2006 (SAFE Port Act, Pub L. 109-347) mandated participation in ITDS for all agencies that require documentation for clearing or licensing the importation

and exportation of cargo. The purpose of ITDS is to eliminate redundant information requirements, to efficiently regulate the flow of commerce, and to effectively enforce laws and regulations relating to international trade, by establishing a single portal system, operated by CBP, for the collection and distribution of standard electronic import and export data required by all participating Federal agencies. TTB is one of the Partner Government Agencies (PGAs) working with CBP to implement ITDS.

The “single window” utilizes the Automated Commercial Environment (ACE), which is maintained by CBP. ACE allows importers and exporters to enter one set of data for each consignment of imported or exported articles. Currently, importers and exporters that are regulated by multiple agencies or that import or export commodities regulated by multiple agencies must submit data to those agencies through various channels, often in paper form. Through the implementation of ITDS, data will be entered into ACE and then made available to each government agency.

The PGA Message Set defines the agency-specific information that importers will submit directly through the Automated Broker Interface (ABI), which transfers data into ACE as part of the CBP entry process. After the importer submits the data, it will be available to TTB, along with certain other data collected through the ABI filing.

#### *Executive Order—Streamlining the Export/Import Process for America’s Businesses*

On February 19, 2014, the President issued Executive Order 13659, “Streamlining the Export/Import Process for America’s Businesses.”<sup>1</sup> The Executive Order mandated that ITDS be operational by December 31, 2016. It also directed Federal agencies that use ITDS to review their existing regulations for the import and export of goods to determine whether those regulations need to be modified to implement ITDS and further improve and streamline existing processes for import and export, and if so, to initiate rulemaking to implement those modifications.

#### **ITDS Pilot Program**

TTB intends to initiate a pilot program beginning no earlier than August 19, 2015, to test the electronic collection and transfer of data from

importers through CBP to TTB. Instead of submitting the paper forms and documents currently required in TTB’s regulations, participating U.S. importers and brokers will follow the draft ACE Filing Instructions for TTB-Regulated Commodities (Filing Instructions), described below, and use the PGA Message Set to send TTB-specific data elements and electronic images through ABI to ACE for review by TTB. The specific data elements are outlined in the draft Filing Instructions. TTB anticipates that this pilot program will help TTB and importers prepare for an efficient transition to ACE.

To be eligible to apply for this pilot, importers must have the ability to file ACE entry summaries and ACE cargo release, and must file entries for TTB-regulated commodities. All pilot program participants are required to use a software program that has completed ACE certification testing for the PGA Message Set.

Upon commencement of this test, a limited number of ports of entry will be accepting PGA Message Set data. A list of those ports and the dates they become operational is provided on the following CBP Web site: <http://www.cbp.gov/document/guidance/list-aceitds-pga-message-set-pilot-ports>. CBP may expand the pilot functionality to additional ports in the future. Test participants and interested parties should consult the above-referenced Web site for changes or additions to the list of ports. Importers must import articles regulated by TTB through a listed port in order to participate in the pilot program.

As discussed earlier, TTB’s import regulations currently require importers to submit to CBP various forms and documents in paper format. Importers who are accepted for participation in the pilot program will be supplying information electronically in accordance with the Filing Instructions. TTB will consider pilot program participants who follow the Filing Instructions to be in compliance with the current requirements to submit paper documents. TTB will provide further details in its approval letters to accepted applicants.

The PGA Message Set that will be used in the pilot program incorporates requirements that will be published in a future issue of the **Federal Register** as a notice of proposed rulemaking, with a solicitation for public comment. (The notice of proposed rulemaking will propose amendments to the regulations both to accommodate the use of ITDS and to improve TTB’s overall import processes, pursuant to the Executive Order discussed above.) The final PGA

<sup>1</sup> See <http://www.whitehouse.gov/the-press-office/2014/02/19/executive-order-streamlining-exportimport-process-america-s-businesses>.

Message Set used for importation of TTB-regulated commodities will be consistent with the TTB regulations established for those commodities.

To apply to participate in the pilot program, please contact John Kyranos, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005; telephone (202) 453-2265, extension 001; or email [regulations@ttb.gov](mailto:regulations@ttb.gov). For technical questions related to the Automated Commercial Environment (ACE) or Automated Broker Interface (ABI) transmissions, contact Steven Zaccaro at [steven.j.zaccaro@cbp.dhs.gov](mailto:steven.j.zaccaro@cbp.dhs.gov).

Please note that acceptance into the pilot program is based on the eligibility of the participant, along with TTB's need to include a broad cross-section of importers of the commodities regulated by TTB in order to evaluate the effectiveness of the system. In addition, participants may have different start dates.

#### **Draft Filing Instructions Available for Comment**

To facilitate implementation of ITDS and ACE for importers of alcohol and tobacco products, TTB is making available for review and comment a draft document containing instructions for importers of TTB-regulated articles on how to use the new system.

The draft ACE Filing Instructions for TTB-Regulated Commodities document made available via this notice is intended to provide a framework for discussion, review, and comment, in order to aid the system development. The draft Filing Instructions document also reflects requirements that TTB may propose through the future publication in the **Federal Register** of a notice of proposed rulemaking, with a solicitation for public comment. The comments TTB receives on that notice of proposed rulemaking, as well as the comments received on the draft Filing Instructions themselves through this notice, may result in changes to the Filing Instructions.

The draft Filing Instructions are available on [Regulations.gov](http://Regulations.gov) as part of Docket No. TTB-2015-0012 on [Regulations.gov](http://Regulations.gov). You can also obtain a copy by contacting John Kyranos as described above.

#### **Public Participation**

##### *Comments Invited*

TTB invites comments from interested members of the public on the draft Filing Instructions. TTB is particularly interested in comments related to the usability of the Filing Instructions. TTB

will also accept comments regarding the pilot program through the duration of the test.

##### *Submitting Comments*

You may submit comments on the Filing Instructions or on the pilot program by using one of the following three methods:

- *Federal e-Rulemaking Portal:* You may send comments via the online comment form posted with this notice within Docket No. TTB-2015-0012 on [Regulations.gov](http://Regulations.gov), the Federal e-rulemaking portal, at <http://www.regulations.gov>. A direct link to that docket is available under Notice No. 156 on the TTB Web site at <http://www.ttb.gov/rrd/fedreg-misc.shtml>. Supplemental files may be attached to comments submitted via [Regulations.gov](http://Regulations.gov). For complete instructions on how to use [Regulations.gov](http://Regulations.gov), visit the site and click on the "Help" tab.

- *U.S. Mail:* You may send comments via postal mail to the Director, Regulations and Rulings Division, Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Box 12, Washington, DC 20005.

- *Hand Delivery/Courier:* You may hand-carry your comments or have them hand-carried to the Alcohol and Tobacco Tax and Trade Bureau, 1310 G Street NW., Suite 400, Washington, DC 20005.

Please submit your comments by the closing date shown above in this notice. Your comments must reference Notice No. 156 and include your name and mailing address. Your comments also must be made in English, be legible, and be written in language acceptable for public disclosure. TTB does not acknowledge receipt of comments, and TTB considers all comments as originals.

In your comment, please clearly state if you are commenting for yourself or on behalf of an association, business, or other entity. If you are commenting on behalf of an entity, your comment must include the entity's name as well as your name and position title. In your comment via [Regulations.gov](http://Regulations.gov), please enter the entity's name in the "Organization" blank of the online comment form. If you comment via postal mail or hand delivery/courier, please submit your entity's comment on letterhead.

##### *Confidentiality*

All submitted comments and attachments are part of the public record and subject to disclosure. Do not enclose any material in your comments

that you consider to be confidential or inappropriate for public disclosure.

##### *Public Disclosure*

TTB will post, and you may view, copies of this notice, the Filing Instructions, and any online or mailed comments received about this proposal within Docket No. TTB-2015-0012 on the Federal e-rulemaking portal, [Regulations.gov](http://Regulations.gov), at <http://www.regulations.gov>. A direct link to that docket is available on the TTB Web site at <http://www.ttb.gov/rrd/fedreg-misc.shtml> under Notice No. 156. You may also reach the relevant docket through the [Regulations.gov](http://Regulations.gov) search page at <http://www.regulations.gov>. For information on how to use [Regulations.gov](http://Regulations.gov), click on the site's "Help" tab.

All posted comments will display the commenter's name, organization (if any), city, and State, and, in the case of mailed comments, all address information, including email addresses. TTB may omit voluminous attachments or material that the Bureau considers unsuitable for posting.

You may also view copies of this notice, the Filing Instructions, and any electronic or mailed comments that TTB receives about this proposal by appointment at the TTB Information Resource Center, 1310 G Street NW., Washington, DC 20005. You may also obtain copies at 20 cents per 8.5- x 11-inch page. Contact TTB's information specialist at the above address or by telephone at 202-453-2270 to schedule an appointment or to request copies of comments or other materials.

##### **Drafting Information**

Andrew Malone of the Regulations and Rulings Division drafted this notice.

Signed: July 30, 2015.

**John J. Manfreda,**  
*Administrator.*

[FR Doc. 2015-19456 Filed 8-6-15; 8:45 am]

BILLING CODE 4810-31-P

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## **DEPARTMENT OF THE TREASURY**

### **[Internal Revenue Service]**

#### **Open Meeting of the Taxpayer Advocacy Panel Taxpayer Assistance Center Improvements Project Committee**

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Notice of Meeting.

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**SUMMARY:** An open meeting of the Taxpayer Advocacy Panel Taxpayer Assistance Center Improvements Project

Committee will be conducted. The Taxpayer Advocacy Panel is soliciting public comments, ideas, and suggestions on improving customer service at the Internal Revenue Service.

**DATES:** The meeting will be held Wednesday, September 9, 2015.

**FOR FURTHER INFORMATION CONTACT:** Otis Simpson at 1-888-912-1227 or 202-317-3332.

**SUPPLEMENTARY INFORMATION:** Notice is hereby given pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1988) that a meeting of the Taxpayer Advocacy Panel Taxpayer Assistance Center Improvements Project Committee will be held Wednesday, September 9, 2015, at 3:00 p.m. Eastern Time. The public is invited to make oral comments or submit written statements for consideration. Due to limited conference lines, notification of intent to participate must be made with Otis Simpson. For more information please contact: Otis Simpson at 1-888-912-1227 or 202-317-3332, TAP Office, 1111 Constitution Avenue NW., Room 1509—National Office, Washington, DC 20224, or contact us at the Web site: <http://www.improveirs.org>.

The committee will be discussing various issues related to the Taxpayer Assistance Centers and public input is welcomed.

Dated: August 3, 2015.

**Sheila Andrews,**

*Director, Taxpayer Advocacy Panel.*

[FR Doc. 2015-19514 Filed 8-6-15; 8:45 am]

**BILLING CODE 4830-01-P**

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## DEPARTMENT OF THE TREASURY

### Submission for OMB Review; Comment Request

**AGENCY:** Department of the Treasury.

**ACTION:** Notice.

The Department of the Treasury will submit the following information collection request 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 September 8, 2015 to be assured of consideration.

**ADDRESSES:** Send comments regarding the burden estimate, or any other aspect of the information collection, 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](mailto:OIRA_Submission@OMB.EOP.gov) and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8140, Washington, DC 20220, or email at [PRA@treasury.gov](mailto:PRA@treasury.gov).

**FOR FURTHER INFORMATION CONTACT:** Copies of the submission(s) may be obtained by email at [PRA@treasury.gov](mailto:PRA@treasury.gov) or the entire information collection request may be found at [www.reginfo.gov](http://www.reginfo.gov).

### SUPPLEMENTARY INFORMATION:

#### Internal Revenue Service (IRS)

*OMB Number:* 1545-1641.

*Type of Review:* Reinstatement without change of a previously approved collection.

*Title:* Rev. Proc. 99-17—Mark to Market Election for Commodities Dealers and Securities and Commodities Traders.

*Abstract:* The revenue procedure prescribes the time and manner for dealers in commodities and traders in securities or commodities to elect to use the mark-to-market method of accounting under section 475(e) or (f) of the Internal Revenue Code. The collections of information of this revenue procedure are required by the IRS in order to facilitate monitoring taxpayers changing accounting methods resulting from making the elections under section 475(e) or (f).

*Affected Public:* Private Sector: Businesses or other for-profits.

*Estimated Annual Burden Hours:* 500.

Dated: August 3, 2015.

**Dawn D. Wolfgang,**

*Treasury PRA Clearance Officer.*

[FR Doc. 2015-19360 Filed 8-6-15; 8:45 am]

**BILLING CODE 4830-01-P**

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## DEPARTMENT OF VETERANS AFFAIRS

### Notice of Establishment of Commission on Care

The Department of Veterans Affairs (VA) hereby gives notice of the establishment of the Commission on Care (“the Commission”), authorized by section 202 of the Veterans Access, Choice, and Accountability Act of 2014 (VACAA),

The Commission will examine the access of Veterans to health care from VA and strategically examine the access of Veterans how best to organize the Veterans Health Administration, locate health care resources, and deliver health care to Veterans during the 20-year

period beginning on the date of the enactment of VACAA, August 7, 2014.

The Commission members will be composed of 15 voting members who are appointed by the President and Congressional leadership for the life of the Commission in accordance with section 202(a)(2) of VACAA.

Any member of the public seeking additional information should contact Ms. Susan Webman, Executive Director (10P1), Veterans Health Administration, Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC or email at [Susan.Webman@va.gov](mailto:Susan.Webman@va.gov) or phone at (202) 461-4057.

Dated: August 3, 2015.

**Rebecca Schiller,**

*Committee Management Officer.*

[FR Doc. 2015-19363 Filed 8-6-15; 8:45 am]

**BILLING CODE 8320-01-P**

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## DEPARTMENT OF VETERANS AFFAIRS

### Publication of Wait-Times for the Department for the Veterans Choice Program

**AGENCY:** Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** In keeping with its commitment to improve transparency, the Department of Veterans Affairs’ (VA) publishes wait-times for the scheduling of appointments in each VA facility for primary care, specialty care, and mental health services twice each month. VA also publishes a **Federal Register** Notice every 90 days with the address of the Web site where this wait-time data can be accessed. This Notice announces the availability of the data on that Web site.

**ADDRESSES:** The wait-time data for all Veterans Health Administration (VHA) medical centers and clinics is available on the following Web site: <http://www.va.gov/health/access-audit.asp>.

**FOR FURTHER INFORMATION CONTACT:** Dr. Joe Francis, Director, Clinical Analytics and Reporting, Veterans Health Administration, 810 Vermont Avenue NW., Washington, DC 20420 Telephone: (202) 302-3310. (This is not a toll-free number.)

**SUPPLEMENTARY INFORMATION:** Section 206 of the Veterans Access, Choice, and Accountability Act of 2014 (Pub. L. 113-146, “the Act”) directed the Department of Veterans Affairs (VA), not later than 90 days after the date of the enactment of the Act, to publish in the **Federal Register**, and on a publicly-accessible Internet Web site of each VA Medical Center, the wait-times for the scheduling of an appointment in each

VA facility for the receipt of primary care, specialty care, and hospital care and medical services based on the general severity of the condition of the veteran. Whenever the wait-times for the scheduling of such an appointment change, the Act also requires the Secretary to publish the revised wait-times on a publicly-accessible Internet Web site of each VA Medical Center not later than 30 days after such change and in the **Federal Register** not later than 90 days after such change.

VA publishes wait-times for the scheduling of appointments in each VA facility for primary care, specialty care, and mental health services twice each month. VA also publishes a **Federal Register** Notice every 90 days to notify the public of the availability of this wait-time data. This wait-time data uses the Veteran's preferred date or the clinically appropriate date for scheduling an appointment.

The wait-time data report, which also includes data at the Community-Based Outpatient Clinic level for all VA facilities, can be found using the following link: <http://www.va.gov/health/access-audit.asp>.

#### Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Robert L. Nabors II, Chief of Staff, approved this document on August 3, 2015, for publication.

Dated: August 4, 2015.

**William F. Russo,**

*Acting Director, Office of Regulation Policy & Management, U.S. Department of Veterans Affairs.*

[FR Doc. 2015-19414 Filed 8-6-15; 8:45 am]

**BILLING CODE 8320-01-P**

## DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900-0674]

### Agency Information Collection—Clarification of a Notice of Disagreement Under OMB Review

**AGENCY:** Board of Veterans' Appeals, Department of Veterans Affairs.

**ACTION:** Notice.

**SUMMARY:** In compliance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3521), this notice announces that the Board of Veterans' Appeals (BVA), Department of Veterans Affairs, will submit the collection of

information abstracted below to the Office of Management and Budget (OMB) for review and comment. The PRA submission describes the nature of the information collection and its expected cost and burden and includes the actual data collection instrument.

**DATES:** Comments must be submitted on or before September 8, 2015.

**ADDRESSES:** Submit written comments on the collection of information through [www.Regulations.gov](http://www.Regulations.gov), or to Office of Information and Regulatory Affairs, Office of Management and Budget, Attn: VA Desk Officer; 725 17th St. NW., Washington, DC 20503 or sent through electronic mail to [oira\\_submission@omb.eop.gov](mailto:oira_submission@omb.eop.gov). Please refer to "OMB Control No. 2900-0674" in any correspondence.

#### FOR FURTHER INFORMATION CONTACT:

Crystal Rennie, Enterprise Records Service (005R1B), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, (202) 632-7492 or email [crystal.rennie@va.gov](mailto:crystal.rennie@va.gov). Please refer to "OMB Control No. 2900-0674" in any correspondence.

#### SUPPLEMENTARY INFORMATION:

*Title:* Clarification of Notice of Disagreement.

*OMB Control Number:* 2900-0674.

*Type of Review:* Revision of a currently approved collection.

*Abstract:* Appellate review of the denial of Department of Veterans Affairs (VA) benefits is initiated by a claimant, or his/her representative, filing a Notice of Disagreement. 38 U.S.C.A. §§ 7105(a), (b)(2). A Notice of Disagreement is a written communication that expresses (1) dissatisfaction or disagreement with an adjudicative determination by the agency of original jurisdiction (AOJ) and (2) a desire to contest the result. 38 U.S.C.A. § 7105; 38 CFR 20.201. No special form or wording is required; however, the Notice of Disagreement must identify the specific determinations with which the claimant disagrees, and must be in terms that can be reasonably construed as disagreement with the AOJ's determination and a desire for appellate review. *Id.* If the AOJ receives a written communication expressing dissatisfaction or disagreement within one year (or 60 days for simultaneously contested claims) of mailing an adverse decision, but cannot clearly identify that communication as expressing an intent to appeal, or cannot identify which claims the claimant wants to appeal, then the AOJ will contact the claimant orally or in writing to request clarification of his/her intent. 38 CFR 19.26(b).

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. The **Federal Register** Notice with a 60-day comment period soliciting comments on this collection of information was published at 80 FR 8764 on February 18, 2015.

*Affected Public:* Individuals or households.

*Estimated Annual Burden:* 122,487.

*Estimated Average Burden per Respondent:* 1 hour.

*Frequency of Response:* On occasion.

*Estimated Number of Respondents:* 122,487.

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. 2015-19479 Filed 8-6-15; 8:45 am]

**BILLING CODE 8320-01-P**

## DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900-0002]

### Proposed Information Collection: Income, Net Worth and Employment Statement (in Support of Claim for Total Disability Benefits) and Application for Pension

**AGENCY:** Veterans Benefits Administration, Department of Veterans Affairs.

**ACTION:** Notice; comment request.

**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 October 6, 2015.

**ADDRESSES:** Submit written comments on the collection of information through Federal Docket Management System (FDMS) at [www.Regulations.gov](http://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](mailto:nancy.kessinger@va.gov). Please refer to

“OMB Control No. 2900–0002” 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:* Income, Net Worth and Employment Statement (In Support of Claim for Total Disability Benefits) (21P–527) and Application for Pension (21P–527EZ).

*OMB Control Number:* 2900–0002.

*Type of Review:* Revision of a currently approved collection.

*Abstract:* VA Form 21P–527 is necessary to obtain current employment, dependency, and family income and net worth information entitlement to disability pension. VA

disability pension benefits are not payable without this information. VA Form 527EZ is the prescribed form for disability pension claims, respectively, claimed under the Fully Developed Claim (FDC) Program.

*Affected Public:* Individuals or households.

*Estimated Annual Burden:* 84,708 hours.

*Estimated Average Burden per Respondent:* 60 minutes for 21P–527 and 25 minutes for 21P–527EZ.

*Frequency of Response:* Annually.

*Estimated Number of Respondents:* 118,197.

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. 2015–19478 Filed 8–6–15; 8:45 am]

**BILLING CODE 8320–01–P**



# FEDERAL REGISTER

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Part II

Department of Labor

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Occupational Safety and Health Administration

29 CFR Part 1910

Occupational Exposure to Beryllium and Beryllium Compounds; Proposed Rule

**DEPARTMENT OF LABOR****Occupational Safety and Health Administration****29 CFR Part 1910**

[Docket No. OSHA-H005C-2006-0870]

RIN 1218-AB76

**Occupational Exposure to Beryllium and Beryllium Compounds**

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

**ACTION:** Proposed rule; request for comments.

**SUMMARY:** The Occupational Safety and Health Administration (OSHA) proposes to amend its existing exposure limits for occupational exposure in general industry to beryllium and beryllium compounds and promulgate a substance-specific standard for general industry regulating occupational exposure to beryllium and beryllium compounds. This document proposes a new permissible exposure limit (PEL), as well as ancillary provisions for employee protection such as methods for controlling exposure, respiratory protection, medical surveillance, hazard communication, and recordkeeping. In addition, OSHA seeks comment on a number of alternatives, including a lower PEL, that could affect construction and maritime, as well as general industry.

**DATES:** *Written comments.* Written comments, including comments on the information collection determination described in Section IX of the preamble (OMB Review under the Paperwork Reduction Act of 1995), must be submitted (postmarked, sent, or received) by November 5, 2015.

*Informal public hearings.* The Agency will schedule an informal public hearing on the proposed rule if requested during the comment period. The location and date of the hearing, procedures for interested parties to notify the Agency of their intention to participate, and procedures for participants to submit their testimony and documentary evidence will be announced in the **Federal Register** if a hearing is requested.

**ADDRESSES:** *Written comments.* You may submit comments, identified by Docket No. OSHA-H005C-2006-0870, by any of the following methods:

*Electronically:* You may submit comments and attachments electronically at <http://www.regulations.gov>, which is the Federal e-Rulemaking Portal. Follow the

instructions on-line for making electronic submissions. When uploading multiple attachments into Regulations.gov, please number all of your attachments because [www.Regulations.gov](http://www.Regulations.gov) will not automatically number the attachments. This will be very useful in identifying all attachments in the beryllium rule. For example, Attachment 1—title of your document, Attachment 2—title of your document, Attachment 3—title of your document, etc. Specific instructions on uploading all documents are found in the Facts, Answer, Questions portion and the commenter check list on Regulations.gov Web page.

*Fax:* If your submissions, including attachments, are not longer than 10 pages, you may fax them to the OSHA Docket Office at (202) 693-1648.

*Mail, hand delivery, express mail, messenger, or courier service:* You may submit your comments to the OSHA Docket Office, Docket No. OSHA-H005C-2006-0870, U.S. Department of Labor, Room N-2625, 200 Constitution Avenue NW., Washington, DC 20210, telephone (202) 693-2350 (OSHA's TTY number is (877) 889-5627). Deliveries (hand, express mail, messenger, or courier service) are accepted during the Docket Office's normal business hours, 8:15 a.m.–4:45 p.m., E.S.T.

*Instructions:* All submissions must include the Agency name and the docket number for this rulemaking (Docket No. OSHA-H005C-2006-0870). All comments, including any personal information you provide, are placed in the public docket without change and may be made available online at <http://www.regulations.gov>. Therefore, OSHA cautions you about submitting personal information such as Social Security numbers and birthdates.

If you submit scientific or technical studies or other results of scientific research, OSHA requests (but is not requiring) that you also provide the following information where it is available: (1) Identification of the funding source(s) and sponsoring organization(s) of the research; (2) the extent to which the research findings were reviewed by a potentially affected party prior to publication or submission to the docket, and identification of any such parties; and (3) the nature of any financial relationships (e.g., consulting agreements, expert witness support, or research funding) between investigators who conducted the research and any organization(s) or entities having an interest in the rulemaking. If you are submitting comments or testimony on the Agency's scientific or technical analyses, OSHA requests that you disclose: (1) The nature of any financial

relationships you may have with any organization(s) or entities having an interest in the rulemaking; and (2) the extent to which your comments or testimony were reviewed by an interested party before you submitted them. Disclosure of such information is intended to promote transparency and scientific integrity of data and technical information submitted to the record. This request is consistent with Executive Order 13563, issued on January 18, 2011, which instructs agencies to ensure the objectivity of any scientific and technological information used to support their regulatory actions. OSHA emphasizes that all material submitted to the rulemaking record will be considered by the Agency to develop the final rule and supporting analyses.

*Docket:* To read or download comments and materials submitted in response to this **Federal Register** notice, go to Docket No. OSHA-H005C-2006-0870 at <http://www.regulations.gov>, or to the OSHA Docket Office at the address above. All comments and submissions are listed in the <http://www.regulations.gov> index; however, some information (e.g., copyrighted material) is not publicly available to read or download through that Web site. All comments and submissions are available for inspection at the OSHA Docket Office.

Electronic copies of this **Federal Register** document are available at <http://www.regulations.gov>. Copies also are available from the OSHA Office of Publications, Room N-3101, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693-1888. This document, as well as news releases and other relevant information, is also available at OSHA's Web site at <http://www.osha.gov>.

OSHA has not provided the document ID numbers for all submissions in the record for this beryllium proposal. The proposal only contains a reference list for all submissions relied upon. The public can find all document ID numbers in an Excel spreadsheet that is posted on OSHA's rulemaking Web page (see [www.osha.gov/berylliumrulemaking](http://www.osha.gov/berylliumrulemaking)). The public will be able to locate submissions in the record in the public docketed Web page: <http://www.regulations.gov>. To locate a particular submission contained in <http://www.regulations.gov>, the public should enter the full document ID number in the search bar.

**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](mailto:meilinger.francis2@dol.gov). For technical inquiries, contact: William Perry or Maureen Ruskin, Directorate of Standards and Guidance, Room N-3718, OSHA, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693-1955 or fax (202) 693-1678; email: [perry.bill@dol.gov](mailto:perry.bill@dol.gov).

#### SUPPLEMENTARY INFORMATION:

The preamble to the proposed standard on occupational exposure to beryllium and beryllium compounds follows this outline:

#### Executive Summary

- I. Issues and Alternatives
- II. Pertinent Legal Authority
- III. Events Leading to the Proposed Standards
- IV. Chemical Properties and Industrial Uses
- V. Health Effects
- VI. Preliminary Risk Assessment
- VII. Response to Peer Review
- VIII. Significance of Risk
- IX. Summary of the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis
- X. OMB Review under the Paperwork Reduction Act of 1995
- XI. Federalism
- XII. State-Plan States
- XIII. Unfunded Mandates Reform Act
- XIV. Protecting Children from Environmental Health and Safety Risks
- XV. Environmental Impacts
- XVI. Consultation and Coordination with Indian Tribal Governments
- XVII. Public Participation
- XVIII. Summary and Explanation of the Proposed Standard
  - (a) Scope and Application
  - (b) Definitions
  - (c) Permissible Exposure Limits (PELs)
  - (d) Exposure Assessment
  - (e) Beryllium Work Areas and Regulated Areas
  - (f) Methods of Compliance
  - (g) Respiratory Protection
  - (h) Personal Protective Clothing and Equipment
  - (i) Hygiene Areas and Practices
  - (j) Housekeeping
  - (k) Medical Surveillance
  - (l) Medical Removal
  - (m) Communication of Hazards to Employees
  - (n) Recordkeeping
  - (o) Dates
- XIX. References

#### Executive Summary

OSHA currently enforces permissible exposure limits (PELs) for beryllium in general industry, construction, and shipyards. These PELs were adopted in 1971, shortly after the Agency was created, and have not been updated since then. The time-weighted average (TWA) PEL for beryllium is 2 micrograms per cubic meter of air ( $\mu\text{g}/\text{m}^3$ ) as an 8-hour time-weighted average.

OSHA is proposing a new TWA PEL of  $0.2 \mu\text{g}/\text{m}^3$  in general industry. OSHA is also proposing other elements of a comprehensive health standard, including requirements for exposure assessment, preferred methods for controlling exposure, respiratory protection, personal protective clothing and equipment (PPE), medical surveillance, medical removal, hazard communication, and recordkeeping.

OSHA's proposal 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 of this preamble, 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 beryllium. The Agency has also assessed the risk of beryllium-related diseases at the current TWA PEL, the proposed TWA PEL and the alternative TWA PELs. These analyses are presented in this preamble at Section V, Health Effects, Section VI, Preliminary Risk Assessment, and Section VIII, Significance of Risk. As discussed in Section VIII of this preamble, Significance of Risk, the available evidence indicates that worker exposure to beryllium at the current PEL poses a significant risk of chronic beryllium disease (CBD) and lung cancer, and that the proposed standard will substantially reduce this risk.

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 proposed rule is presented in the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis (PEA) (OSHA, 2014), and is summarized in Section IX of this preamble, Summary of the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis. OSHA has preliminarily concluded that the proposed PEL of  $0.2 \mu\text{g}/\text{m}^3$  is technologically feasible for all affected industries and application groups. Thus, OSHA preliminarily concludes that engineering and work practices will be sufficient to reduce and maintain beryllium exposures to the proposed PEL of  $0.2 \mu\text{g}/\text{m}^3$  or below in most operations most of the time in the affected industries. For those few

operations within an industry or application group where compliance with the proposed PEL cannot be achieved even when employers implement all feasible engineering and work practice controls, the proposed standard would require employers to supplement controls with respirators.

OSHA developed quantitative estimates of the compliance costs of the proposed 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 preliminarily concluded that compliance with the requirements of the proposed rule would be economically feasible in every affected industry sector.

The Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), requires that OSHA either certify that a rule would not have a significant economic impact on a substantial number of small entities or prepare a regulatory flexibility analysis and hold a Small Business Advocacy Review (SBAR) Panel prior to proposing the rule. OSHA has determined that a regulatory flexibility analysis is needed and has provided this analysis in Chapter IX of the PEA (OSHA, 2014). A summary is provided in Section IX of this preamble, Summary of the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis. OSHA also previously held a SBAR Panel for this rule. The recommendations of the Panel and OSHA's response to them are summarized in Section IX of this preamble.

Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated an economically significant regulatory action under section 3(f)(1) of Executive Order 12866. Accordingly, this proposed rule has been reviewed by the Office of Management and Budget. The remainder of this section summarizes the key findings of the analysis with respect to costs and benefits of the proposed standard, presents alternatives



to the proposed standard, and requests comments on a number of issues.

Table I-1, which is derived from material presented in the PEA, provides a summary of OSHA's best estimate of the costs and benefits of this proposed rule. As shown, this proposed rule is estimated to prevent 96 fatalities and 50 non-fatal beryllium-related illnesses annually once it is fully effective, and the monetized annualized benefits of the proposed rule are estimated to be

\$576 million using a 3-percent discount rate and \$255 million using a 7-percent discount rate. Also as shown in Table I-1, the estimated annualized cost of the rule is \$37.6 million using a 3-percent discount rate and \$39.1 million using a 7-percent discount rate. This proposed rule is estimated to generate net benefits of \$538 million annually using a 3-percent discount rate and \$216 million annually using a 7-percent discount rate. These estimates

are for informational purposes only and have not been used by OSHA as the basis for its decision concerning the choice of a PEL or of other ancillary requirements for this proposed beryllium rule. The courts have ruled that OSHA may not use benefit-cost analysis or a criterion of maximizing net benefits as a basis for setting OSHA health standards.<sup>1</sup>

TABLE I-1—ANNUALIZED COSTS, BENEFITS AND NET BENEFITS OF OSHA'S PROPOSED BERYLLIUM STANDARD OF 0.2 µg/M<sup>3</sup>

Discount rate		3%	7%
Annualized Costs			
Engineering Controls .....		\$9,540,189	\$10,334,036
Respirators .....		249,684	252,281
Exposure Assessment .....		2,208,950	2,411,851
Regulated Areas and Beryllium Work Areas .....		629,031	652,823
Medical Surveillance .....		2,882,076	2,959,448
Medical Removal .....		148,826	166,054
Exposure Control Plan .....		1,769,506	1,828,766
Protective Clothing and Equipment .....		1,407,365	1,407,365
Hygiene Areas and Practices .....		389,241	389,891
Housekeeping .....		12,574,921	12,917,944
Training .....		5,797,535	5,826,975
Total Annualized Costs (Point Estimate) .....		37,597,325	39,147,434
Annual Benefits: Number of Cases Prevented			
Fatal Lung Cancer .....	4.0		
CBD-Related Mortality .....	92.0		
Total Beryllium Related Mortality .....	96.0	572,981,864	253,743,368
Morbidity .....	49.5	2,844,770	1,590,927
Monetized Annual Benefits (midpoint estimate) .....		575,826,633	255,334,295
Net Benefits .....		538,229,308	216,186,861

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.

Both the costs and benefits of Table I-1 reflect the incremental costs and benefits associated with achieving full compliance with the proposed standard. They do not include costs and benefits associated with employers' current exposure control measures or other aspects of the proposed standard they have already implemented. For example, for employers whose exposures are already below the proposed PEL, OSHA's estimated costs and benefits for the proposed standard do not include the costs of their exposure control measures or the benefits of these employers' compliance with the proposed PEL. The costs and benefits of Table I-1 also do not include costs and benefits associated with achieving compliance with existing requirements, to the extent that some employers may currently not be fully complying with applicable regulatory requirements.

**I. Issues and Alternatives**

In addition to the proposed standard itself, this preamble discusses more than two dozen regulatory alternatives, including various sub-alternatives, to the proposed standard and requests comments and information on a variety of topics pertinent to the proposed standard. The regulatory alternatives OSHA is considering include alternatives to the proposed scope of the standard, regulatory alternatives to the proposed TWA PEL of 0.2 µg/m<sup>3</sup> and proposed STEL of 2 µg/m<sup>3</sup>, a regulatory alternative that would modify the proposed methods of compliance, and regulatory alternatives that affect proposed ancillary provisions. The Agency solicits comment on the proposed phase-in schedule for the various provisions of the standard. Additional requests for comments and information follow the summaries of regulatory alternatives, under the "Issues" heading.

*Regulatory Alternatives*

OSHA believes that inclusion of regulatory alternatives serves two important functions. The first is to explore the possibility of less costly ways (than the proposed standard) to provide an adequate level of worker protection from exposure to beryllium. The second is tied to the Agency's statutory requirement, which underlies the proposed standard, to reduce significant risk to the extent feasible. Each regulatory alternative presented here is described and analyzed more fully elsewhere in this preamble or in the PEA. Where appropriate, the alternative is included in this preamble at the end of the relevant section of Section XVIII, Summary and Explanation of the Proposed Standard, to facilitate comparison of the alternative to the proposed standard. For example, alternative PELs under consideration by the Agency are presented in the discussion of paragraph (c) in Section XVIII. In addition, all

<sup>1</sup> Am. Textile Mfrs. Inst., Inc. v. Nat'l Cotton Council of Am., 452 U.S. 490, 513 (1981); Pub.

Citizen Health Research Group v. U.S. Dep't of Labor, 557 F.3d 165, 177 (3d Cir. 2009).

alternatives are discussed in the PEA, Chapter VIII: Regulatory Alternatives (OSHA, 2014). The costs and benefits of each regulatory alternative are presented both in Section IX of this preamble and in Chapter VIII of the PEA.

The more than two dozen regulatory alternatives, including various sub-alternatives regulatory alternatives under consideration are summarized below, and are organized into the following categories: alternatives to the proposed scope of the standard; alternatives to the proposed PELs; alternatives to the proposed methods of compliance; alternatives to the proposed ancillary provisions; and the timing of the standard.

#### Scope

OSHA has examined three alternatives that would alter the groups of employers and employees covered by this rulemaking. Regulatory Alternative #1a would expand the scope of the proposed standard to include all operations in general industry where beryllium exists only as a trace contaminant; that is, where the materials used contain no more than 0.1% beryllium by weight. Regulatory Alternative #1b is similar to Regulatory Alternative #1a, but exempts operations where the employer can show that employees' exposures will not meet or exceed the action level or exceed the STEL. Where the employer has objective data demonstrating that a material containing beryllium or a specific process, operation, or activity involving beryllium cannot release beryllium in concentrations at or above the proposed action level or above the proposed STEL under any expected conditions of use, that employer would be exempt from the proposed standard except for recordkeeping requirements pertaining to the objective data. Alternative #1a and Alternative #1b, like the proposed rule, would not cover employers or employees in construction or shipyards.

Regulatory Alternative #2a would expand the scope of the proposed standard to also include employers in construction and maritime. For example, this alternative would cover abrasive blasters, pot tenders, and cleanup staff working in construction and shipyards who have the potential for airborne beryllium exposure during blasting operations and during cleanup of spent media. Regulatory Alternative #2b would update §§ 1910.1000 Tables Z-1 and Z-2, 1915.1000 Table Z, and 1926.55 Appendix A so that the proposed TWA PEL and STEL would apply to all employers and employees in general industry, shipyards, and construction, including occupations

where beryllium exists only as a trace contaminant. However, all other provisions of the standard would be in effect only for employers and employees that fall within the scope of the proposed rule. More detailed discussion of Regulatory Alternatives #1a, #1b, #2a, and #2b appears in Section IX of this preamble and in Chapter VIII of the PEA (OSHA, 2014). In addition, Section XVIII of this preamble, Summary and Explanation, includes a discussion of paragraph (a) that describes the scope of the proposed rule, issues with the proposed scope, and Regulatory Alternatives #1a, #1b, #2a, and #2b.

Another regulatory alternative that would impact the scope of affected industries, extending eligibility for medical surveillance to employees in shipyards, construction, and parts of general industry excluded from the scope of the proposed standard, is discussed along with other medical surveillance alternatives later in this section (Regulatory Alternative #21) and in the discussion of paragraph (k) in this preamble at Section XVIII, Summary and Explanation of the Proposed Standard.

#### Permissible Exposure Limits

OSHA has examined several regulatory alternatives that would modify the TWA PEL or STEL for the proposed rule. Under Regulatory Alternative #3, OSHA would adopt a STEL of 5 times the proposed PEL. Thus, this alternative STEL would be 1.0  $\mu\text{g}/\text{m}^3$  if OSHA adopts a PEL of 0.2  $\mu\text{g}/\text{m}^3$ ; it would be 0.5  $\mu\text{g}/\text{m}^3$  if OSHA adopts a PEL of 0.1  $\mu\text{g}/\text{m}^3$ ; and it would be 2.5  $\mu\text{g}/\text{m}^3$  if OSHA adopts a PEL of 0.5  $\mu\text{g}/\text{m}^3$  (see Regulatory Alternatives #4 and #5). Under Regulatory Alternative #4, the proposed PEL would be lowered from 0.2  $\mu\text{g}/\text{m}^3$  to 0.1  $\mu\text{g}/\text{m}^3$ . Under Regulatory Alternative #5, the proposed PEL would be raised from 0.2  $\mu\text{g}/\text{m}^3$  to 0.5  $\mu\text{g}/\text{m}^3$ . In addition, for informational purposes, OSHA examined a regulatory alternative that would maintain the TWA PEL at 2.0  $\mu\text{g}/\text{m}^3$ , but all of the other proposed provisions would be required with their triggers remaining the same as in the proposed rule. This alternative is not one OSHA could legally adopt because the absence of a more protective requirement for engineering controls would not be consistent with section 6(b)(5) of the OSH Act. More detailed discussion of these alternatives to the proposed PEL appears in Section IX of this preamble and in Chapter VIII of the PEA (OSHA, 2014). In addition, in Section XVIII of this preamble, Summary and Explanation of the Proposed Standard, the discussion of

proposed paragraph (c) describes the proposed TWA PEL and STEL, issues with the proposed exposure limits, and Regulatory Alternatives #3, #4, and #5.

#### Methods of Compliance

The proposed standard would require employers to implement engineering and work practice controls to reduce employees' exposures to or below the TWA PEL and STEL. Where engineering and work practice controls are insufficient to reduce exposures to or below the TWA PEL and STEL, employers would still be required to implement them to reduce exposure as much as possible, and to supplement them with a respiratory protection program. In addition, for each operation where there is airborne beryllium exposure, the employer must ensure that one or more of the engineering and work practice controls listed in paragraph (f)(2) are in place, unless all of the listed controls are infeasible, or the employer can demonstrate that exposures are below the action level based on two samples taken seven days apart. Regulatory Alternative #6 would eliminate the engineering and work practice controls provision currently specified in paragraph (f)(2). This regulatory alternative does not eliminate the need for engineering controls to lower exposure levels to or below the TWA PEL and STEL; rather, it dispenses with the mandatory use of certain engineering controls that must be installed above the action level but at or below the TWA PEL.

More detailed discussion of Regulatory Alternative #6 appears in Section IX of this preamble and in Chapter VIII of the PEA (OSHA, 2014). In addition, the discussion of paragraph (f) in Section XVIII of this preamble, Summary and Explanation, provides a more detailed explanation of the proposed methods of compliance, issues with the proposed methods of compliance, and Regulatory Alternative #6.

#### Ancillary Provisions

The proposed rule contains several ancillary provisions, including requirements for exposure assessment, personal protective clothing and equipment (PPE), medical surveillance, medical removal, training, and regulated areas or access control. OSHA has examined a variety of regulatory alternatives involving changes to one or more of these ancillary provisions. OSHA has preliminarily determined that several of these ancillary provisions will increase the benefits of the proposed rule, for example, by helping to ensure the TWA PEL is not exceeded

or by lowering the risks to workers given the significant risk remaining at the proposed TWA PEL. However, except for Regulatory Alternative #7 (involving the elimination of all ancillary provisions), OSHA did not estimate changes in monetized benefits for the regulatory alternatives that affect ancillary provisions. Two regulatory alternatives that involve all ancillary provisions are presented below (#7 and #8), followed by regulatory alternatives for exposure monitoring (#9, #10, and #11), for regulated areas (#12), for personal protective clothing and equipment (#13), for medical surveillance (#14 through #21), and for medical removal (#22).

#### All Ancillary Provisions

During the Small Business Regulatory Fairness Act (SBREFA) process conducted in 2007, the SBAR Panel recommended that OSHA analyze a PEL-only standard as a regulatory alternative. The Panel also recommended that OSHA consider applying ancillary provisions of the standard so as to minimize costs for small businesses where exposure levels are low (OSHA, 2008b). In response to these recommendations, OSHA analyzed Regulatory Alternative #7, a PEL-only standard, and Regulatory Alternative #8, which would only apply ancillary provisions of the beryllium standard at exposures above the proposed PEL of 0.2  $\mu\text{g}/\text{m}^3$  or the proposed STEL of 2  $\mu\text{g}/\text{m}^3$ . Regulatory Alternative #7 would update the Z tables for § 1910.1000, so that the proposed TWA PEL and STEL would apply to all workers in general industry. All other provisions of the proposed standard would be dropped.

As indicated previously, OSHA has preliminarily determined that there is significant risk remaining at the proposed PEL of 0.2  $\mu\text{g}/\text{m}^3$ . However, the available evidence on feasibility suggests that 0.2  $\mu\text{g}/\text{m}^3$  may be the lowest feasible PEL (see Chapter IV of the PEA, OSHA 2014). Therefore, the Agency believes that it is necessary to include ancillary provisions in the proposed rule to further reduce the remaining risk. In addition, the recommended standard provided to OSHA by representatives of the primary beryllium manufacturing industry and the Steelworkers Union further supports the importance of ancillary provisions in protecting workers from the harmful effects of beryllium exposure (Materion and USW, 2012).

Under Regulatory Alternative #8, several ancillary provisions that the current proposal would require under a variety of exposure conditions (*e.g.*,

dermal contact; any airborne exposure; exposure at or above the action level) would instead only apply where exposure levels exceed the TWA PEL or STEL. Regulatory Alternative #8 affects the following provisions of the proposed standard:

- Exposure monitoring. Whereas the proposed standard requires annual monitoring where exposure levels are at or above the action level and at or below the TWA PEL, Alternative #8 would require annual exposure monitoring only where exposure levels exceed the TWA PEL or STEL;
- Written exposure control plan. Whereas the proposed standard requires written exposure control plans to be maintained in any facility covered by the standard, Alternative #8 would require only facilities with exposures above the TWA PEL or STEL to maintain a plan;
- PPE. Whereas the proposed standard requires PPE for employees under a variety of conditions, such as exposure to soluble beryllium or visible contamination with beryllium, Alternative #8 would require PPE only for employees exposed above the TWA PEL or STEL;
- Housekeeping. Whereas the proposed standard's housekeeping requirements apply across a wide variety of beryllium exposure conditions, Alternative #8 would limit housekeeping requirements to areas with exposures above the TWA PEL or STEL.
- Medical Surveillance. Whereas the proposed standard's medical surveillance provisions require employers to offer medical surveillance to employees with signs or symptoms of beryllium-related health effects regardless of their exposure level, Alternative #8 would make surveillance available to such employees only if they were exposed above the TWA PEL or STEL.

More detailed discussions of Regulatory Alternatives #7 and #8, including a description of the considerations pertinent to these alternatives, appear in Section IX of this preamble and in Chapter VIII of the PEA (OSHA, 2014).

#### Exposure Monitoring

OSHA has examined three regulatory alternatives that would modify the proposed standard's provisions on exposure monitoring, which require periodic monitoring annually where exposures are at or above the action level and at or below the TWA PEL. Under Regulatory Alternative #9, employers would be required to perform periodic exposure monitoring every 180

days where exposures are at or above the action level or above the STEL, and at or below the TWA PEL. Under Regulatory Alternative #10, employers would be required to perform periodic exposure monitoring every 180 days where exposures are at or above the action level or above the STEL, including where exposures exceed the TWA PEL. Under Regulatory Alternative #11, employers would be required to perform periodic exposure monitoring every 180 days where exposures are at or above the action level or above the STEL, and every 90 days where exposures exceed the TWA PEL. More detailed discussions of Regulatory Alternatives #9, #10, and #11 appear in Section IX of this preamble and in Chapter VIII of the PEA (OSHA, 2014). In addition, the discussion of proposed paragraph (d) in Section XVIII of this preamble, Summary and Explanation of the Proposed Standard, provides a more detailed explanation of the proposed requirements for exposure monitoring, issues with exposure monitoring, and the considerations pertinent to Regulatory Alternatives #9, #10, and #11.

#### Regulated Areas

The proposed standard would require employers to establish and maintain two types of areas: beryllium work areas, wherever employees are, or can reasonably be expected to be, exposed to any level of airborne beryllium; and regulated areas, wherever employees are, or can reasonably be expected to be, exposed to airborne beryllium at levels above the TWA PEL or STEL. Employers are required to demarcate beryllium work areas, but are not required to restrict access to beryllium work areas or provide respiratory protection or other forms of PPE within work areas that are not also regulated areas. Employers must demarcate regulated areas, restrict access to them, post warning signs and provide respiratory protection and other PPE within regulated areas, as well as medical surveillance for employees who work in regulated areas for more than 30 days in a 12-month period. During the SBREFA process conducted in 2007, the SBAR Panel recommended that OSHA consider dropping or limiting the provision for regulated areas (OSHA, 2008b). In response to this recommendation, OSHA analyzed Regulatory Alternative #12, which would not require employers to establish regulated areas. More detailed discussion of Regulatory Alternative #12 appears in Section IX of this preamble and in Chapter VIII of the PEA (OSHA, 2014). In addition, the discussion of

paragraph (e) in Section XVIII of this preamble, Summary and Explanation, provides a more detailed explanation of the proposed requirements for regulated areas, issues with regulated areas, and considerations pertinent to Regulatory Alternative #12.

#### Personal Protective Clothing and Equipment (PPE)

Regulatory Alternative #13 would modify the proposed requirements for PPE, which require PPE where exposure exceeds the TWA PEL or STEL; where employees' clothing or skin may become visibly contaminated with beryllium; and where employees may have skin contact with soluble beryllium compounds. The requirement to use PPE where work clothing or skin may become "visibly contaminated" with beryllium differs from prior standards that do not require contamination to be visible in order for PPE to be required. In the case of beryllium, which OSHA has preliminarily concluded can sensitize through dermal exposure, the exposure levels capable of causing adverse health effects and the PELs in effect are so low that beryllium surface contamination is unlikely to be visible (see this preamble at section V, Health Effects). OSHA is therefore considering Regulatory Alternative #13, which would require appropriate PPE wherever there is potential for skin contact with beryllium or beryllium-contaminated surfaces. More detailed discussion of Regulatory Alternative #13 is provided in Section IX of this preamble and in Chapter VIII of the PEA (OSHA, 2014). In addition, the discussion of paragraph (h) in Section XVIII of this preamble, Summary and Explanation, provides a more detailed explanation of the proposed requirements for PPE, issues with PPE, and the considerations pertinent to Regulatory Alternative #13.

#### Medical Surveillance

The proposed requirements for medical surveillance include: (1) Medical examinations, including a test for beryllium sensitization, for employees who are exposed to beryllium above the proposed PEL for 30 days or more per year, who are exposed to beryllium in an emergency, or who show signs or symptoms of CBD; and (2) low-dose helical tomography (low-dose computed tomography, hereafter referred to as "CT scans"), for employees who were exposed above the proposed PEL for more than 30 days in a 12-month period for 5 years or more. This type of CT scan is a method of detecting tumors, and is commonly used to diagnose lung cancer. The proposed

standard would require periodic medical exams to be provided for employees in the medical surveillance program annually, while tests for beryllium sensitization and CT scans would be provided to eligible employees biennially.

OSHA has examined eight regulatory alternatives (#14 through #21) that would modify the proposed rule's requirements for employee eligibility, the types of exam that must be offered, and the frequency of periodic exams. Medical surveillance was a subject of special concern to SERs during the SBREFA process, and the SBREFA Panel offered many comments and recommendations related to medical surveillance for OSHA's consideration. Some of the Panel's concerns have been addressed in this proposal, which was modified since the SBREFA Panel was convened (see this preamble at Section XVIII, Summary and Explanation of the Proposed Standard, for more detailed discussion). Several of the alternatives presented here (#16, #18, and #20) also respond to recommendations by the SBREFA Panel to reduce burdens on small businesses by dropping or reducing the frequency of medical surveillance requirements. OSHA also seeks to ensure that the requirements of the final standard offer workers adequate medical surveillance while limiting the costs to employers. Thus, OSHA requests feedback on several additional alternatives and on a variety of issues raised later in this section of the preamble.

Regulatory Alternatives #14, #15, and #21 would expand eligibility for medical surveillance to a broader group of employees than would be eligible in the proposed standard. Under Regulatory Alternative #14, medical surveillance would be available to employees who are exposed to beryllium above the proposed PEL, including employees exposed for fewer than 30 days per year. Regulatory Alternative #15 would expand eligibility for medical surveillance to employees who are exposed to beryllium above the proposed action level, including employees exposed for fewer than 30 days per year. Regulatory Alternative #21 would extend eligibility for medical surveillance as set forth in proposed paragraph (k) to all employees in shipyards, construction, and general industry who meet the criteria of proposed paragraph (k)(1) (or any of the alternative criteria under consideration). However, all other provisions of the standard would be in effect only for employers and employees that fall within the scope of the proposed rule.

Regulatory Alternatives #16 and #17 would modify the proposed standard's requirements to offer beryllium sensitization testing to eligible employees. Under Regulatory Alternative #16, employers would not be required to offer employees testing for beryllium sensitization. Regulatory Alternative #17 would increase the frequency of periodic sensitization testing, from the proposed standard's biennial requirement to annual testing. Regulatory Alternatives #18 and #19 would similarly modify the proposed standard's requirements to offer CT scans to eligible employees. Regulatory Alternative #18 would drop the CT scan requirement from the proposed rule, whereas Regulatory Alternative #19 would increase the frequency of periodic CT scans from biennial to annual scans. Finally, under Regulatory Alternative #20, all periodic components of the medical surveillance exams would be available biennially to eligible employees. Instead of requiring employers to offer eligible employees a medical examination every year, employers would be required to offer eligible employees a medical examination every other year. The frequency of testing for beryllium sensitization and CT scans would also be biennial for eligible employees, as in the proposed standard.

More detailed discussions of Regulatory Alternatives #14, #15, #16, #17, #18, #19, #20, and #21 appear in Section IX of this preamble and in Chapter VIII of the PEA (OSHA, 2014). In addition, Section XVIII of this preamble, Summary and Explanation, paragraph (k) provides a more detailed explanation of the proposed requirements for medical surveillance, issues with medical surveillance, and the considerations pertinent to Regulatory Alternatives #14 through #21.

#### Medical Removal Protection (MRP)

The proposed requirements for medical removal protection provide an option for medical removal to an employee who is working in a job with exposure at or above the action level and is diagnosed with CBD or confirmed positive for beryllium sensitization. If the employee chooses removal, the employer must either remove the employee to comparable work in a work environment where exposure is below the action level, or if comparable work is not available, must place the employee on paid leave for 6 months or until such time as comparable work becomes available. In either case, the employer must maintain for 6 months the employee's base earnings, seniority,

and other rights and benefits that existed at the time of removal. During the SBREFA process, the Panel recommended that OSHA give careful consideration to the impacts that an MRP requirement could have on small businesses (OSHA, 2008b). In response to this recommendation, OSHA analyzed Regulatory Alternative #22, which would not require employers to offer MRP. More detailed discussion of Regulatory Alternative #22 appears in Section IX of this preamble and in Chapter VIII of the PEA (OSHA, 2014). In addition, the discussion of paragraph (l) in section XVIII of this preamble, Summary and Explanation, provides a more detailed explanation of the proposed requirements for MRP, issues with MRP, and considerations pertinent to Regulatory Alternative #22.

#### Timing of the Standard

The proposed standard would become effective 60 days following publication of the final standard in the **Federal Register**. The effective date is the date on which the standard imposes compliance obligations on employers. However, the standard would not become enforceable by OSHA until 90 days following the effective date for exposure monitoring, work areas and regulated areas, written exposure control plan, respiratory protection, other personal protective clothing and equipment, hygiene areas and practices (except change rooms), housekeeping, medical surveillance, and medical removal. The proposed requirement for change rooms would not be enforceable until one year after the effective date, and the requirements for engineering controls would not be enforceable until two years after the effective date. In summary, employers will have some period of time after the standard becomes effective to come into compliance before OSHA will begin enforcing it: 90 days for most provisions, one year for change rooms, and two years for engineering controls. Beginning 90 days following the effective date, during periods necessary to install or implement feasible engineering controls where exposure exceed the TWA PEL or STEL, employers must provide employees with respiratory protection as described in the proposed standard under section (g), Respiratory Protection.

OSHA invites comment and suggestions for phasing in requirements for engineering controls, medical surveillance, and other provisions of the standard. A longer phase-in time would have several advantages, such as reducing initial costs of the standard or allowing employers to coordinate their

environmental and occupational safety and health control strategies to minimize potential costs. However, a longer phase-in would also postpone and reduce the benefits of the standard. Suggestions for alternatives may apply to specific industries (e.g., industries where first-year or annualized cost impacts are highest), specific size-classes of employers (e.g., employers with fewer than 20 employees), combinations of these factors, or all firms covered by the rule.

OSHA requests comments on these regulatory alternatives, including the Agency's choice of regulatory alternatives (and whether there are other regulatory alternatives the Agency should consider) and the Agency's analysis of them. In addition, OSHA requests comments and information on a number of specific topics and issues pertinent to the proposed standard. These are summarized below.

#### Regulatory Issues

In this section, we solicit public feedback on issues associated with the proposed standard and request information that would help the Agency craft the final standard. In addition to the issues specified here, OSHA also raises issues for comment on technical questions and discussions of economic issues in the PEA (OSHA, 2014). OSHA requests comment on all relevant issues, including health effects, risk assessment, significance of risk, technological and economic feasibility, and the provisions of the proposed regulatory text. In addition, OSHA requests comments on all of the issues raised by the Small Business Advocacy Review (SBAR) Panel, as summarized in the SBAR report (OSHA, 2008b)

We present these issues and requests for information in the first chapter of the preamble to assist readers as they review the preamble and consider any comments they may want to submit. The issues are presented here in summary form. However, to fully understand the questions in this section and provide substantive input in response to them, the sections of the preamble relevant to these issues should be reviewed. These include: Section V, Health Effects; Section VI, the Preliminary Risk Assessment; Section VIII, Significance of Risk; Section IX, Summary of the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis; and Section XVIII, Summary and Explanation of the Proposed Standard.

OSHA requests that comments be organized, to the extent possible, around the following issues and numbered questions. Comment on particular

provisions should contain a heading setting forth the section and the paragraph in the proposed standard that the comment addresses. Comments addressing more than one section or paragraph will have correspondingly more headings.

Submitting comments in an organized manner and with clear reference to the issue raised will enable all participants to easily see what issues the commenter addressed and how they were addressed. Many commenters, especially small businesses, are likely to confine their comments to the issues that affect them, and they will benefit from being able to quickly identify comments on these issues in others' submissions. The Agency welcomes comments concerning all aspects of this proposal. However, OSHA is especially interested in responses, supported by evidence and reasons, to the following questions:

#### Health Effects

1. OSHA has described a variety of studies addressing the major adverse health effects that have been associated with exposure to beryllium. Using currently available epidemiologic and experimental studies, OSHA has made a preliminary determination that beryllium presents risks of lung cancer; sensitization; CBD at 0.1 µg/m<sup>3</sup>; and at higher exposures acute beryllium disease, and hepatic, renal, cardiovascular and ocular diseases. Is this determination correct? Are there additional studies or other data OSHA should consider in evaluating any of these health outcomes?

2. Has OSHA adequately identified and documented all critical health impairments associated with occupational exposure to beryllium? If not, what other adverse health effects should be added? Are there additional studies or other data OSHA should consider in evaluating any of these health outcomes?

3. Are there any additional studies, other data, or information that would affect the information discussed or significantly change the determination of material health impairment?

Please submit any relevant information, data, or additional studies (or citations to studies), and explain your reasons for recommending any studies you suggest.

#### Risk Assessment and Significance of Risk

4. OSHA has developed an analysis of health risks associated with occupational beryllium exposure, including an analysis of sensitization and CBD based on a selection of recent

studies in the epidemiological literature, a data set on a population of beryllium machinists provided by the National Jewish Medical Research Center (NJMRC), and an assessment of lung cancer risk using an analysis provided by NIOSH. Did OSHA rely on the best available evidence in its risk assessment? Are there additional studies or other data OSHA should consider in evaluating risk for these health outcomes? Please provide the studies, citations to studies, or data you suggest.

5. OSHA preliminarily concluded that there is significant risk of material health impairment (lung cancer or CBD) from a working lifetime of occupational exposure to beryllium at the current TWA PEL of 2 µg/m<sup>3</sup>, which would be substantially reduced by the proposed TWA PEL of 0.2 µg/m<sup>3</sup> and the alternative TWA PEL of 0.1 µg/m<sup>3</sup>. OSHA's preliminary risk assessment also concludes that there is still significant risk of CBD and lung cancer at the proposed PEL and the alternative PELs, although substantially less than at the current PEL. Are these preliminary conclusions reasonable, based on the best available evidence? If not, please provide a detailed explanation of your position, including data to support your position and a detailed analysis of OSHA's risk assessment if appropriate.

6. Please provide comment on OSHA's analysis of risk for beryllium sensitization, CBD and lung cancer. Are there important gaps or uncertainties in the analysis, such that the Agency's preliminary conclusions regarding significance of risk at the current, proposed, and alternative PELs may be in error? If so, please provide a detailed explanation and suggestions for how OSHA's analysis should be corrected or improved.

7. OSHA has made a preliminary determination that the available data are not sufficient or suitable for risk analysis of effects other than beryllium sensitization, CBD and lung cancer. Do you have, or are you aware of, studies or data that would be suitable for a risk assessment for these adverse health effects? Please provide the studies, citations to studies, or data you suggest.

*(a) Scope*

8. Has OSHA defined the scope of the proposed standard appropriately? Does it currently include employers who should not be covered, or exclude employers who should be covered by a comprehensive beryllium standard? Are you aware of employees in construction or maritime, or in general industry who deal with beryllium only as a trace contaminant, who may be at significant risk from occupational beryllium

exposure? Please provide the basis for your response and any applicable supporting information.

*(b) Definitions*

9. Has OSHA defined the Beryllium lymphocyte proliferation test appropriately? If not, please provide the definition that you believe is appropriate. Please provide rationale and citations supporting your comments.

10. Has OSHA defined CBD Diagnostic Center appropriately? In particular, should a CBD diagnostic center be required to analyze biological samples on-site, or should diagnostic centers be allowed to send samples off-site for analysis? Is the list of tests and procedures a CBD Diagnostic Center is required to be able to perform appropriate? Should any of the tests or procedures be removed from the definition? Should other tests or procedures be added to the definition? Please provide rationale and information supporting your comments.

*(d) Exposure Monitoring*

11. Do you currently monitor for beryllium exposures in your workplace? If so, how often? Please provide the reasoning for the frequency of your monitoring. If periodic monitoring is performed at your workplace for exposures other than beryllium, with what frequency is it repeated?

12. Is it reasonable to allow discontinuation of monitoring based on one sample below the action level? Should more than one result below the action level be required to discontinue monitoring?

*(e) Work Areas and Regulated Areas*

The proposed standard would require employers to establish and maintain two types of areas: beryllium work areas, wherever employees are, or can reasonably be expected to be, exposed to any level of airborne beryllium; and regulated areas, wherever employees are, or can reasonably be expected to be, exposed to airborne beryllium at levels above the TWA PEL or STEL. Employers are required to demarcate beryllium work areas, but are not required to restrict access to beryllium work areas or provide respiratory protection or other forms of PPE within work areas with exposures at or below the TWA PEL or STEL. Employers must also demarcate regulated areas, including posting warning signs; restrict access to regulated areas; and provide respiratory protection and other PPE within regulated areas.

13. Does your workplace currently have regulated areas? If so, how are regulated areas demarcated?

14. Please describe work settings where establishing regulated areas could be problematic or infeasible. If establishing regulated areas is problematic, what approaches might be used to warn employees in such work settings of high risk areas?

*(f) Methods of Compliance*

Paragraph (f)(2) of the proposed standard would require employers to implement engineering and work practice controls to reduce employees' exposures to or below the TWA PEL and STEL. Where engineering and work practice controls are insufficient to reduce exposures to or below the TWA PEL and STEL, employers would still be required to implement them to reduce exposure as much as possible, and to supplement them with a respiratory protection program. In addition, for each operation where there is airborne beryllium exposure, the employer must ensure that at least one of the engineering and work practice controls listed in paragraph (f)(2) is in place, unless all of the listed controls are infeasible, or the employer can demonstrate that exposures are below the action level based on no fewer than two samples taken seven days apart.

15. Do you usually use engineering or work practice controls (local exhaust ventilation, isolation, substitution) to reduce beryllium exposures? If so, which controls do you use?

16. Are the controls and processes listed in paragraph (f)(2)(i)(A) appropriate for controlling beryllium exposures? Are there additional controls or processes that should be added to paragraph (f)(2)(i)(A)?

*(g) Respiratory Protection*

17. OSHA's asbestos standard (CFR 1910.1001) requires employers to provide each employee with a tight-fitting, powered air-purifying respirator (PAPR) instead of a negative pressure respirator when the employee chooses to use a PAPR and it provides adequate protection to the employee. Should the beryllium standard similarly require employers to provide PAPRs (instead of allowing a negative pressure respirator) when requested by the employee? Are there other circumstances where a PAPR should be specified as the appropriate respiratory protection? Please provide the basis for your response and any applicable supporting information.

*(h) Personal Protective Clothing and Equipment*

18. Do you currently require specific PPE or respirators when employees are working with beryllium? If so, what type?

19. The proposal requires PPE wherever work clothing or skin may become visibly contaminated with beryllium; where employees' skin can reasonably be expected to be exposed to soluble beryllium compounds; or where employee exposure exceeds or can reasonably be expected to exceed the TWA PEL or STEL. The requirement to use PPE where work clothing or skin may become "visibly contaminated" with beryllium differs from prior standards which do not require contamination to be visible in order for PPE to be required. Is "visibly contaminated" an appropriate trigger for PPE? Is there reason to require PPE where employees' skin can be exposed to insoluble beryllium compounds? Please provide the basis for your response and any applicable supporting information.

*(i) Hygiene Areas and Practices*

20. The proposal requires employers to provide showers in their facilities if (A) Exposure exceeds or can reasonably be expected to exceed the TWA PEL or STEL; and (B) Beryllium can reasonably be expected to contaminate employees' hair or body parts other than hands, face, and neck. Is this requirement reasonable and adequately protective of beryllium-exposed workers? Should OSHA amend the provision to require showers in facilities where exposures exceed the PEL or STEL, without regard to areas of bodily contamination?

*(j) Housekeeping*

21. The proposed rule prohibits dry sweeping or brushing for cleaning surfaces in beryllium work areas unless HEPA-filtered vacuuming or other methods that minimize the likelihood and level of exposure have been tried and were not effective. Please comment on this provision. What methods do you use to clean work surfaces at your facility? Are HEPA-filtered vacuuming or other methods to minimize beryllium exposure used to clean surfaces at your facility? Have they been effective? Are there any circumstances under which dry sweeping or brushing are necessary? Please explain your response.

22. The proposed rule requires that materials designated for recycling that are visibly contaminated with beryllium particulate shall be cleaned to remove visible particulate, or placed in sealed, impermeable enclosures. However,

small particles (<10 µg) may not be visible to the naked eye, and there are studies suggesting that small particles may penetrate the skin, beyond which beryllium sensitization can occur (Tinkle et al., 2003). OSHA requests feedback on this provision. Should OSHA require that all material to be recycled be decontaminated regardless of perceived surface cleanliness? Should OSHA require that all material disposed or discarded be in enclosures regardless of perceived surface cleanliness? Please provide explanation or data to support your comments.

*(k) Medical Surveillance*

The proposed requirements for medical surveillance include: (1) Medical examinations, including a test for beryllium sensitization, for employees who are exposed to beryllium above the proposed PEL for 30 days or more per year, who are exposed to beryllium in an emergency, or who show signs or symptoms of CBD; and (2) CT scans for employees who were exposed above the proposed PEL for more than 30 days in a 12-month period for 5 years or more. The proposed standard would require periodic medical exams to be provided for employees in the medical surveillance program annually, while tests for beryllium sensitization and CT scans would be provided to eligible employees biennially.

23. Is medical surveillance being provided for beryllium-exposed employees at your worksite? If so:

a. Do you provide medical surveillance to employees under another OSHA standard or as a matter of company policy? What OSHA standard(s) does the program address?

b. How many employees are included, and how do you determine which employees receive medical surveillance (e.g., by exposure level, other factors)?

c. Who administers and implements the medical surveillance (e.g., company doctor, nurse practitioner, physician assistant, or nurse; or outside doctor, nurse practitioner, physician assistant, or nurse)?

d. What examinations, tests, or evaluations are included in the medical surveillance program, and with what frequency are they administered? Does your program include a surveillance program specifically for beryllium-related health effects (e.g., the BeLPT or other tests for beryllium sensitization)?

e. If your facility offers the BeLPT, please provide feedback and data on your experience with the BeLPT, including the analytical or interpretive procedure you use and its role in your facility's exposure control program. Has

identification of sensitized workers led to interventions to reduce exposures to sensitized individuals, or in the facility generally? If a worker is found to be sensitized, do you track worker health and possible progression of disease beyond sensitization? If so, how is this done?

f. What difficulties and benefits (e.g., health, reduction in absenteeism, or financial) have you experienced with your medical surveillance program? If applicable, please discuss benefits and difficulties you have experienced with the use of the BeLPT, providing detailed information or examples if possible.

g. What are the costs of your medical surveillance program? How do your costs compare with OSHA's estimated unit costs for the physical examination and employee time involved in the medical surveillance program? Are OSHA's baseline assumptions and cost estimates for medical surveillance consistent with your experiences providing medical surveillance to your employees?

24. Please review paragraph (k) of the proposed rule, Medical Surveillance, and comment on the frequency and contents of medical surveillance in the proposed rule. Is 30 days from initial assignment a reasonable time at which to provide a medical exam? Should there be a requirement for beryllium sensitization testing at time of employment? Should there be a requirement for beryllium sensitization testing at an employee's exit exam, regardless of when the employee's most recent sensitization test was administered? Are the tests required and the testing frequencies specified appropriate? Should sensitized employees have the opportunity to be examined at a CBD Diagnostic Center more than once following a confirmed positive BeLPT? Are there additional tests or alternate testing schedules you would suggest? Should the skin be examined for signs and symptoms of beryllium exposure or other medical issues, as well as for breaks and wounds? Please explain the basis for your position and provide data or studies if applicable.

25. Please provide comments on the proposed requirements regarding referral of a sensitized employee to a CBD diagnostic center, which specify referral to a diagnostic center "mutually agreed upon" by the employer and employee. Is this requirement for mutual agreement necessary and appropriate? How should a diagnostic center be chosen if the employee and employer cannot come to agreement? Should OSHA consider alternate language, such as referral for CBD

evaluation at a diagnostic center in a reasonable location?

26. In the proposed rule, OSHA specifies that all medical examinations and procedures required by the standard must be performed by or under the direction of a licensed physician. Are physicians available in your geographic area to provide medical surveillance to workers who are covered by the proposed rule? Are other licensed health care professionals available to provide medical surveillance? Do you have access to other qualified personnel such as qualified X-ray technicians, and pulmonary specialists? Should the proposal be amended to allow examination by, or under the direction of, a physician or other licensed health care professional (PLHCP)? Please explain your position. Please note what you consider your geographic area in responding to this question.

27. The proposed standard requires the employer to obtain the Licensed Physician's Written Medical Opinion from the PLHCP within 30 days of the examination. Should OSHA revise the medical surveillance provisions of the proposed standard to allow employees to choose what, if any, medical information goes to the employer from the PLHCP? For example, the employer could instead be required to obtain a certification from the PLHCP within 30 days of the examination stating (1) when the examination took place, (2) that the examination complied with the standard, and (3) that the PLHCP provided the employee a copy of the Licensed Physician's Written Medical Opinion required by the standard. The PLHCP would need the employee's written consent to send the employer the Licensed Physician's Written Medical Opinion or any other medical information about the employee. This approach might lead to corresponding changes in proposed paragraphs (f)(1) (written exposure control program), (l) (medical removal) and (n) (recordkeeping) to reflect that employers will not automatically be receiving any medical information about employees as a result of the medical surveillance required by the proposed standard, but would instead only receive medical information the employee chooses to share with the employer. Please comment on the relative merits of the proposed standard's requirement that employers obtain the PLHCP's written opinion or an alternative that would provide employees with greater discretion over the information that goes to employers, and explain the basis for your position and the potential impact on the benefits of medical surveillance.

28. Appendix A to the proposed standard reviews procedures for conducting and interpreting the results of BeLPT testing for beryllium sensitization. Is there now, or should there be, a standard method for BeLPT laboratory procedure? If yes, please describe the existing or proposed method. Is there now, or should there be, a standard algorithm for interpreting BeLPT results to determine sensitization? Please describe the existing or proposed laboratory method or interpretation algorithm. Should OSHA require that BeLPTs performed to comply with the medical surveillance provisions of this rule adhere to the Department of Energy (DOE) analytical and interpretive specifications issued in 2001? Should interpretation of laboratory results be delegated to the employee's occupational physician or PLHCP?

29. Should OSHA require the clinical laboratories performing the BeLPT to be accredited by the College of American Pathologists or another accreditation organization approved under the Clinical Laboratory Improvement Amendments (CLIA)? What other standards, if any, should be required for clinical laboratories providing the BeLPT?

30. Are there now, or are there being developed, alternative tests to the BeLPT you would suggest? Please explain the reasons for your suggestion. How should alternative tests for beryllium sensitization be evaluated and validated? How should OSHA determine whether a test for beryllium sensitization is more reliable and accurate than the BeLPT? Please see Appendix A to the proposed standard for a discussion of the accuracy of the BeLPT.

31. The proposed rule requires employers to provide OSHA with the results of BeLPTs performed to comply with the medical surveillance provisions upon request, provided that the employer obtains a release from the tested employee. Will this requirement be unduly burdensome for employers? Are there alternative organizations that would be appropriate to send test results to?

#### *(l) Medical Removal Protection*

The proposed requirements for medical removal protection provide an option for medical removal to an employee who is working in a job with exposure at or above the action level and is diagnosed with CBD or confirmed positive for beryllium sensitization. If the employee chooses removal, the employer must remove the employee to comparable work in a work

environment where exposure is below the action level, or if comparable work is not available, must place the employee on paid leave for 6 months or until such time as comparable work becomes available. In either case, the employer must maintain for 6 months the employee's base earnings, seniority, and other rights and benefits that existed at the time of removal.

32. Do you provide MRP at your facility? If so, please comment on the program's benefits, difficulties, and costs, and the extent to which eligible employees make use of MRP.

33. OSHA has included requirements for medical removal protection (MRP) in the proposed rule, which includes provisions for medical removal for employees with beryllium sensitization or CBD, and an extension of removed employees' rights and benefits for six months. Are beryllium sensitization and CBD appropriate triggers for medical removal? Are there other medical conditions or findings that should trigger medical removal? For what amount of time should a removed employee's benefits be extended?

#### *(p) Appendices*

34. Some OSHA health standards include appendices that address topics such as the hazards associated with the regulated substance, health screening considerations, occupational disease questionnaires, and PLHCP obligations. In this proposed rule, OSHA has included a non-mandatory appendix to describe and discuss the BeLPT (Appendix A), and a non-mandatory appendix presenting a non-exhaustive list of engineering controls employers may use to comply with paragraph (f) (Appendix B). What would be the advantages and disadvantages of including each appendix in the final rule? What would be the advantages and disadvantages of providing this information in guidance materials?

35. What additional information, if any, should be included in the appendices? What additional information, if any, should be provided in guidance materials?

#### *General*

36. The current beryllium proposal includes triggers that require employers to initiate certain provisions, programs, and activities to protect workers from beryllium exposure. All employers covered under an OSHA health standard are required to initiate certain activities such as initial monitoring to evaluate the potential hazard to employees. OSHA health standards typically include ancillary provisions with various triggers indicating when an



employer covered under the standard would need to comply with a provision. The most common triggers are ones based on an exposure level such as the PEL or action level. These exposure level triggers are sometimes combined with a minimum duration of exposure (e.g.,  $\geq$  30 days per year). Other triggers may include reasonably anticipated exposure, medical surveillance findings, certain work activities, or simply the presence of the regulated substance in the workplace.

For the current Proposal, exposures to beryllium above the TWA PEL or STEL trigger the provisions for regulated areas, additional or enhanced engineering or work practice controls to reduce airborne exposures to or below the TWA PEL and STEL, personal protective clothing and equipment, medical surveillance, showers, and respiratory protection if feasible engineering and work practice controls cannot reduce airborne exposures to or below the TWA PEL and STEL. Exposures at or above the action level in turn trigger the provisions for periodic exposure monitoring, and medical removal eligibility (along with a diagnosis of CBD or confirmed positive for beryllium sensitization). Finally, an employer covered under the scope of the proposed standard must establish a beryllium work area where employees are, or can reasonably be expected to be, exposed to airborne beryllium regardless of the level of exposure. In beryllium work areas, employers must implement a written exposure control plan, provide washing facilities and change rooms (change rooms are only necessary if employees are required to remove their personal clothing), and follow housekeeping provisions. The employers must also implement at least one of the engineering and work practice controls listed in paragraph (f)(2) of the proposed standard. An employer is exempt from this requirement if he or she can demonstrate that such controls are not feasible or that exposures are below the action level.

Certain provisions are triggered by one condition and other provisions are triggered only if multiple conditions are present. For example, medical removal is only triggered if an employee has CBD or is confirmed positive AND the employee is exposed at or above the action level.

OSHA is requesting comment on the triggers in the proposed beryllium standard. Are the triggers OSHA has proposed appropriate? OSHA is also requesting comment on these triggers relative to the regulatory alternatives affecting the scope and PELs as

described in this preamble in section I, Issues and Alternatives. For example, are the triggers in the proposed standard appropriate for Alternative #1a, which would expand the scope of the proposed standard to include all operations in general industry where beryllium exists only as a trace contaminant (less than 0.1% beryllium by weight)? Are the triggers appropriate for the alternatives that change the TWA PEL, STEL, and action level? Please specify the trigger and the alternative, if applicable, and why you agree or disagree with the trigger.

*Relevant Federal Rules Which May Duplicate, Overlap, or Conflict With the Proposed Rule*

37. In Section IX—Preliminary Economic Analysis under the *Initial Regulatory Flexibility Analysis*, OSHA identifies, to the extent practicable, all relevant Federal rules which may duplicate, overlap, or conflict with the proposed rule. One potential area of overlap is with the U.S. Department of Energy (DOE) beryllium program. In 1999, DOE established a chronic beryllium disease prevention program (CBDPP) to reduce the number of workers (DOE employees and DOE contractors) exposed to beryllium at DOE facilities (10 CFR part 850, published at 64 FR 68854–68914 (Dec. 8, 1999)). In establishing this program, DOE has exercised its statutory authority to prescribe and enforce occupational safety and health standards. Therefore pursuant to section 4(b)(1) of the OSH Act, 29 U.S.C. 653(b)(1), the DOE facilities are exempt from OSHA jurisdiction.

Nevertheless, under 10 CFR 850.22, DOE has included in its CBDPP regulation a requirement for compliance with the current OSHA permissible exposure limit (PEL), and any lower PEL that OSHA establishes in the future. Thus, although DOE has preempted OSHA's standard from applying at DOE facilities and OSHA cannot exercise any authority at those facilities, DOE relies on OSHA's PEL in implementing its own program. However, DOE's decision to tie its own standard to OSHA's PEL has little consequence to this rulemaking because the requirements in DOE's beryllium program (controls, medical surveillance, etc.) are triggered by DOE's action level of  $0.2 \mu\text{g}/\text{m}^3$ , which is much lower than DOE's existing PEL and the same as OSHA's proposed PEL. DOE's action level is not tied to OSHA's standard, so 10 CFR 850.22 would not require the CBDPP's action level or any non-PEL requirements to be automatically adjusted as a result of OSHA's

rulemaking. For this reason, DOE has indicated to OSHA that OSHA's proposed rule would not have any impact on DOE's CBDPP, particularly since 10 CFR 850.25(b), *Exposure reduction and minimization*, requires DOE contractors to reduce exposures to below the DOE's action level of  $0.2 \mu\text{g}/\text{m}^3$ , if practicable.

DOE has expressed to OSHA that DOE facilities are already in compliance with 10 CFR 850 and its action level of  $0.2 \mu\text{g}/\text{m}^3$ ,<sup>2</sup> so the only potential impact on DOE's CBDPP that could flow from OSHA's rulemaking would be if OSHA ultimately adopted a PEL of  $0.1 \mu\text{g}/\text{m}^3$ , as discussed in alternative #4, instead of the proposed PEL of  $0.2 \mu\text{g}/\text{m}^3$ , and DOE did not make any additional adjustments to its standards. Even in that hypothetical scenario, the impact would still be limited because of the odd result that DOE's PEL would drop below its own action level, while the action level would continue to serve as the trigger for most of DOE's program requirements.

DOE also has noted some potential overlap with a separate DOE provision in 10 CFR part 851, which requires its contractors to comply with DOE's CBDPP (10 CFR 851.23(a)(1)) and also with all OSHA standards under 29 CFR part 1910 except "Ionizing Radiation" (§ 1910.1096) (10 CFR 851.23(a)(3)). These requirements, which DOE established in 2006 (71 FR 6858 (February 9, 2006)), make sense in light of OSHA's current regulation because OSHA's only beryllium protection is a PEL, so compliance with 10 CFR 851.23(a)(1) and (3) merely make OSHA's current PEL the relevant level for purposes of the CBDPP. However, its function would be less clear if OSHA adopts a beryllium standard as proposed. OSHA's proposed beryllium standard would establish additional substantive protections beyond the PEL. Consequently, notwithstanding the CBDPP's preemptive effect on the OSHA beryllium standard as a result of 29 U.S.C. 653(b)(1), 10 CFR 851.23(a)(3) could be read to require DOE contractors to comply with all provisions in OSHA's proposal (if finalized), including the ancillary provisions, creating a dual regulatory scheme for beryllium protection at DOE facilities.

DOE officials have indicated that this is not their intent. Instead, their intent is that DOE contractors comply solely with the CBDPP provisions in 10 CFR part 850 for protection from beryllium.

<sup>2</sup> This would mean the prevailing beryllium exposures at DOE facilities are at or below  $0.2 \mu\text{g}/\text{m}^3$ .

Based on its discussions with DOE officials, OSHA anticipates that DOE will clarify that its contractors do not need to comply with any ancillary provisions in a beryllium standard that OSHA may promulgate.

OSHA can envision several potential scenarios developing from its rulemaking, ranging from OSHA retaining the proposed PEL of 0.2  $\mu\text{g}/\text{m}^3$  and action level of 0.1  $\mu\text{g}/\text{m}^3$  in the final rule to adopting the PEL of 0.1  $\mu\text{g}/\text{m}^3$ , as discussed in alternative #4. Because OSHA's beryllium standard does not apply directly to DOE facilities, and the only impact of its rules on those facilities is the result of DOE's regulatory choices, there is also a range of actions that DOE could take to minimize any potential impact of any change to OSHA's rules, including (1) taking no action at all, (2) simply clarifying the CBDPP, as described above, to mean that OSHA's beryllium standard (other than its PEL) does not apply to contractors, or (3) revising both parts 850 and 851 to completely disassociate DOE's regulation of beryllium at DOE facilities from OSHA's regulation of beryllium.

OSHA is aware that, in the preamble to its 1999 CBDPP rule, DOE analyzed the costs for implementing the CBDPP for action levels of 0.1  $\mu\text{g}/\text{m}^3$ , 0.2  $\mu\text{g}/\text{m}^3$ , and 0.5  $\mu\text{g}/\text{m}^3$  (64 FR 68875, December 8, 1999). DOE estimated costs for periodic exposure monitoring, notifying workers of the results of such monitoring, exposure reduction and minimization, regulated areas, change rooms and showers, respiratory protection, protective clothing, and disposal of protective clothing. All of these provisions are triggered by DOE's action level (64 FR 68874, December 8, 1999). Although DOE's rule is not identical to OSHA's proposed standard, OSHA believes that DOE's costs are sufficiently representative to form the basis of a preliminary estimate of the costs that could flow from OSHA's standard, if finalized.

Based on the range of potential scenarios and the prior DOE cost estimates, OSHA estimates that the annual cost impact on DOE facilities could range from \$0 to \$4,065,768 (2010 dollars). The upper end of the cost range would reflect the unlikely scenario in which OSHA promulgates a final PEL of 0.1  $\mu\text{g}/\text{m}^3$ , 10 CFR 851.23(a)(3) is found to compel DOE contractors to comply with OSHA's comprehensive beryllium standard in addition to DOE's CBDPP, and DOE takes no action to clarify that OSHA's beryllium standard does not apply to DOE contractors. The lower end of the cost range assumes OSHA promulgates its rule as proposed with a

PEL of 0.2  $\mu\text{g}/\text{m}^3$  and action level of 0.1  $\mu\text{g}/\text{m}^3$ , and DOE clarifies that it intends its contractors to follow DOE's CBDPP and not OSHA's beryllium standard, so that the ancillary provisions of OSHA's beryllium standard do not apply to DOE facilities. Additionally, OSHA assumes that DOE contractors are in compliance with DOE's current rule and therefore took the difference in cost between implementation of an action level of 0.2  $\mu\text{g}/\text{m}^3$  and an action level of 0.1  $\mu\text{g}/\text{m}^3$  for the above estimates. Finally, OSHA used the GDP price deflator to present the cost estimate in 2010 dollars.

OSHA requests comment on the potential overlap of DOE's rule with OSHA's proposed rule.

## II. Pertinent Legal Authority

The purpose of the Occupational Safety and Health Act, 29 U.S.C. 651 *et seq.* ("the 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 promulgate and enforce occupational safety and health standards. 29 U.S.C. 654(b) (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 Act provides that in promulgating health standards dealing with toxic materials or harmful physical agents, such as this proposed standard regulating occupational exposure to beryllium, 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. See 29 U.S.C. 655(b)(5).

The Supreme Court has held that before the Secretary can promulgate any permanent health or safety standard, he must make a threshold finding that significant risk is present and that such risk can be eliminated or lessened by a change in practices. *Industrial Union Dept., AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 641–42 (1980) (plurality opinion) ("*The Benzene case*"). Thus, section 6(b)(5) of the Act requires health standards to reduce significant risk to the extent feasible. *Id.*

The Court further observed that what constitutes "significant risk" is "not a mathematical straitjacket" and must be "based largely on policy considerations." *The Benzene case*, 448 U.S. at 655. The Court gave the example that if,

. . . the odds are one in a billion that a person will die from cancer . . . the risk clearly could not be considered significant. On the other hand, if the odds are one in one thousand that regular inhalation of gasoline vapors that are 2% benzene will be fatal, a reasonable person might well consider the risk significant. [*Id.*]

OSHA standards must be both technologically and economically feasible. *United Steelworkers v. Marshall*, 647 F.2d 1189, 1264 (D.C. Cir. 1980) ("*The Lead I case*"). The Supreme Court has defined feasibility as "capable of being done." *Am. Textile Mfrs. Inst. v. Donovan*, 452 U.S. 490, 509–510 (1981) ("*The Cotton Dust case*"). The courts have further 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. [*See The Lead I case*, 647 F.2d at 1272]

With respect to economic feasibility, the courts have held that a standard is feasible if it does not threaten massive dislocation to or imperil the existence of the industry. *Id.* at 1265. A court must 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 . . . [T]he practical question is whether the standard threatens the competitive stability of an industry, . . . or whether any intra-industry or inter-industry discrimination in the standard might wreck such stability or lead to undue concentration. [*Id.* (citing *Indus. Union Dep't, AFL-CIO v. Hodgson*, 499 F.2d 467 (D.C. Cir. 1974))]

The courts have further observed that granting companies reasonable time to comply with new PELs may enhance economic feasibility. *The Lead I case* at 1265. While a standard must be economically feasible, the Supreme Court has held that a cost-benefit analysis of health standards is not required by the Act because a feasibility analysis is required. *The Cotton Dust case*, 453 U.S. at 509.

Finally, sections 6(b)(7) and 8(c) of the Act authorize OSHA to include among a standard's requirements labeling, monitoring, medical testing, and other information-gathering and -transmittal provisions. 29 U.S.C. 655(b)(7), 657(c).

### III. Events Leading to the Proposed Standards

The first occupational exposure limit for beryllium was set in 1949 by the Atomic Energy Commission (AEC), which required that beryllium exposure in the workplaces under its jurisdiction be limited to 2  $\mu\text{g}/\text{m}^3$  as an 8-hour time-weighted average (TWA), and 25  $\mu\text{g}/\text{m}^3$  as a peak exposure never to be exceeded (Department of Energy, 1999). These exposure limits were adopted by all AEC installations handling beryllium, and were binding on all AEC contractors involved in the handling of beryllium.

In 1956, the American Industrial Hygiene Association (AIHA) published a Hygienic Guide which supported the AEC exposure limits. In 1959, the American Conference of Governmental Industrial Hygienists (ACGIH<sup>®</sup>) also adopted a Threshold Limit Value (TLV<sup>®</sup>) of 2  $\mu\text{g}/\text{m}^3$  as an 8-hour TWA (Borak, 2006).

In 1971, OSHA adopted, under Section 6(a) of the Occupational Safety and Health Act of 1970, and made applicable to general industry, a national consensus standard (ANSI Z37.29-1970) for beryllium and beryllium compounds. The standard set a permissible exposure limit (PEL) for beryllium and beryllium compounds at 2  $\mu\text{g}/\text{m}^3$  as an 8-hour TWA; 5  $\mu\text{g}/\text{m}^3$  as an acceptable ceiling concentration; and 25  $\mu\text{g}/\text{m}^3$  as an acceptable maximum peak above the acceptable ceiling concentration for a maximum duration of 30 minutes in an 8-hour shift (OSHA, 1971).

Section 6(a) stipulated that in the first two years after the effective date of the Act, OSHA was 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, in 1971, OSHA promulgated approximately 425 PELs for air contaminants, including beryllium, 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, in turn, had been adopted primarily from ACGIH<sup>®</sup>'s TLV<sup>®</sup>s.

The National Institute for Occupational Safety and Health (NIOSH) issued a document entitled *Criteria for a Recommended Standard: Occupational Exposure to Beryllium* (Criteria Document) in June 1972. OSHA

reviewed the findings and recommendations contained in the Criteria Document along with the AEC control requirements for beryllium exposure. OSHA also considered existing data from animal and epidemiological studies, and studies of industrial processes of beryllium extraction, refinement, fabrication, and machining. In 1975, OSHA asked NIOSH to update the evaluation of the existing data pertaining to the carcinogenic potential of beryllium. In response to OSHA's request, the Director of NIOSH stated that, based on animal data and through all possible routes of exposure including inhalation, “beryllium in all likelihood represents a carcinogenic risk to man.”

In October 1975, OSHA proposed a new beryllium standard for all industries based on information that beryllium caused cancer in animal experiments (40 FR 48814 (October 17, 1975)). Adoption of this proposal would have lowered the 8-hour TWA exposure limit from 2  $\mu\text{g}/\text{m}^3$  to 1  $\mu\text{g}/\text{m}^3$ . In addition, the proposal included ancillary provisions for such topics as exposure monitoring, hygiene facilities, medical surveillance, and training related to the health hazards from beryllium exposure. The rulemaking was never completed.

In 1977, NIOSH recommended an exposure limit of 0.5  $\mu\text{g}/\text{m}^3$  and identified beryllium as a potential occupational carcinogen. In December 1998, ACGIH published a Notice of Intended Change for its beryllium exposure limit. The notice proposed a lower TLV of 0.2  $\mu\text{g}/\text{m}^3$  over an 8-hour TWA based on evidence of CBD and sensitization in exposed workers.

In 1999, the Department of Energy (DOE) issued a Chronic Beryllium Disease Prevention Program (CBDPP) Final Rule for employees exposed to beryllium in its facilities (DOE, 1999). The DOE rule set an action level of 0.2  $\mu\text{g}/\text{m}^3$  and adopted OSHA's PEL of 2  $\mu\text{g}/\text{m}^3$  or any more stringent PEL OSHA might adopt in the future. The DOE action level triggers workplace precautions and control measures such as periodic monitoring, exposure reduction or minimization, regulated areas, hygiene facilities and practices, respiratory protection, protective clothing and equipment, and warning signs (DOE, 1999).

Also in 1999, OSHA was petitioned by the Paper, Allied-Industrial, Chemical and Energy Workers International Union (PACE) (OSHA, 2002) and by Dr. Lee Newman and Ms. Margaret Mroz, from the National Jewish Medical Research Center (NJMRC) (OSHA, 2002), to promulgate

an Emergency Temporary Standard (ETS) for beryllium in the workplace. In 2001, OSHA was petitioned for an ETS by Public Citizen Health Research Group and again by PACE (OSHA, 2002). In order to promulgate an ETS, the Secretary of Labor must prove (1) that employees are exposed to grave danger from exposure to a hazard, and (2) that such an emergency standard is necessary to protect employees from such danger (29 U.S.C. 655(c)). The burden of proof is on the Department and because of the difficulty of meeting this burden, the Department usually proceeds when appropriate with 6(b) rulemaking rather than a 6(c) ETS. Thus, instead of granting the ETS requests, OSHA instructed staff to further collect and analyze research regarding the harmful effects of beryllium.

On November 26, 2002, OSHA published a Request for Information (RFI) for “Occupational Exposure to Beryllium” (OSHA, 2002). The RFI contained questions on employee exposure, health effects, risk assessment, exposure assessment and monitoring methods, control measures and technological feasibility, training, medical surveillance, and impact on small business entities. In the RFI, OSHA expressed concerns about health effects such as CBD, lung cancer, and beryllium sensitization. OSHA pointed to studies indicating that even short-term exposures below OSHA's PEL of 2  $\mu\text{g}/\text{m}^3$  could lead to CBD. The RFI also cited studies describing the relationship between beryllium sensitization and CBD (67 FR at 70708). In addition, OSHA stated that beryllium had been identified as a carcinogen by organizations such as NIOSH, the International Agency for Research on Cancer (IARC), and the Environmental Protection Agency (EPA); and cancer had been evidenced in animal studies (67 FR at 70709).

On November 15, 2007, OSHA convened a Small Business Advocacy Review Panel for a draft proposed standard for occupational exposure to beryllium. OSHA convened this panel under Section 609(b) of the Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (5 U.S.C. 601 *et seq.*).

The Panel included representatives from OSHA, the Solicitor's Office of the Department of Labor, the Office of Advocacy within the Small Business Administration, and the Office of Information and Regulatory Affairs of the Office of Management and Budget. Small Entity Representatives (SERs) made oral and written comments on the

draft rule and submitted them to the panel.

The SBREFA Panel issued a report which included the SERs' comments on January 15, 2008. SERs expressed concerns about the impact of the ancillary requirements such as exposure monitoring and medical surveillance. Their comments addressed potential costs associated with compliance with the draft standard, and possible impacts of the standard on market conditions, among other issues. In addition, many SERs sought clarification of some of the ancillary requirements such as the meaning of "routine" contact or "contaminated surfaces."

The SBREFA Panel issued a number of recommendations, which OSHA carefully considered. In section XVIII of this preamble, Summary and Explanation, OSHA has responded to the Panel's recommendations and clarified the requirements about which SERs expressed confusion. OSHA also examined the regulatory alternatives recommended by the SBREFA Panel. The regulatory alternatives examined by OSHA are listed in section I of this preamble, Issues and Alternatives. The alternatives are discussed in greater detail in section XVIII of this preamble, Summary and Explanation, and in the PEA (OSHA, 2014). In addition, the Agency intends to develop interpretive guidance documents following the publication of a final rule.

In 2010, OSHA hired a contractor to oversee an independent scientific peer review of a draft preliminary beryllium health effects evaluation (OSHA, 2010a) and a draft preliminary beryllium risk assessment (OSHA, 2010b). The contractor identified experts familiar with beryllium health effects research and ensured that these experts had no conflict of interest or apparent bias in performing the review. The contractor selected five experts with expertise in such areas as pulmonary and

occupational medicine, CBD, beryllium sensitization, the BeLPT, beryllium toxicity and carcinogenicity, and medical surveillance. Other areas of expertise included animal modeling, occupational epidemiology, biostatistics, risk and exposure assessment, exposure-response modeling, beryllium exposure assessment, industrial hygiene, and occupational/environmental health engineering.

Regarding the health effects evaluation, the peer reviewers concluded that the health effect studies were described accurately and in sufficient detail, and OSHA's conclusions based on the studies were reasonable. The reviewers agreed that the OSHA document covered the significant health endpoints related to occupational beryllium exposure. Peer reviewers considered the preliminary conclusions regarding beryllium sensitization and CBD to be reasonable and well presented in the draft health evaluation section. All reviewers agreed that the scientific evidence supports sensitization as a necessary condition in the development of CBD. In response to reviewers' comments, OSHA made revisions to more clearly describe certain sections of the health effects evaluation. In addition, OSHA expanded its discussion regarding the BeLPT.

Regarding the preliminary risk assessment, the peer reviewers were highly supportive of the Agency's approach and major conclusions. The peer reviewers stated that the key studies were appropriate and their selection clearly explained in the document. They regarded the preliminary analysis of these studies to be reasonable and scientifically sound. The reviewers supported OSHA's conclusion that substantial risk of sensitization and CBD were observed in facilities where the highest exposure

generating processes had median full-shift exposures around 0.2  $\mu\text{g}/\text{m}^3$  or higher, and that the greatest reduction in risk was achieved when exposures for all processes were lowered to 0.1  $\mu\text{g}/\text{m}^3$  or below.

In February 2012 the Agency received for consideration a draft recommended standard for beryllium (Materion and USW, 2012). This draft proposal was the product of a joint effort between two stakeholders: Materion Corporation, a leading producer of beryllium and beryllium products in the United States, and the United Steelworkers, an international labor union representing workers who manufacture beryllium alloys and beryllium-containing products in a number of industries. The United Steelworkers and Materion sought to craft an OSHA-like model beryllium standard that would have support from both labor and industry. OSHA has considered this proposal along with other information submitted during the development of the Notice of Proposed Rulemaking for beryllium.

#### IV. Chemical Properties and Industrial Uses

##### *Chemical and Physical Properties*

Beryllium (Be; CAS Number 7440–41–7) is a silver-grey to greyish-white, strong, lightweight, and brittle metal. It is a Group IIA element with an atomic weight of 9.01, atomic number of 4, melting point of 1,287 °C, boiling point of 2,970°C, and a density of 1.85 at 20 °C (NTP 2014). It occurs naturally in rocks, soil, coal, and volcanic dust (ATSDR, 2002). Beryllium is insoluble in water and soluble in acids and alkalis. It has two common oxidation states, Be(0) and Be(+2). There are several beryllium compounds with unique CAS numbers and chemical and physical properties. Table IV–1 describes the most common beryllium compounds.

TABLE IV—1, PROPERTIES OF BERYLLIUM AND BERYLLIUM COMPOUNDS

Chemical name	CAS No.	Synonyms and trade names	Molecular weight	Melting point (°C)	Description	Density (g/cm <sup>3</sup> )	Solubility
Beryllium metal	7440–41–7	Beryllium; beryllium-9, beryllium element; beryllium metallic.	9.0122	1287 .....	Grey, close-packed, hexagonal, brittle metal.	1.85 (20 °C).	Soluble in most dilute acids and alkali; decomposes in hot water; insoluble in mercury and cold water.
Beryllium chloride.	7787–47–5	Beryllium dichloride.	79.92	399.2 .....	Colorless to slightly yellow; orthorhombic, deliquescent crystal.	1.899 (25 °C).	Soluble in water, ethanol, diethyl ether and pyridine; slightly soluble in benzene, carbon disulfide and chloroform; insoluble in acetone, ammonia, and toluene.

TABLE IV—1, PROPERTIES OF BERYLLIUM AND BERYLLIUM COMPOUNDS—Continued

Chemical name	CAS No.	Synonyms and trade names	Molecular weight	Melting point (°C)	Description	Density (g/cm <sup>3</sup> )	Solubility
Beryllium fluoride.	7787–49–7 (12323–05–6)	Beryllium difluoride.	47.01	555 .....	Colorless or white, amorphous, hygroscopic solid.	1.986 .....	Soluble in water, sulfuric acid, mixture of ethanol and diethyl ether; slightly soluble in ethanol; insoluble in hydrofluoric acid.
Beryllium hydroxide.	13327–32–7 (1304–49–0)	Beryllium dihydroxide.	43.3	138 (decomposes to beryllium oxide).	White, amorphous, amphoteric powder.	1.92 .....	Soluble in hot concentrated acids and alkali; slightly soluble in dilute alkali; insoluble in water.
Beryllium sulfate	13510–49–1	Sulfuric acid, beryllium salt (1:1).	105.07	550–600 °C (decomposes to beryllium oxide).	Colorless crystal	2.443 .....	Forms soluble tetrahydrate in hot water; insoluble in cold water.
Beryllium sulfate tetrahydrate.	7787–56–6	Sulfuric acid; beryllium salt (1:1), tetrahydrate.	177.14	100 °C .....	Colorless, tetragonal crystal.	1.713 .....	Soluble in water; slightly soluble in concentrated sulfuric acid; insoluble in ethanol.
Beryllium Oxide	1304–56–9	Beryllia; beryllium monoxide thermalox TM.	25.01	2508–2547 °C	Colorless to white, hexagonal crystal or amorphous, amphoteric powder.	3.01 (20 °C).	Soluble in concentrated acids and alkali; insoluble in water.
Beryllium carbonate.	1319–43–3	Carbonic acid, beryllium salt, mixture with beryllium hydroxide.	112.05	No data .....	White powder ....	No data ....	Soluble in acids and alkali; insoluble in cold water; decomposes in hot water.
Beryllium nitrate trihydrate.	7787–55–5	Nitric acid, beryllium salt, trihydrate.	187.97	60 .....	White to faintly yellowish, deliquescent mass.	1.56 .....	Very soluble in water and ethanol.
Beryllium phosphate.	13598–15–7	Phosphoric acid, beryllium salt (1:1).	104.99	No data .....	Not reported .....	Not reported.	Slightly soluble in water.

ATSDR, 2002.

The physical and chemical properties of beryllium were realized early in the 20th century, and it has since gained commercial importance in a wide range of industries. Beryllium is lightweight, hard, spark resistant, non-magnetic, and has a high melting point. It lends strength, electrical and thermal conductivity, and fatigue resistance to alloys (NTP, 2014). Beryllium also has a high affinity for oxygen in air and water, which can cause a thin surface film of beryllium oxide to form on the bare metal, making it extremely resistant to corrosion. These properties make beryllium alloys highly suitable for defense, nuclear, and aerospace applications (IARC, 1993).

There are approximately 45 mineralized forms of beryllium. In the United States, the predominant mineral form mined commercially and refined into pure beryllium and beryllium alloys is bertrandite. Bertrandite, while containing less than 1% beryllium

compared to 4% in beryl, is easily and efficiently processed into beryllium hydroxide (IARC, 1993). Imported beryl is also converted into beryllium hydroxide as the United States has very little beryl that can be economically mined (USGS, 2013a).

#### Industrial Uses

Materion Corporation, formerly called Brush Wellman, is the only producer of primary beryllium in the United States. Beryllium is used in a variety of industries, including aerospace, defense, telecommunications, automotive, electronic, and medical specialty industries. Pure beryllium metal is used in a range of products such as X-ray transmission windows, nuclear reactor neutron reflectors, nuclear weapons, precision instruments, rocket propellants, mirrors, and computers (NTP, 2014). Beryllium oxide is used in components such as ceramics, electrical insulators, microwave oven

components, military vehicle armor, laser structural components, and automotive ignition systems (ATSDR, 2002). Beryllium oxide ceramics are used to produce sensitive electronic items such as lasers and satellite heat sinks.

Beryllium alloys, typically beryllium/copper or beryllium/aluminum, are manufactured as high beryllium content or low beryllium content alloys. High content alloys contain greater than 30% beryllium. Low content alloys are typically less than 3% beryllium. Beryllium alloys are used in automotive electronics (*e.g.*, electrical connectors and relays and audio components), computer components, home appliance parts, dental appliances (*e.g.*, crowns), bicycle frames, golf clubs, and other articles (NTP, 2014; Ballance et al., 1978; Cunningham et al., 1998; Mroz, et al., 2001). Electrical components and conductors are stamped and formed from beryllium alloys. Beryllium-copper

alloys are used to make switches in automobiles (Ballance et al., 1978, 2002; Cunningham et al., 1998) and connectors, relays, and switches in computers, radar, satellite, and telecommunications equipment (Mroz et al., 2001). Beryllium-aluminum alloys are used in the construction of aircraft, high resolution medical and industrial X-ray equipment, and mirrors to measure weather patterns (Mroz et al., 2001). High content and low content beryllium alloys are precision machined for military and aerospace applications. Some welding consumables are also manufactured using beryllium.

Beryllium is also found as a trace metal in materials such as aluminum ore, abrasive blasting grit, and coal fly ash. Abrasive blasting grits such as coal slag and copper slag contain varying concentrations of beryllium, usually less than 0.1% by weight. The burning of bituminous and sub-bituminous coal for power generation causes the naturally occurring beryllium in coal to accumulate in the coal fly ash byproduct. Scrap and waste metal for smelting and refining may also contain beryllium. A detailed discussion of the industries and job tasks using beryllium is included in the Preliminary Economic Analysis (OSHA, 2014).

Occupational exposure to beryllium can occur from inhalation of dusts, fume, and mist. Beryllium dusts are created during operations where beryllium is cut, machined, crushed, ground, or otherwise mechanically sheared. Mists can also form during operations that use machining fluids. Beryllium fume can form while welding with or on beryllium components, and from hot processes such as those found in metal foundries.

Occupational exposure to beryllium can also occur from skin, eye, and mucous membrane contact with beryllium particulate or solutions.

## V. Health Effects

Beryllium-associated health effects, including acute beryllium disease (ABD), beryllium sensitization (also referred to in this preamble as “sensitization”), chronic beryllium disease (CBD), and lung cancer, can lead to a number of highly debilitating and life-altering conditions including pneumonitis, loss of lung capacity (reduction in pulmonary function leading to pulmonary dysfunction), loss of physical capacity associated with reduced lung capacity, systemic effects related to pulmonary dysfunction, and decreased life expectancy (NIOSH, 1972).

This Health Effects section presents information on beryllium and its compounds, the fate of beryllium in the body, research that relates to its toxic mechanisms of action, and the scientific literature on the adverse health effects associated with beryllium exposure, including ABD, sensitization, CBD, and lung cancer. OSHA considers CBD to be a progressive illness with a continuous spectrum of symptoms ranging from no symptomatology at its earliest stage following sensitization to mild symptoms such as a slight almost imperceptible shortness of breath, to loss of pulmonary function, debilitating lung disease, and, in many cases, death. This section also discusses the nature of these illnesses, the scientific evidence that they are causally associated with occupational exposure to beryllium, and the probable mechanisms of action with a more thorough review of the supporting studies.

### A. Beryllium and Beryllium Compounds

#### 1. Particle Physical/Chemical Properties

Beryllium (Be; CAS No. 7440–41–7) is a steel-grey, brittle metal with an atomic number of 4 and an atomic weight of 9.01 (Group IIA of the periodic table). Because of its high reactivity, beryllium

is not found as a free metal in nature; however, there are approximately 45 mineralized forms of beryllium. Beryllium compounds and alloys include commercially valuable metals and gemstones.

Beryllium has two oxidative states: Be(0) and Be(2+) Agency for Toxic Substance and Disease Registry (ATSDR) 2002). It is likely that the Be(2+) state is the most biologically reactive and able to form a bond with peptides leading to it becoming antigenic (Snyder *et al.*, 2003). This will be discussed in more detail in the Beryllium Sensitization section below. Beryllium has a high charge-to-radius ratio and in addition to forming various types of ionic bonds, beryllium has a strong tendency for covalent bond formation (*e.g.*, it can form organometallic compounds such as Be(CH<sub>3</sub>)<sub>2</sub> and many other complexes) (ATSDR, 2002; Greene *et al.*, 1998). However, it appears that few, if any, toxicity studies exist for the organometallic compounds. Additional physical/chemical properties for beryllium compounds that may be important in their biological response are summarized in Table 1 below. This information was obtained from their International Chemical Safety Cards (ICSC) (beryllium metal (ICSC 0226), beryllium oxide (ICSC 1325), beryllium sulfate (ICSC 1351), beryllium nitrate (ICSC 1352), beryllium carbonate (ICSC 1353), beryllium chloride (ICSC 1354), beryllium fluoride (ICSC 1355)) and from the hazardous substance data bank (HSDB) for beryllium hydroxide (CASRN: 13327–32–7), and beryllium phosphate (CASRN: 13598–15–7). Additional information on chemical and physical properties as well as industrial uses for beryllium can be found in this preamble at Section IV, Chemical Properties and Industrial Uses.

TABLE 1—PHYSICAL/CHEMICAL PROPERTIES OF BERYLLIUM AND COMPOUNDS

Compound name	Physical appearance	Chemical formula	Molecular mass	Acute physical hazards	Solubility in water at 20 °C
Beryllium Metal .....	Grey to White Powder.	Be .....	9.0	Combustible; Finely dispersed particles—Explosive.	None.
Beryllium Oxide .....	White Crystals or Powder.	BeO .....	25.0	Not combustible or explosive .....	Very sparingly soluble.
Beryllium Carbonate	White Powder .....	Be <sub>2</sub> CO <sub>3</sub> (OH)/ Be <sub>2</sub> CO <sub>3</sub> H <sub>2</sub> .	181.07	Not combustible or explosive .....	None.
Beryllium Sulfate .....	Colorless Crystals	BeSO <sub>4</sub> .....	105.1	Not combustible or explosive .....	Slightly soluble.
Beryllium Nitrate .....	White to Yellow Solid.	BeN <sub>2</sub> O <sub>6</sub> /Be(NO <sub>3</sub> ) <sub>2</sub>	133.0	Enhances combustion of other substances.	Very soluble (1.66 × 10 <sup>6</sup> mg/L).
Beryllium Hydroxide	White amorphous powder or crystalline solid.	Be(OH) <sub>2</sub> .....	43.0	Not reported .....	Slightly soluble 0.8 × 10 <sup>-4</sup> mol/L (3.44 mg/L).
Beryllium Chloride ..	Colorless to Yellow Crystals.	BeCl <sub>2</sub> .....	79.9	Not combustible or explosive .....	Soluble.
Beryllium Fluoride ...	Colorless Lumps ...	BeF <sub>2</sub> .....	47.0	Not combustible or explosive .....	Very soluble.

TABLE 1—PHYSICAL/CHEMICAL PROPERTIES OF BERYLLIUM AND COMPOUNDS—Continued

Compound name	Physical appearance	Chemical formula	Molecular mass	Acute physical hazards	Solubility in water at 20 °C
Beryllium Phosphate	White solid .....	Be <sub>3</sub> (PO <sub>4</sub> ) <sub>2</sub> .....	271.0	Not reported .....	Soluble.

**Source:** International Chemical Safety Cards (except beryllium phosphate and hydroxide—HSDB).

Beryllium shows a high affinity for oxygen in air and water, resulting in a thin surface film of beryllium oxide on the bare metal. If the surface film is disturbed, it may become airborne or dermal exposure may occur. The solubility, particle surface area, and particle size of some beryllium compounds are examined in more detail below. These properties have been evaluated in many toxicological studies. In particular, the properties related to the calcination (firing temperatures) and differences in crystal size and solubility are important aspects in their toxicological profile.

## 2. Factors Affecting Potency and Effect of Beryllium Exposure

The effect and potency of beryllium and its compounds, as for any toxicant, immunogen, or immunotoxicant, may be dependent upon the physical state in which they are presented to a host. For occupational airborne materials and surface contaminants, it is especially critical to understand those physical parameters in order to determine the extent of exposure to the respiratory tract and skin since these are generally the initial target organs for either route of exposure.

For example, large particles may have less of an effect in the lung than smaller particles due to reduced potential to stay airborne to be inhaled or be deposited along the respiratory tract. In addition, once inhalation occurs particle size is critical in determining where the particle will deposit along the respiratory tract. Solubility also has an important part in determining the toxicity and bioavailability of airborne materials as well. Respiratory tract retention and skin penetration are directly influenced by the solubility and reactivity of airborne material.

These factors may be responsible, at least in part, for the process by which beryllium sensitization progresses to CBD in exposed workers. Other factors influencing beryllium-induced toxicity include the surface area of beryllium particles and their persistence in the lung. With respect to dermal exposure, the physical characteristics of the particle are important as well since they can influence skin absorption and bioavailability. This section addresses certain physical characteristics (*i.e.*,

solubility, particle size, particle surface area) that are important in influencing the toxicity of beryllium materials in occupational settings.

### a. Solubility

Solubility may be an important determinant of the toxicity of airborne materials, influencing the deposition and persistence of inhaled particles in the respiratory tract, their bioavailability, and the likelihood of presentation to the immune system. A number of chemical agents, including metals that contact and penetrate the skin, are able to induce an immune response, such as sensitization (Boeniger, 2003; Mandervelt *et al.*, 1997). Similar to inhaled agents, the ability of materials to penetrate the skin is also influenced by solubility since dermal absorption may occur at a greater rate for soluble materials than insoluble materials (Kimber *et al.*, 2011).

This section reviews the relevant information regarding solubility, its importance in a biological matrix and its relevance to sensitization and beryllium lung disease. The weight of evidence presented below suggests that both soluble and non-soluble forms of beryllium can induce a sensitization response and result in progression of lung disease.

Beryllium salts, including the chloride (BeCl<sub>2</sub>), fluoride (BeF<sub>2</sub>), nitrate (Be(NO<sub>3</sub>)<sub>2</sub>), phosphate (Be<sub>3</sub>(PO<sub>4</sub>)<sub>2</sub>), and sulfate (tetrahydrate) (BeSO<sub>4</sub> · 4H<sub>2</sub>O) salts, are all water soluble. However, soluble beryllium salts can be converted to less soluble forms in the lung (Reeves and Vorwald, 1967). Aqueous solutions of the soluble beryllium salts are acidic as a result of the formation of Be(OH)<sub>2</sub> 2<sup>+</sup>, the tetrahydrate, which will react to form insoluble hydroxides or hydrated complexes within the general physiological range of pH values (between 5 and 8) (EPA, 1998). This may be an important factor in the development of CBD since lower-solubility forms of beryllium have been shown to persist in the lung for longer periods of time and persistence in the lung may be needed in order for this disease to occur (NAS, 2008).

Beryllium oxide (BeO), hydroxide (Be(OH)<sub>2</sub>), carbonate (Be<sub>2</sub>CO<sub>3</sub>(OH)<sub>2</sub>), and sulfate (anhydrous) (BeSO<sub>4</sub>) are either

insoluble, slightly soluble, or considered to be sparingly soluble (almost insoluble or having an extremely slow rate of dissolution). The solubility of beryllium oxide, which is prepared from beryllium hydroxide by calcining (heating to a high temperature without fusing in order to drive off volatile chemicals) at temperatures between 500 and 1,750 °C, has an inverse relationship with calcination temperature. Although the solubility of the low-fired crystals can be as much as 10 times that of the high-fired crystals, low-fired beryllium oxide is still only sparingly soluble (Delic, 1992). In a study that measured the dissolution kinetics (rate to dissolve) of beryllium compounds calcined at different temperatures, Hoover *et al.*, compared beryllium metal to beryllium oxide particles and found them to have similar solubilities. This was attributed to a fine layer of beryllium oxide that coats the metal particles (Hoover *et al.*, 1989). A study conducted by Deubner *et al.*, (2011) determined ore materials to be more soluble than beryllium oxide at pH 7.2 but similar in solubility at pH 4.5. Beryllium hydroxide was more soluble than beryllium oxide at both pHs (Deubner *et al.*, 2011).

Investigators have also attempted to determine how biological fluids can dissolve beryllium materials. In two studies, insoluble beryllium, taken up by activated phagocytes, was shown to be ionized by myeloperoxidases (Leonard and Lauwerys, 1987; Lansdown, 1995). The positive charge resulting from ionization enabled the beryllium to bind to receptors on the surface of cells such as lymphocytes or antigen-presenting cells which could make it more biologically active (NAS, 2008). In a study utilizing phagolysosomal-simulating fluid (PSF) with a pH of 4.5, both beryllium metal and beryllium oxide dissolved at a greater rate than that previously reported in water or SUF (simulant fluid) (Stefaniak *et al.*, 2006), and the rate of dissolution of the multi-constituent (mixed) particles was greater than that of the single-constituent beryllium oxide powder. The authors speculated that copper in the particles rapidly dissolves, exposing the small inclusions of beryllium oxide, which have higher specific surface areas (SSA)

and therefore dissolve at a higher rate. A follow-up study by the same investigational team (Duling *et al.*, 2012) confirmed dissolution of beryllium oxide by PSF and determined the release rate was biphasic (initial rapid diffusion followed by a latter slower surface reaction-driven release). During the latter phase, dissolution half-times were 1,400 to 2,000 days. The authors speculated this indicated bertrandite was persistent in the lung (Duling *et al.*, 2012).

In a recent study investigating the dissolution and release of beryllium ions for 17 beryllium-containing materials (ore, hydroxide, metal, oxide, alloys, and processing intermediates) using artificial human airway epithelial lining fluid, Stefaniak *et al.*, (2011) found release of beryllium ions within 7 days (beryl ore melter dust). The authors calculated dissolution half-times ranging from 30 days (reduction furnace material) to 74,000 days (hydroxide). Stefaniak *et al.*, (2011) speculated that despite the rapid mechanical clearance, billions of beryllium ions could be released in the respiratory tract via dissolution in airway lining fluid (ALF). Under this scenario beryllium-containing particles depositing in the respiratory tract dissolving in ALF could provide beryllium ions for absorption in the lung and interact with immune cells in the respiratory tract (Stefaniak *et al.*, 2011).

Huang *et al.*, (2011) investigated the effect of simulated lung fluid (SLF) on dissolution and nanoparticle generation and beryllium-containing materials. Bertrandite-containing ore, beryl-containing ore, frit (a processing intermediate), beryllium hydroxide (a processing intermediate) and silica (used as a control), were equilibrated in SLF at two pH values (4.5 and 7.2) to reflect inter- and intra-cellular environments in the lung tissue. Concentrations of beryllium, aluminum, and silica ions increased linearly during the first 20 days in SLF, rose slowly thereafter, reaching equilibrium over time. The study also found nanoparticle formation (in the size range of 10–100 nm) for all materials (Huang *et al.*, 2011).

In an *in vitro* skin model, Sutton *et al.*, (2003) demonstrated the dissolution of beryllium compounds (insoluble beryllium hydroxide, soluble beryllium phosphate) in a simulated sweat fluid. This model showed beryllium can be dissolved in biological fluids and be available for cellular uptake in the skin. Duling *et al.*, (2012) confirmed dissolution and release of ions from

bertrandite ore in an artificial sweat model (pH 5.3 and pH 6.5).

#### b. Particle Size

The toxicity of beryllium as exemplified by beryllium oxide also is dependent, in part, on the particle size, with smaller particles (<10  $\mu\text{m}$ ) able to penetrate beyond the larynx (Stefaniak *et al.*, 2008). Most inhalation studies and occupational exposures involve quite small (<1–2  $\mu\text{m}$ ) beryllium oxide particles that can penetrate to the pulmonary regions of the lung (Stefaniak *et al.*, 2008). In inhalation studies with beryllium ores, particle sizes are generally much larger, with deposition occurring in several areas throughout the respiratory tract for particles <10  $\mu\text{m}$ .

The temperature at which beryllium oxide is calcined influences its particle size, surface area, solubility, and ultimately its toxicity (Delic, 1992). Low-fired (500  $^{\circ}\text{C}$ ) beryllium oxide is predominantly made up of poorly crystallized small particles, while higher firing temperatures (1000–1750  $^{\circ}\text{C}$ ) result in larger particle sizes (Delic, 1992).

In order to determine the extent to which particle size plays a role in the toxicity of beryllium in occupational settings, several key studies are reviewed and detailed below. The findings on particle size have been related, where possible, to work process and biologically relevant toxicity endpoints of either sensitization or CBD.

Numerous studies have been conducted evaluating the particle size generated during basic industrial and machining operations. In a study by Cohen *et al.*, (1983), a multi-cyclone sampler was utilized to measure the size mass distribution of the beryllium aerosol at a beryllium-copper alloy casting operation. Briefly, Cohen *et al.*, (1983) found variable particle size generation based on the operations being sampled with particle size ranging from 3 to 16  $\mu\text{m}$ . Hoover *et al.*, (1990) also found variable particle sizes being generated based on operations. In general, Hoover *et al.*, (1990) found that milling operations generated smaller particle sizes than sawing operations. Hoover *et al.*, (1990) also found that beryllium metal generated higher concentrations than metal alloys. Martyny *et al.*, (2000) characterized generation of particle size during precision beryllium machining processes. The study found that more than 50 percent of the beryllium machining particles collected in the breathing zone of machinists were less than 10  $\mu\text{m}$  in aerodynamic diameter with 30 percent of that fraction being

particles of less than 0.6  $\mu\text{m}$ . A study by Thorat *et al.*, (2003) found similar results with ore mixing, crushing, powder production and machining ranging from 5.0 to 9.5  $\mu\text{m}$ . Kent *et al.*, (2001) measured airborne beryllium using size-selective samplers in five furnace areas at a beryllium processing facility. A statistically significant linear trend was reported between the above alveolar-deposited particle mass concentration and prevalence of CBD and sensitization in the furnace production areas. The study authors suggested that the concentration of alveolar-deposited particles (*e.g.*, <3.5  $\mu\text{m}$ ) may be a better predictor of sensitization and CBD than the total mass concentration of airborne beryllium.

A recent study by Virji *et al.* (2011) evaluated particle size distribution, chemistry and solubility in areas with historically elevated risk of sensitization and CBD at a beryllium metal powder, beryllium oxide, and alloy production facility. The investigators observed that historically, exposure-response relationships have been inconsistent when using mass concentration to identify process-related risk, possibly due to incomplete particle characterization. Two separate exposure surveys were conducted in March 1999 and June–August 1999 using multi-stage personal impactor samplers (to determine particle size distribution) and personal 37 mm closed face cassette (CFC) samplers, both located in workers' breathing zones. One hundred and ninety eight time-weighted-average (TWA) personal impactor samples were analyzed for representative jobs and processes. A total of 4,026 CFC samples were collected over the 5-month collection period and analyzed for mass concentration, particle size, chemical content and solubility and compared to process areas with high risk of sensitization and CBD. The investigators found that total beryllium concentration varied greatly between workers and among process areas. Analysis of chemical form and solubility also revealed wide variability among process areas, but high risk process areas had exposures to both soluble and insoluble forms of beryllium. Analysis of particle size revealed most process areas had particles ranging from 5–14  $\mu\text{m}$  mass median aerodynamic diameter (MMAD). Rank order correlating jobs to particle size showed high overall consistency (Spearman  $r=0.84$ ) but moderate correlation (Pearson  $r=0.43$ ). The investigators concluded that consideration of relevant aspects of exposure such as particle size



distribution, chemical form, and solubility will likely improve exposure assessments (Virji *et al.*, 2011)

#### c. Particle Surface Area.

Particle surface area has been postulated as an important metric for beryllium exposure. Several studies have demonstrated a relationship between the inflammatory and tumorigenic potential of ultrafine particles and their increased surface area (Driscoll, 1996; Miller, 1995; Oberdorster *et al.*, 1996). While the exact mechanism explaining how particle surface area influences its biological activity is not known, a greater particle surface area has been shown to increase inflammation, cytokine production, anti-oxidant defenses and apoptosis (Elder *et al.*, 2005; Carter *et al.*, 2006; Refsne *et al.*, 2006).

Finch *et al.*, (1988) found that beryllium oxide calcined at 500 °C had 3.3 times greater specific surface area (SSA) than beryllium oxide calcined at 1000 °C, although there was no difference in size or structure of the particles as a function of calcining temperature. The beryllium-metal aerosol (airborne beryllium particles), although similar to the beryllium oxide aerosols in aerodynamic size, had an SSA about 30 percent that of the beryllium oxide calcined at 1000 °C. As discussed above, a later study by Delic (1992) found calcining temperatures had an effect on SSA as well as particle size.

Several studies have investigated the lung toxicity of beryllium oxide calcined at different temperatures and generally had found that those calcined at lower temperatures have greater toxicity and effect than materials calcined at higher temperatures. This may be because beryllium oxide fired at the lower temperature has a loosely formed crystalline structure with greater specific surface area than the fused crystal structure of beryllium oxide fired at the higher temperature. For example, beryllium oxide calcined at 500 °C has

been found to have stronger pathogenic effects than material calcined at 1,000 °C, as shown in several of the beagle dog, rat, mouse and guinea pig studies discussed in the section on CBD pathogenesis that follows (Finch *et al.*, 1988; Polak *et al.*, 1968; Haley *et al.*, 1989; Haley *et al.*, 1992; Hall *et al.*, 1950). Finch *et al.* have also observed higher toxicity of beryllium oxide calcined at 500 °C, an observation they attribute to the greater surface area of beryllium particles calcined at the lower temperature (Finch *et al.*, 1988). These authors found that the *in vitro* cytotoxicity to Chinese hamster ovary (CHO) cells and cultured lung epithelial cells of 500 °C beryllium oxide was greater than that of 1,000 °C beryllium oxide, which in turn was greater than that of beryllium metal. However, when toxicity was expressed in terms of particle surface area, the cytotoxicity of all three forms was similar. Similar results were observed in a study comparing the cytotoxicity of beryllium metal particles of various sizes to cultured rat alveolar macrophages, although specific surface area did not entirely predict cytotoxicity (Finch *et al.*, 1991).

Stefaniak *et al.*, (2003b) investigated the particle structure and surface area of particles (powder and process-sampled) of beryllium metal, beryllium oxide, and copper-beryllium alloy. Each of these samples was separated by aerodynamic size, and their chemical compositions and structures were determined with x-ray diffraction and transmission electron microscopy, respectively. In summary, beryllium-metal powder varied remarkably from beryllium oxide powder and alloy particles. The metal powder consisted of compact particles, in which SSA decreases with increasing surface diameter. In contrast, the alloys and oxides consisted of small primary particles in clusters, in which the SSA remains fairly constant with particle size. SSA for the metal powders varied based on production and manufacturing process with variations among samples

as high as a factor of 37. Stefaniak *et al.* (2003b) found lesser variation in SSA for the alloys or oxides. This is consistent with data from other studies summarized above showing that process may affect particle size and surface area. Particle size and/or surface area may explain differences in the rate of BeS and CBD observed in some epidemiological studies. However, these properties have not been consistently characterized in most studies.

#### B. Kinetics and Metabolism of Beryllium

Beryllium enters the body by inhalation, ingestion, or absorption through the skin. For occupational exposure, the airways and the skin are the primary routes of uptake.

##### 1. Exposure via the Respiratory System

The respiratory tract, especially the lung, is the primary target of inhalation exposure in workers. Inhaled beryllium particles are deposited along the respiratory tract in a size dependent manner. In general, particles larger than 10 µm tend to deposit in the upper respiratory tract or nasal region and do not appreciably penetrate lower in the tracheobronchial or pulmonary regions (Figure 1). Particles less than 10 µm increasingly penetrate and deposit in the tracheobronchial and pulmonary regions with peak deposition in the pulmonary region occurring below 5 µm in particle diameter. The CBD pathology of concern is found in the pulmonary region. For particles below 1 µm, regional deposition changes dramatically. Ultrafine particles (generally considered to be 100 nm or lower) have a higher rate of deposition along the entire respiratory system (ICRP model, 1994). Those particles depositing in the lung and along the entire respiratory tract may encounter immunologic cells or may move into the vascular system where they are free to leave the lung and can contribute to systemic beryllium concentrations.

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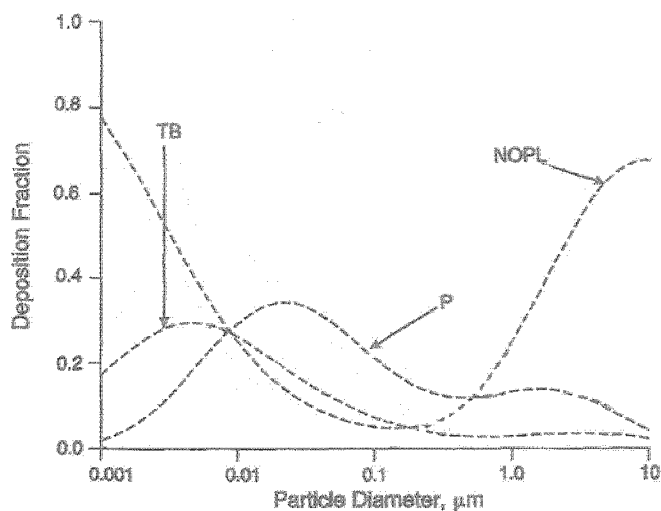


Figure 1, ICRP model: Regional Deposition Model in Humans (Adapted from Yeh et al., 1996)

NOPL - naso-oral-pharyngolaryngeal region

TB – tracheobronchial region

P – pulmonary region

Beryllium is removed from the respiratory tract by various clearance mechanisms. Soluble beryllium is removed from the respiratory tract via absorption. Sparingly soluble or insoluble beryllium may remain in the lungs for many years after exposure, as has been observed in workers (Schepers, 1962). Clearance mechanisms for sparingly soluble or insoluble beryllium particles include: In the nasal passage, sneezing, mucociliary transport to the throat, or dissolution; in the tracheobronchial region, mucociliary transport, coughing, phagocytosis, or dissolution; in the pulmonary or alveolar region, phagocytosis, movement through the interstitium (translocation), or dissolution (Schlesinger, 1997).

Clearance mechanisms may occur slowly in humans, which is consistent with some animal studies. For example, subjects in the Beryllium Case Registry (BCR), which identifies and tracks cases of acute and chronic beryllium diseases, had elevated concentrations of beryllium in lung tissue (e.g., 3.1  $\mu\text{g/g}$  of dried lung tissue and 8.5  $\mu\text{g/g}$  in a mediastinal node) more than 20 years after termination of short-term (generally between 2 and 5 years) occupational exposure to beryllium (Sprince *et al.*, 1976).

Clearance rates may depend on the solubility, dose, and size of the beryllium particles inhaled as well as the sex and species of the animal tested. As reviewed in a WHO Report (2001), more soluble beryllium compounds generally tend to be cleared from the respiratory system and absorbed into the bloodstream more rapidly than less soluble compounds (Van Cleave and Kaylor, 1955; Hart *et al.*, 1980; Finch *et al.*, 1990). Animal inhalation or intratracheal instillation studies administering soluble beryllium salts demonstrated significant absorption of approximately 20 percent of the initial lung burden, while sparingly soluble compounds such as beryllium oxide demonstrated that absorption was slower and less significant (Delic, 1992). Additional animal studies have demonstrated that clearance of soluble and sparingly soluble beryllium compounds was biphasic: A more rapid initial mucociliary transport phase of particles from the tracheobronchial tree to the gastrointestinal tract, followed by a slower phase via translocation to tracheobronchial lymph nodes, alveolar macrophages uptake, and beryllium particles dissolution (Camner *et al.*, 1977; Sanders *et al.*, 1978; Delic, 1992; WHO, 2001). Confirmatory studies in rats have shown the half-time for the rapid phase between 1–60 days, while

the slow phase ranged from 0.6–2.3 years. It was also shown that this process was influenced by the solubility of the beryllium compounds: Weeks/months for soluble compounds, months/years for sparingly soluble compounds (Reeves and Vorwald, 1967; Reeves *et al.*, 1967; Zorn *et al.*, 1977; Rhoads and Sanders, 1985). Studies in guinea-pigs and rats indicate that 40–50 percent of the inhaled soluble beryllium salts are retained in the respiratory tract. Similar data could not be found for the sparingly or less soluble beryllium compounds or metal administered by this exposure route. (WHO, 2001; ATSDR, 2002).

Evidence from animal studies suggests that greater amounts of beryllium deposited in the lung may result in slower clearance times. A comparative study of rats and mice using a single dose of inhaled aerosolized beryllium metal demonstrated that an acute inhalation exposure to beryllium metal can slow particle clearance and induce lung damage in rats (Haley *et al.*, 1990) and mice (Finch *et al.*, 1998a). In another study Finch *et al.* (1994) exposed male F344/N rats to beryllium metal at concentrations resulting in beryllium lung burdens of 1.8, 10, and 100  $\mu\text{g}$ . These exposure levels resulted in an estimated clearance half-life ranging

from 250–380 days for the three concentrations. For mice (Finch *et al.*, 1998a), lung clearance half-lives were 91–150 days (for 1.7- and 2.6- $\mu\text{g}$  lung burden groups) or 360–400 days (for 12- and 34- $\mu\text{g}$  lung burden groups). While the lower exposure groups were quite different for rats and mice, the highest groups were similar in clearance half-lives for both species.

Beryllium absorbed from the respiratory system is mainly distributed to the tracheobronchial lymph nodes via the lymph system, bloodstream, and skeleton, which is the ultimate site of beryllium storage (Stokinger *et al.*, 1953; Clary *et al.*, 1975; Sanders *et al.*, 1975; Finch *et al.*, 1990). Trace amounts are distributed throughout the body (Zorn *et al.*, 1977; WHO, 2001). Studies in rats have demonstrated accumulation of beryllium chloride in the skeletal system following intraperitoneal injection (Crowley *et al.*, 1949; Scott *et al.*, 1950) and accumulation of beryllium phosphate and beryllium sulfate in both nonparenchymal and parenchymal cells of the liver after intravenous administration in rats (Skilleter and Price, 1978). Studies have also demonstrated intracellular accumulation of beryllium oxide in bone marrow throughout the skeletal system after intravenous administration to rabbits (Fodor, 1977; WHO, 2001).

Systemic distribution of the more soluble compounds appears to be greater than that of the insoluble compounds (Stokinger *et al.*, 1953). Distribution has also been shown to be dose dependent in research using intravenous administration of beryllium in rats; small doses were preferentially taken up in the skeleton, while higher doses were initially distributed preferentially to the liver. Beryllium was later mobilized from the liver and transferred to the skeleton (IARC, 1993). A half-life of 450 days has been estimated for beryllium in the human skeleton (ICRP, 1960). This indicates the skeleton may serve as a repository for beryllium that may later be reabsorbed by the circulatory system, making beryllium available to the immunological system.

## 2. Dermal Exposure

Beryllium compounds have been shown to cause skin irritation and sensitization in humans and certain animal models (Van Orstrand *et al.*, 1945; de Nardi *et al.*, 1953; Nishimura 1966; Epstein 1990; Belman, 1969; Tinkle *et al.*, 2003; Delic, 1992). The Agency for Toxic Substances and Disease Registry (ATSDR) estimated that less than 0.1 percent of beryllium compounds are absorbed through the

skin (ATSDR, 2002). However, even minute contact and absorption across the skin may directly elicit an immunological sensitization response (Deubner *et al.*, 2001; Toledo *et al.*, 2011). Recent studies by Tinkle *et al.* (2003) showed that penetration of beryllium oxide particles was possible *ex vivo* for human intact skin at particle sizes of  $\leq 1\mu\text{m}$ , as confirmed by scanning electron microscopy. Using confocal microscopy, Tinkle *et al.* demonstrated that surrogate fluorescent particles up to 1  $\mu\text{m}$  in size could penetrate the mouse epidermis and dermis layers in a model designed to mimic the flexing and stretching of human skin in motion. Other poorly soluble particles, such as titanium dioxide, have been shown to penetrate normal human skin (Tan *et al.*, 1996) suggesting the flexing and stretching motion as a plausible mechanism for dermal penetration of beryllium as well. As earlier summarized, insoluble forms of beryllium can be solubilized in biological fluids (*e.g.*, sweat) making them available for absorption through intact skin (Sutton *et al.*, 2003; Stefaniak *et al.*, 2011; Duling *et al.*, 2012).

Although its precise role remains to be elucidated, there is evidence to indicate that dermal exposure can contribute to beryllium sensitization. As early as the 1940s it was recognized that dermatitis experienced by workers in primary beryllium production facilities was linked to exposures to the soluble beryllium salts. Except in cases of wound contamination, dermatitis was rare in workers whose exposures were restricted to exposure to poorly soluble beryllium-containing particles (Van Orstrand *et al.*, 1945). Further investigation by McCord in 1951 indicated that direct skin contact with soluble beryllium compounds, but not beryllium hydroxide or beryllium metal, caused dermal lesions (reddened, elevated, or fluid-filled lesions on exposed body surfaces) in susceptible persons. Curtis, in 1951, demonstrated skin sensitization to beryllium with patch testing using soluble and insoluble forms of beryllium in beryllium-naïve subjects. These subjects later developed granulomatous skin lesions with the classical delayed-type contact dermatitis following repeat challenge (Curtis, 1951). These lesions appeared after a latent period of 1–2 weeks, suggesting a delayed allergic reaction. The dermal reaction occurred more rapidly and in response to smaller amounts of beryllium in those individuals previously sensitized (Van Orstrand *et al.*, 1945). Contamination of cuts and scrapes with beryllium can

result in the beryllium becoming embedded within the skin causing a granuloma to develop in the skin (Epstein, 1991). Introduction of soluble or insoluble beryllium compounds into or under the skin as a result of abrasions or cuts at work has been shown to result in chronic ulcerations with granuloma formation (Van Orstrand *et al.*, 1945; Lederer and Savage, 1954). Beryllium absorption through bruises and cuts has been demonstrated as well (Rossman *et al.*, 1991). In a study by Invannikov *et al.*, (1982), beryllium chloride was applied directly to the skin of live animals with three types of wounds: abrasions (superficial skin trauma), cuts (skin and superficial muscle trauma), and penetration wounds (deep muscle trauma). The percentage of the applied dose absorbed into the systemic circulation during a 24-hour exposure was significant, ranging from 7.8 percent to 11.4 percent for abrasions, from 18.3 percent to 22.9 percent for cuts, and from 34 percent to 38.8 percent for penetration wounds (WHO, 2001).

A study by Deubner *et al.*, (2001) concluded that exposure across damaged skin can contribute as much systemic loading of beryllium as inhalation (Deubner *et al.*, 2001). Deubner *et al.*, (2001) estimated dermal loading (amount of particles penetrating into the skin) in workers as compared to inhalation exposure. Deubner's calculations assumed a dermal loading rate for beryllium on skin of 0.43  $\mu\text{g}/\text{cm}^2$ , based on the studies of loading on skin after workers cleaned up (Sanderson *et al.*, 1999), multiplied by a factor of 10 to approximate the workplace concentrations and the very low absorption rate of 0.001 percent (taken from EPA estimates). It should be noted that these calculations did not take into account absorption of soluble beryllium salts that might occur across nasal mucus membranes, which may result from contact between contaminated skin and the nose (EPA, 1998).

A study conducted by Day *et al.* (2007) evaluated the effectiveness of a dermal protection program implemented in a beryllium alloy facility in 2002. The investigators evaluated levels of beryllium in air, on workplace surfaces, on cotton gloves worn over nitrile gloves, and on the necks and faces of workers over a six day period. The investigators found a good correlation between air samples and work surface contamination at this facility. The investigators also found measurable levels of beryllium on the skin of workers as a result of work processes even from workplace areas

promoted as “visually clean” by the company housekeeping policy. Importantly, the investigators found that the beryllium contamination could be transferred from body region to body region (e.g., hand to face, neck to face). The investigators demonstrated multiple pathways of exposure which could lead to sensitization, increasing risk for developing CBD (Day, *et al.*, 2007).

The same group of investigators (Armstrong *et al.*, 2014) extended their work on investigating multiple exposure pathways contributing to sensitization and CBD. The investigators evaluated four different beryllium manufacturing and processing facilities to assess the contribution of various exposure pathways on worker exposure. Airborne, work surface and cotton glove beryllium concentrations were evaluated. The investigators found strong correlations between air-surface concentrations, glove-surface concentrations, and air-glove concentrations at this facility. This work confirms findings from Day *et al.* (2007) demonstrating the importance of airborne beryllium concentrations to surface contamination and dermal exposure even at exposures below the current OSHA PEL (Armstrong *et al.*, 2014).

### 3. Oral and Gastrointestinal Exposure

According to the WHO Report (2001), gastrointestinal absorption of beryllium can occur by both the inhalation and oral routes of exposure. Through inhalation exposure, a fraction of the inhaled material is transported to the gastrointestinal tract by the mucociliary escalator or by the swallowing of the insoluble material deposited in the upper respiratory tract (WHO, 2001). Gastrointestinal absorption of beryllium can occur by both the inhalation and oral routes of exposure. In the case of inhalation, a portion of the inhaled material is transported to the gastrointestinal tract by the mucociliary escalator or by the swallowing of the insoluble material deposited in the upper respiratory tract (Schlesinger, 1997). Animal studies have shown oral administration of beryllium compounds to result in very limited absorption and storage (as reviewed by U.S. EPA, 1998). In animal ingestion studies using radio-labeled beryllium chloride in rats, mice, dogs, and monkeys, the vast majority of the ingested dose passed through the gastrointestinal tract unabsorbed and was excreted in the feces. In most studies, <1 percent of the administered radioactivity was absorbed into the bloodstream and subsequently excreted in the urine (Crowley *et al.*, 1949; Furchner *et al.*, 1973; LeFevre and Joel,

1986). Research using soluble beryllium sulfate has shown that as the compound passes into the intestine, which has a higher pH than the stomach (approximate pH of 6 to 8 for the intestine, pH of 1 or 2 for the stomach), the beryllium is precipitated as the insoluble phosphate and thus is no longer available for absorption (Reeves, 1965; WHO, 2001).

Urinary excretion of beryllium has been shown to correlate with the amount of occupational exposure (Klemperer *et al.*, 1951). Beryllium that is absorbed into the bloodstream is excreted primarily in the urine (Crowley *et al.*, 1949; Scott *et al.*, 1950; Furchner *et al.*, 1973; Stiefel *et al.*, 1980), whereas excretion of unabsorbed beryllium is primarily via the fecal route (Hart *et al.*, 1980; Finch *et al.*, 1990). A far higher percentage of the beryllium administered parenterally in various animal species was eliminated in the urine than in the feces (Crowley *et al.*, 1949; Scott *et al.*, 1950; Furchner *et al.*, 1973), confirming that beryllium found in the feces following oral exposure is primarily unabsorbed material. A study using percutaneous incorporation of soluble beryllium nitrate in rats similarly demonstrated that more than 90 percent of the beryllium in the bloodstream was eliminated via urine (Zorn *et al.*, 1977; WHO, 2001). More than 99 percent of ingested beryllium chloride was excreted in the feces (Mullen *et al.*, 1972). Elimination half-times of 890–1,770 days (2.4–4.8 years) were calculated for mice, rats, monkeys, and dogs injected intravenously with beryllium chloride (Furchner *et al.*, 1973). Mean daily excretion of beryllium metal was  $4.6 \times 10^{-5}$  percent of the dose administered by intratracheal instillation in baboons and  $3.1 \times 10^{-5}$  percent in rats (Andre *et al.*, 1987).

### 4. Metabolism

Beryllium and its compounds are not metabolized or biotransformed, but soluble beryllium salts may be converted to less soluble forms in the lung (Reeves and Vorwald, 1967). As stated earlier, solubility is an important factor for persistence of beryllium in the lung. Insoluble beryllium, engulfed by activated phagocytes, can be ionized by an acidic environment and by myeloperoxidases (Leonard and Lauwerys, 1987; Lansdown, 1995; WHO, 2001), and this positive charge could potentially make it more biologically reactive because it may allow the beryllium to bind to a peptide or protein and be presented to the T cell receptor or antigen-presenting cell (Fontenot, 2000).

### 5. Preliminary Conclusion for Particle Characterization and Kinetics of Beryllium

The forms and concentrations of beryllium across the workplace vary substantially based upon location, process, production and work task. Many factors influence the potency of beryllium including concentration, composition, structure, size and surface area of the particle.

Studies have demonstrated that beryllium sensitization can occur via the skin or inhalation from soluble or poorly soluble beryllium particles. Beryllium must be presented to a cell in a soluble form for activation of the immune system (NAS, 2008), and this will be discussed in more detail in the section to follow. Poorly soluble beryllium can be solubilized via intracellular fluid, lung fluid and sweat (Sutton *et al.*, 2003; Stefaniak *et al.*, 2011). For beryllium to persist in the lung it needs to be insoluble. However, soluble beryllium has been shown to precipitate in the lung to form insoluble beryllium (Reeves and Vorwald, 1967).

Some animal and epidemiological studies suggest that the form of beryllium may affect the rate of development of BeS and CBD. Beryllium in an inhalable form (either as soluble or insoluble particles or mist) can deposit in the respiratory tract and interact with immune cells located along the entire respiratory tract (Scheslinger, 1997). However, more study is needed to precisely determine the physiochemical characteristics of beryllium that influence toxicity and immunogenicity.

### C. Acute Beryllium Diseases

Acute beryllium disease (ABD) is a relatively rapid onset inflammatory reaction resulting from breathing high airborne concentrations of beryllium. It was first reported in workers extracting beryllium oxide (Van Ordstrand *et al.*, 1943). Since the Atomic Energy Commission's adoption of occupational exposure limits for beryllium beginning in 1949, cases of ABD have been rare. According to the World Health Organization (2001), ABD is generally associated with exposure to beryllium levels at or above  $100 \mu\text{g}/\text{m}^3$  and may be fatal in 10 percent of cases. However, cases have been reported with beryllium exposures below  $100 \mu\text{g}/\text{m}^3$  (Cummings *et al.*, 2009). The disease involves an inflammatory reaction that may include the entire respiratory tract, involving the nasal passages, pharynx, bronchial airways and alveoli. Other tissues including skin and conjunctivae may be affected as well. The clinical features of

ABD include a nonproductive cough, chest pain, cyanosis, shortness of breath, low-grade fever and a sharp drop in functional parameters of the lungs. Pathological features of ABD include edematous distension, round cell infiltration of the septa, proteinaceous materials, and desquamated alveolar cells in the lung. Monocytes, lymphocytes and plasma cells within the alveoli are also characteristic of the acute disease process (Freiman and Hardy, 1970).

Two types of acute beryllium disease have been characterized in the literature: a rapid and severe course of acute fulminating pneumonitis generally developing within 48 to 72 hours of a massive exposure, and a second form that takes several days to develop from exposure to lower concentrations of beryllium (still above the levels set by regulatory and guidance agencies) (Hall, 1950; DeNardi *et al.*, 1953; Newman and Kreiss, 1992). Evidence of a dose-response relationship to the concentration of beryllium is limited (Eisenbud *et al.*, 1948; Stokinger, 1950; Sterner and Eisenbud, 1951). Recovery from either type of ABD is generally complete after a period of several weeks or months (DeNardi *et al.*, 1953). However, deaths have been reported in more severe cases (Freiman and Hardy, 1970). There have been documented cases of progression to CBD (ACCP, 1965; Hall, 1950) suggesting the possibility of an immune component to this disease (Cummings *et al.*, 2009) as well. According to the BCR, in the United States, approximately 17 percent of ABD patients developed CBD (BCR, 2010). The majority of ABD cases occurred between 1932 and 1970 (Eisenbud, 1983; Middleton, 1998). ABD is extremely rare in the workplace today due to more stringent exposure controls implemented following occupational and environmental standards set in 1970–1972 (OSHA, 1971; ACGIH, 1971; ANSI, 1970) and 1974 (EPA, 1974).

#### D. Chronic Beryllium Disease

This section provides an overview of the immunology and pathogenesis of BeS and CBD, with particular attention to the role of skin sensitization, particle size, beryllium compound solubility, and genetic variability in individuals' susceptibility to beryllium sensitization and CBD.

Chronic beryllium disease (CBD), formerly known as "berylliosis" or "chronic berylliosis," is a granulomatous disorder primarily affecting the lungs. CBD was first described in the literature by Hardy and Tabershaw (1946) as a chronic granulomatous pneumonitis. It was

proposed as early as 1951 that CBD could be a chronic disease resulting from an immune sensitization to beryllium (Sterner and Eisenbud, 1951; Curtis, 1959; Nishimura, 1966). However, for a time, there remained some controversy as to whether CBD was a delayed-onset hypersensitivity disease or a toxicant-induced disease (NAS, 2008). Wide acceptance of CBD as a hypersensitivity lung disease did not occur until bronchoscopy studies and bronchoalveolar lavage (BAL) studies were performed demonstrating that BAL cells from CBD patients responded to beryllium challenge (Epstein *et al.*, 1982; Rossman *et al.*, 1988; Saltini *et al.*, 1989).

CBD shares many clinical and histopathological features with pulmonary sarcoidosis, a granulomatous lung disease of unknown etiology. This includes such debilitating effects as airway obstruction, diminishment of physical capacity associated with reduced lung function, possible depression associated with decreased physical capacity, and decreased life expectancy. Without appropriate information, CBD may be difficult to distinguish from sarcoidosis. It is estimated that up to 6 percent of all patients diagnosed with sarcoidosis may actually have CBD (Fireman *et al.*, 2003; Rossman and Kreiber, 2003). Among patients diagnosed with sarcoidosis in which beryllium exposure can be confirmed, as many as 40 percent may actually have CBD (Muller-Quernheim *et al.*, 2006; Cherry *et al.*, 2015).

Clinical signs and symptoms of CBD may include, but are not limited to, a simple cough, shortness of breath or dyspnea, fever, weight loss or anorexia, skin lesions, clubbing of fingers, cyanosis, night sweats, cor pulmonale, tachycardia, edema, chest pain and arthralgia. Changes or loss of pulmonary function also occur with CBD such as decrease in vital capacity, reduced diffusing capacity, and restrictive breathing patterns. The signs and symptoms of CBD constitute a continuum of symptoms that are progressive in nature with no clear demarcation between any stages in the disease (Rossman, 1996; NAS, 2008). Besides these listed symptoms from CBD patients, there have been reported cases of CBD that remained asymptomatic (Muller-Quernheim, 2005; NAS, 2008).

Unlike ABD, CBD can result from inhalation exposure to beryllium at levels below the current OSHA PEL, can take months to years after initial beryllium exposure before signs and symptoms of CBD occur (Newman 1996, 2005 and 2007; Henneberger, 2001;

Seidler *et al.*, 2012; Schuler *et al.*, 2012), and may continue to progress following removal from beryllium exposure (Newman, 2005; Sawyer *et al.*, 2005; Seidler *et al.*, 2012). Patients with CBD can progress to a chronic obstructive lung disorder resulting in loss of quality of life and the potential for decreased life expectancy (Rossman, *et al.*, 1996; Newman *et al.*, 2005). The NAS report (2008) noted the general lack of published studies on progression of CBD from an early asymptomatic stage to functionally significant lung disease (NAS, 2008). The report emphasized that risk factors and time course for clinical disease have not been fully delineated. However, for people now under surveillance, clinical progression from immunological sensitization and early pathological lesions (*i.e.*, granulomatous inflammation) prior to onset of symptoms to symptomatic disease appears to be slow, although more follow-up is needed (NAS, 2008). A study by Newman (1996) emphasized the need for prospective studies to determine the natural history and time course from BeS and asymptomatic CBD to full-blown disease (Newman, 1996). Drawing from his own clinical experience, Newman was able to identify the sequence of events for those with symptomatic disease as follows: Initial determination of beryllium sensitization; gradual emergence of chronic inflammation of the lung; pathologic alterations with measurable physiologic changes (*e.g.*, pulmonary function and gas exchange); progression to a more severe lung disease (with extrapulmonary effects such as clubbing and cor pulmonale in some cases); and finally death in some cases (reported between 5.8 to 38 percent) (NAS, 2008; Newman, 1996).

In contrast to some occupationally related lung diseases, the early detection of chronic beryllium disease may be useful since treatment of this condition can lead not only to regression of the signs and symptoms, but also may prevent further progression of the disease in certain individuals (Marchand-Adam, 2008; NAS, 2008). The management of CBD is based on the hypothesis that suppression of the hypersensitivity reaction (*i.e.*, granulomatous process) will prevent the development of fibrosis. However, once fibrosis has developed, therapy cannot reverse the damage.

To date, there have been no controlled studies to determine the optimal treatment for CBD (Rossman, 1996; NAS 2008; Sood, 2009). Management of CBD is generally modeled after sarcoidosis treatment. Oral corticosteroid treatment can be initiated in patients with

evidence of disease (either by bronchoscopy or other diagnostic measures before progression of disease or after clinical signs of pulmonary deterioration occur). This includes treatment with other anti-inflammatory agents (NAS, 2008; Maier *et al.*, 2012; Salvator *et al.*, 2013) as well. It should be noted, however, that treatment with corticosteroids has side-effects of their own that need to be measured against the possibility of progression of disease (Gibson *et al.*, 1996; Zaki *et al.*, 1987). Alternative treatments such as azathiopurine and infliximab, while successful at treating symptoms of CBD, have been demonstrated to have side-effects as well (Pallavicino *et al.*, 2013; Freeman, 2012).

#### 1. Development of Beryllium Sensitization

Sensitization to beryllium is an essential step for worker development of CBD. Sensitization to beryllium can result from inhalation exposure to beryllium (Newman *et al.*, 2005; NAS, 2008), as well as from skin exposure to beryllium (Curtis, 1951; Newman *et al.*, 1996; Tinkle *et al.*, 2003). Sensitization

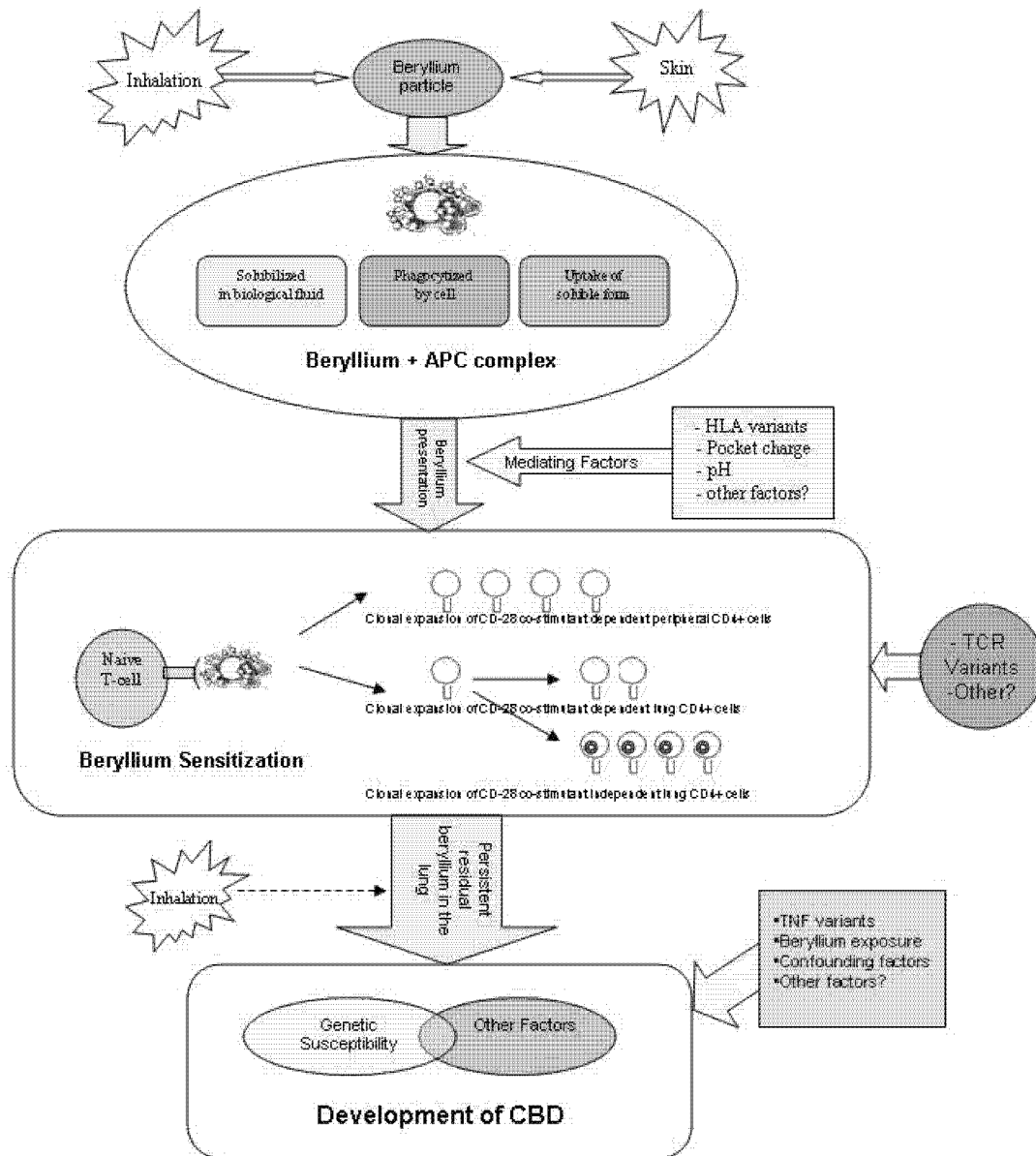
is currently detected using a laboratory blood test described in Appendix A. Although there may be no clinical symptoms associated with BeS, a sensitized worker's immune system has been activated to react to beryllium exposures such that subsequent exposure to beryllium can progress to serious lung disease (Kreiss *et al.*, 1996; Kreiss *et al.*, 1997; Kelleher *et al.*, 2001; and Rossman, 2001). Since the pathogenesis of CBD involves a beryllium-specific, cell-mediated immune response, CBD cannot occur in the absence of sensitization (NAS, 2008). Various factors, including genetic susceptibility, have been shown to influence risk of developing sensitization and CBD (NAS 2008) and will be discussed later in this section.

While various mechanisms or pathways may exist for beryllium sensitization, the most plausible mechanisms supported by the best available and most current science are discussed below. Sensitization occurs via the formation of a beryllium-protein complex (an antigen) that causes an immunological response. In some instances, onset of sensitization has

been observed in individuals exposed to beryllium for only a few months (Kelleher *et al.*, 2001; Henneberger *et al.*, 2001). This suggests the possibility that relatively brief, short-term beryllium exposures may be sufficient to trigger the immune hypersensitivity reaction. Several studies (Newman *et al.*, 2001; Henneberger *et al.*, 2001; Rossman, 2001; Schuler *et al.*, 2005; Donovan *et al.*, 2007; Schuler *et al.*, 2012) have detected a higher prevalence of sensitization among workers with less than one year of employment compared to some cross-sectional studies which, due to lack of information regarding initial exposure, cannot determine time of sensitization (Kreiss *et al.*, 1996; Kreiss *et al.*, 1997). While only very limited evidence has described humoral changes in certain patients with CBD (Cianciara *et al.*, 1980), clear evidence exists for an immune cell-mediated response, specifically the T-cell (NAS, 2008). Figure 2 delineates the major steps required for progression from beryllium contact to sensitization to CBD.

BILLING CODE 4510-26-P

Figure 2 – Schematic of beryllium presentation through to formation of CBD



## BILLING CODE 4510-26-C

Beryllium presentation to the immune system is believed to occur either by direct presentation or by antigen processing. It has been postulated that beryllium must be presented to the immune system in an ionic form for cell-mediated immune activation to occur (Kreiss *et al.*, 2007). Some soluble forms of beryllium are readily presented, since the soluble beryllium form disassociates into its ionic components. However, for insoluble forms, dissolution may need to occur. A study by Harmsen *et al.* (1986) suggested that a sufficient rate of dissolution of small amounts of poorly soluble beryllium compounds might

occur in the lungs to allow persistent low-level beryllium presentation to the immune system. Stefaniak *et al.* (2005 and 2012) reported that insoluble beryllium particles phagocytized by macrophages were dissolved in phagolysosomal fluid (Stefaniak *et al.*, 2005; Stefaniak *et al.*, 2012) and that the dissolution rate stimulated by phagolysosomal fluid was different for various forms of beryllium (Stefaniak *et al.*, 2006; Duling *et al.*, 2012). Several studies have demonstrated that macrophage uptake of beryllium can induce aberrant apoptotic processes leading to the continued release of beryllium ions which will continually stimulate T-cell activation (Sawyer *et*

*al.*, 2000; Sawyer *et al.*, 2004; Kittle *et al.*, 2002). Antigen processing can be mediated by antigen-presenting cells (APC). These may include macrophages, dendritic cells, or other antigen-presenting cells, although this has not been well defined in most studies (NAS, 2008).

Because of their strong positive charge, beryllium ions have the ability to haptenate and alter the structure of peptides occupying the antigen-binding cleft of major histocompatibility complex (MHC) class II on antigen-presenting cells (APC). The MHC class II antigen-binding molecule for beryllium is the human leukocyte antigen (HLA) with specific alleles (*e.g.*,

HLA-DP, HLA-DR, HLA-DQ) associated with the progression to CBD (NAS, 2008; Yucesoy and Johnson, 2011). Several studies have also demonstrated that the electrostatic charge of HLA may be a factor in binding beryllium (Snyder *et al.*, 2003; Bill *et al.*, 2005; Dai *et al.*, 2010). The strong positive ionic charge of the beryllium ion would have a strong attraction for the negatively charged patches of certain HLA alleles (Snyder *et al.*, 2008; Dai *et al.*, 2010). Alternatively, beryllium oxide has been demonstrated to bind to the MHC class II receptor in a neutral pH. The six carboxylates in the amino acid sequence of the binding pocket provide a stable

bond with the Be-O-Be molecule when the pH of the substrate is neutral (Keizer *et al.*, 2005). The direct binding of BeO may eliminate the biological requirement for antigen processing or dissolution of beryllium oxide to activate an immune response.

Next in sequence is the beryllium-MHC-APC complex binding to a T-cell receptor (TCR) on a naïve T-cell which stimulates the proliferation and accumulation of beryllium-specific CD4<sup>+</sup> (cluster of differentiation 4<sup>+</sup>) T-cells (Saltini *et al.*, 1989 and 1990; Martin *et al.*, 2011) as depicted in Figure 3. Fontenot *et al.* (1999) demonstrated that diversely different variants of TCR were expressed by CD4<sup>+</sup> T-cells in

peripheral blood cells of CBD patients. However, the CD4<sup>+</sup> T-cells from the lung were more homologous in expression of TCR variants in CBD patients, suggesting clonal expansion of a subset of T-cells in the lung (Fontenot *et al.*, 1999). This may also indicate a pathogenic potential for subsets of T-cell clones expressing this homologous TCR (NAS, 2008). Fontenot *et al.* (2006) reported beryllium self-presentation by HLA-DP expressing BAL CD4<sup>+</sup> T-cells. Self-presentation by BAL T-cells in the lung granuloma may result in activation-induced cell death, which may then lead to oligoclonality of the T-cell population characteristic of CBD (NAS, 2008).

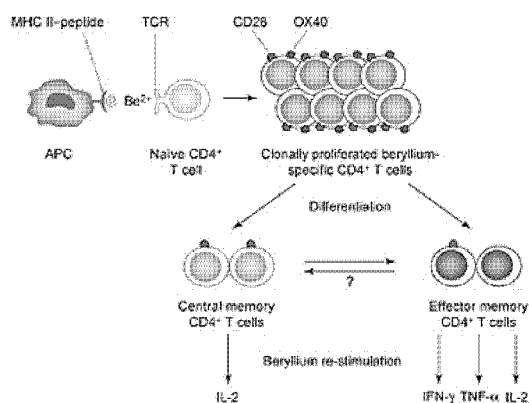


FIGURE 3 - Immune response to beryllium. Source: Fontenot and Maier

2005. Reprinted with permission; copyright 2005, [Trends in Immunology](#).

As CD4<sup>+</sup> T-cells proliferate, clonal expansion of various subsets of the CD4<sup>+</sup> beryllium specific T-cells occurs (Figure 3). In the peripheral blood, the beryllium-specific CD4<sup>+</sup> T cells require co-stimulation with a co-stimulant CD28 (cluster of differentiation 28). During the proliferation and differentiation process CD4<sup>+</sup> T-cells secrete pro-inflammatory cytokines that may influence this process (Sawyer *et al.*, 2004; Kimber *et al.*, 2011).

## 2. Development of CBD

The continued persistence of residual beryllium in the lung leads to a T-cell maturation process. A large portion of beryllium-specific CD4<sup>+</sup> T cells were shown to cease expression of CD28 mRNA and protein, indicating these cells no longer required co-stimulation with the CD28 ligand (Fontenot *et al.*, 2003). This change in phenotype correlated with lung inflammation (Fontenot *et al.*, 2003). The CD4<sup>+</sup> independent cells continued to secrete

cytokines necessary for additional recruitment of inflammatory and immunological cells; however, they were less proliferative and less susceptible to cell death compared to the CD28 dependent cells (Fontenot *et al.*, 2005; Mack *et al.*, 2008). These beryllium-specific CD4<sup>+</sup> independent cells are considered to be mature memory effector cells (Ndejemi *et al.*, 2006; Bian *et al.*, 2005). Repeat exposure to beryllium in the lung resulting in a mature population of T cell development independent of co-stimulation by CD28 and development of a population of T effector memory cells (T<sub>em</sub> cells) may be one of the mechanisms that lead to the more severe reactions observed specifically in the lung (Fontenot *et al.*, 2005).

CD4<sup>+</sup> T cells created in the sensitization process recognize the beryllium antigen, and respond by proliferating and secreting cytokines and inflammatory mediators, including IL-2, IFN-γ, and TNF-α (Tinkle *et al.*,

1997a and b; Fontenot *et al.*, 2002) and MIP-1α and GRO-1 (Hong-Geller, 2006). This also results in the accumulation of various types of inflammatory cells including mononuclear cells (mostly CD4<sup>+</sup> T cells) in the bronchoalveolar lavage fluid (BAL fluid) (Saltini *et al.*, 1989, 1990).

The development of granulomatous inflammation in the lung of CBD patients has been associated with the accumulation of beryllium responsive CD4<sup>+</sup> T<sub>em</sub> cells in BAL fluid (NAS, 2008). The subsequent release of pro-inflammatory cytokines, chemokines and reactive oxygen species by these cells may lead to migration of additional inflammatory/immune cells and the development of a microenvironment that contributes to the development of CBD (Sawyer *et al.*, 2005; Tinkle *et al.*, 1996; Hong-Geller *et al.*, 2006; NAS, 2008).

The cascade of events described above results in the formation of a noncaseating granulomatous lesion.



Release of cytokines by the accumulating T cells leads to the formation of granulomatous lesions that are characterized by an outer ring of histiocytes surrounding non-necrotic tissue with embedded multi-nucleated giant cells (Saltini *et al.*, 1989, 1990).

Over time, the granulomas spread and can lead to lung fibrosis and abnormal pulmonary function, with symptoms including a persistent dry cough and shortness of breath (Saber and Dweik, 2000). Fatigue, night sweats, chest and joint pain, clubbing of fingers (due to impaired oxygen exchange), loss of appetite or unexplained weight loss, and cor pulmonale have been experienced in certain patients as the disease progresses (Conradi *et al.*, 1971; ACCP, 1965; Kriebel *et al.*, 1988a and b). While CBD primarily affects the lungs, it can also involve other organs such as the liver, skin, spleen, and kidneys (ATSDR, 2002).

As previously mentioned, the uptake of beryllium may lead to an aberrant apoptotic process with rerelease of beryllium ions and continual stimulation of beryllium-responsive CD4<sup>+</sup> cells in the lung (Sawyer *et al.*, 2000; Kittle *et al.*, 2002; Sawyer *et al.*, 2004). Several research studies suggest apoptosis may be one mechanism that enhances inflammatory cell recruitment, cytokine production and inflammation, thus creating a scenario for progressive granulomatous inflammation (Palmer *et al.*, 2008; Rana, 2008). Macrophages and neutrophils can phagocytize beryllium particles in an attempt to remove the beryllium from the lung (Ding, *et al.*, 2009). Multiple studies (Sawyer *et al.*, 2004; Kittle *et al.*, 2002) using BAL cells (mostly macrophages and neutrophils) from patients with CBD found that *in vitro* stimulation with beryllium sulfate induced the production of TNF- $\alpha$  (one of many cytokines produced in response to beryllium), and that production of TNF- $\alpha$  might induce apoptosis in CBD and sarcoidosis patients (Bost *et al.*, 1994; Dai *et al.*, 1999). The stimulation of CBD-derived macrophages by beryllium sulphate resulted in cells becoming apoptotic, as measured by propidium iodide. These results were confirmed in a mouse macrophage cell-line (p388D1) (Sawyer *et al.*, 2000). However, other factors may influence the development of CBD and are outlined in the following section.

### 3. Genetic and Other Susceptibility Factors

Evidence from a variety of sources indicates genetic susceptibility may play an important role in the development of CBD in certain individuals, especially at levels low

enough not to invoke a response in other individuals. Early occupational studies proposed that CBD was an immune reaction based on the high susceptibility of some individuals to become sensitized and progress to CBD and the lack of CBD in others who were exposed to levels several orders of magnitude higher (Stern and Eisenbud, 1951). Additional *in vitro* human research has identified genes coding for specific protein molecules on the surface of their immune cells that place carriers at greater risk of becoming sensitized to beryllium and developing CBD (McCanlies *et al.*, 2004). Recent studies have confirmed genetic susceptibility to CBD involves either HLA variants, T-cell receptor clonality, tumor necrosis factor (TNF- $\alpha$ ) polymorphisms and/or transforming growth factor-beta (TGF- $\beta$ ) polymorphisms (Fontenot *et al.*, 2000; Amicosante *et al.*, 2005; Tinkle *et al.*, 1996; Gaede *et al.*, 2005; Van Dyke *et al.*, 2011; Silveira *et al.*, 2012).

Single Nucleotide Polymorphisms (SNPs) have been studied with regard to genetic variations associated with increased risk of developing CBD. SNPs are the most abundant type of human genetic variation. Polymorphisms in MHC class II and pro-inflammatory genes have been shown to contribute to variations in immune responses contributing to the susceptibility and resistance in many diseases including auto-immunity, and beryllium sensitization and CBD (McClesky *et al.*, 2009). Specific SNPs have been evaluated as a factor in Glu69 variant from the HLA-DPB1 locus (Richeldi *et al.*, 1993; Cai *et al.*, 2000; Saltini *et al.*, 2001; Silveira *et al.*, 2012; Dai *et al.*, 2013), HLA-DRPhe $\beta$ 47 (Amicosante *et al.*, 2005).

HLA-DPB1 with a glutamic acid at amino position 69 (Glu 69) has been shown to confer increased risk of beryllium sensitization and CBD (Richeldi *et al.*, 1993; Saltini *et al.*, 2001; Amicosante *et al.*, 2005; Van Dyke *et al.*, 2011; Silveira *et al.*, 2012). Fontenot *et al.* (2000) demonstrated that beryllium presentation by certain alleles of the class II human leukocyte antigen-DP (HLA-DP) to CD4<sup>+</sup> T cells is the mechanism underlying the development of CBD. Richeldi *et al.* (1993) reported a strong association between the MHC class II allele HLA-DP 1 and the development of CBD in beryllium-exposed workers from a Tucson, AZ facility. This marker was found in 32 of the 33 workers who developed CBD, but in only 14 of 44 similarly exposed workers without CBD. The more common allele of the HLA-DP 1 variant is negatively charged at this site and

could directly interact with the positively charged beryllium ion. The high percentage (~30 percent) of beryllium-exposed workers without CBD who had this allele indicates that other factors also contribute to the development of CBD (EPA, 1998). Additional studies by Amicosante *et al.* (2005) using blood lymphocytes derived from beryllium-exposed workers found a high frequency of this gene in those sensitized to beryllium. In a study of 82 CBD patients (beryllium-exposed workers), Stubbs *et al.* (1996) also found a relationship between the HLA-DP 1 allele and BeS. The glutamate-69 allele was present in 86 percent of sensitized subjects, but in only 48 percent of beryllium-exposed, non-sensitized subjects. Some variants of the HLA-DPB1 allele convey higher risk of BeS and CBD than others. For example, HLA-DPB1\*0201 yielded an approximately 3-fold increase in disease outcome relative to controls; HLA-DPB1\*1901 yielded an approximately 5-fold increase, and HLA-DPB1\*1701 an approximately 10-fold increase (Weston *et al.*, 2005; Snyder *et al.*, 2008). By assigning odds ratios for specific alleles on the basis of previous studies discussed above, the researchers found a strong correlation (88 percent) between the reported risk of CBD and the predicted surface electrostatic potential and charge of the isotypes of the genes. They were able to conclude that the alleles associated with the most negatively charged proteins carry the greatest risk of developing beryllium sensitization and CBD. This confirms the importance of beryllium charge as a key factor in haptogenic potential.

In contrast, the HLA-DRB1 allele, which lacks Glu 69, has also been shown to increase the risk of developing sensitization and CBD (Amicosante *et al.*, 2005; Maier *et al.*, 2003). Bill *et al.* (2005) found that HLA-DR has a glutamic acid at position 71 of the  $\beta$  chain, functionally equivalent to the Glu 69 of HLA-DP (Bill *et al.*, 2005). Associations with BeS and CBD have also been reported with the HLA-DQ markers (Amicosante *et al.*, 2005; Maier *et al.*, 2003). Stubbs *et al.* also found a biased distribution of the MHC class II HLA-DR gene between sensitized and non-sensitized subjects. Neither of these markers was completely specific for CBD, as each study found beryllium sensitization or CBD among individuals without the genetic risk factor. While there remains uncertainty as to which of the MHC class II genes interact directly with the beryllium ion, antibody inhibition data suggest that the HLA-DR gene product may be involved in the

presentation of beryllium to T lymphocytes (Amicosante *et al.*, 2002). In addition, antibody blocking experiments revealed that anti-HLA-DP strongly reduced proliferation responses and cytokine secretion by BAL CD4 T cells (Chou *et al.*, 2005). In the study by Chou (2005), anti-HLA-DR ligand antibodies mainly affected beryllium-induced proliferation responses with little impact on cytokines other than IL-2, thus implying that nonproliferating BAL CD4 T cells may still contribute to inflammation leading to the progression of CBD (Chou *et al.*, 2005).

TNF alpha (TNF- $\alpha$ ) polymorphisms and TGF beta (TGF- $\beta$ ) polymorphisms have also been shown to confer a genetic susceptibility for developing CBD in certain individuals. TNF- $\alpha$  is a pro-inflammatory cytokine associated with a more severe pulmonary disease in CBD (NAS, 2008). Beryllium exposure has been shown to upregulate transcription factors AP-1 and NF- $\kappa$ B (Sawyer *et al.*, 2007) inducing an inflammatory response by stimulating production of pro-inflammatory cytokines such as TNF- $\alpha$  by inflammatory cells. Polymorphisms in the 308 position of the TNF- $\alpha$  gene have been demonstrated to increase production of the cytokine and increase severity of disease (Maier *et al.*, 2001; Saltini *et al.*, 2001; Dotti *et al.*, 2004). While a study by McCanlies *et al.* (2007) found no relationship between TNF- $\alpha$  polymorphism and BeS or CBD, the inconsistency may be due to misclassification, exposure differences or statistical power (NAS, 2008).

Other genetic variations have been shown to be associated with increased risk of beryllium sensitization and CBD (NAS, 2008). These include TGF- $\beta$  (Gaede *et al.*, 2005), angiotensin-1 converting enzyme (ACE) (Newman *et al.*, 1992; Maier *et al.*, 1999) and an enzyme involved in glutathione synthesis (glutamate cysteine ligase) (Bekris *et al.*, 2006). McCanlies *et al.* (2010) evaluated the association between polymorphisms in a select group of interleukin genes (IL-1A; IL-1B, IL-1RN, IL-2, IL-9, IL-9R) due to their role in immune and inflammatory processes. The study evaluated SNPs in three groups of workers from large beryllium manufacturing facilities in OH and AZ. The investigators found a significant association between variants IL-1A-1142, IL-1A-3769 and IL-1A-4697 and CBD but not with beryllium sensitization. However, these still require confirmation in larger studies (NAS, 2008).

In addition to the genetic factors which may contribute to the susceptibility and severity of disease,

other factors such as smoking and gender may play a role in the development of CBD (NAS, 2008). A recent longitudinal cohort study by Mroz *et al.* (2009) of 229 individuals identified with beryllium sensitization or CBD through workplace medical surveillance found that the prevalence of CBD among ever smokers was significantly lower than among never smokers (38.1 percent versus 49.4 percent,  $p=0.025$ ). BeS subjects that never smoked were found to be more likely to develop CBD over the course of the study compared to current smokers (12.6 percent versus 6.4 percent,  $p=0.10$ ). The authors suggested smoking may confer a protective effect against development of lung granulomas as has been demonstrated with hypersensitivity pneumonitis (Mroz *et al.*, 2009).

#### 4. Beryllium Sensitization and CBD in the Workforce

Sensitization to beryllium is currently detected in the workforce with the beryllium lymphocyte proliferation test (BeLPT), a laboratory blood test developed in the 1980s, also referred to as the LTT (Lymphocyte Transformation Test) or BeLT (Beryllium Lymphocyte Transformation Test). In this test, lymphocytes obtained from either bronchoalveolar lavage fluid (the BAL BeLPT) or from peripheral blood (the blood BeLPT) are cultured *in vitro* and exposed to beryllium sulfate to stimulate lymphocyte proliferation. The observation of beryllium-specific proliferation indicates beryllium sensitization. Hereafter, "BeLPT" generally refers to the blood BeLPT, which is typically used in screening for beryllium sensitization. This test is described in more detail in subsection D.5.b.

CBD can be detected at an asymptomatic stage by a number of techniques including bronchoalveolar lavage and biopsy (Cordeiro *et al.*, 2007; Maier, 2001). Bronchoalveolar lavage is a method of "washing" the lungs with fluid inserted via a flexible fiberoptic instrument known as a bronchoscope, removing the fluid and analyzing the content for the inclusion of immune cells reactive to beryllium exposure, as described earlier in this section. Fiberoptic bronchoscopy can be used to detect granulomatous lung inflammation prior to the onset of CBD symptoms as well, and has been used in combination with the BeLPT to diagnose pre-symptomatic CBD in a number of recent screening studies of beryllium-exposed workers, which are discussed in the following section detailing diagnostic procedures. Of

workers who were found to be sensitized and underwent clinical evaluation, 31–49 percent of them were diagnosed with CBD (Kreiss *et al.*, 1993; Newman *et al.*, 1996, 2005, 2007; Mroz, 2009), however some estimate that with increased surveillance the percent could be much higher (Newman, 2005; Mroz, 2009). It has been estimated from ongoing surveillance studies of sensitized individuals with an average follow-up time of 4.5 years that 31 percent of beryllium-sensitized employees were estimated to progress to CBD (Newman *et al.*, 2005). A study of nuclear weapons facility employees enrolled in an ongoing medical surveillance program found that only 20 percent of sensitized workers employed less than 5 years eventually were diagnosed with CBD, while 40 percent of sensitized workers employed 10 years or more developed CBD (Stange *et al.*, 2001). One limitation for all these studies is lack of long-term follow-up. It may be necessary to continue to monitor these workers in order to determine whether all BeS workers will develop CBD (Newman *et al.*, 2005).

CBD has a clinical spectrum ranging from evidence of beryllium sensitization and granulomas in the lung with little symptomatology to loss of lung function and end stage disease which may result in the need for lung transplantation and decreased life expectancy. Unfortunately, there are very few published clinical studies describing the full range and progression of CBD from the beginning to the end stages and very few of the risk factors for progression of disease have been delineated (NAS, 2008). Clinical management of CBD is modeled after sarcoidosis where oral corticosteroid treatment is initiated in patients who have evidence of progressive lung disease, although progressive lung disease has not been well defined (NAS, 2008). In advanced cases of CBD, corticosteroids are the standard treatment (NAS, 2008). No comprehensive studies have been published measuring the overall effect of removal of workers from beryllium exposure on sensitization and CBD (NAS, 2008) although this has been suggested as part of an overall treatment regime for CBD (Mapel *et al.*, 2002; Sood *et al.*, 2004; Maier *et al.*, 2006; Sood, 2009; Maier *et al.*, 2012). Sood *et al.* reported that cessation of exposure can sometimes have beneficial effects on lung function (Sood *et al.*, 2004). However, this was based on anecdotal evidence from six patients with CBD, so more research is needed to better determine the relationship between

exposure duration and disease progression

##### 5. Human Epidemiological Studies

This section describes the human epidemiological data supporting the mechanistic overview of beryllium-induced disease in workers. It has been divided into reviews of epidemiological studies performed prior to development and implementation of the BeLPT in the late 1980s and after wide use of the BeLPT for screening purposes. Use of the BeLPT has allowed investigators to screen for beryllium sensitization and CBD prior to the onset of clinical symptoms, providing a more sensitive and thorough analysis of the worker population. The discussion of the studies has been further divided by manufacturing processes that may have similar exposure profiles. Table A.1 in the Appendix summarizes the prevalence of beryllium sensitization and CBD, range of exposure measurements, and other salient information from the key epidemiological studies.

It has been well-established that beryllium exposure, either via inhalation or skin, may lead to beryllium sensitization, or, with inhalation exposure, may lead to the onset and progression of CBD. The available published epidemiological literature discussed below provides strong evidence of beryllium sensitization and CBD in workers exposed to airborne beryllium well below the current OSHA PEL of  $2 \mu\text{g}/\text{m}^3$ . Several studies demonstrate the prevalence of sensitization and CBD is related to the level of airborne exposure, including a cross-sectional survey of employees at a beryllium ceramics plant in Tucson, AZ (Henneberger *et al.*, 2001), case-control studies of workers at the Rocky Flats nuclear weapons facility (Viet *et al.*, 2000), and workers from a beryllium machining plant in Cullman, AL (Kelleher *et al.*, 2001). The prevalence of beryllium sensitization also may be related to dermal exposure. An increased risk of CBD has been reported in workers with skin lesions, potentially increasing the uptake of beryllium (Curtis, 1951; Johnson *et al.*, 2001; Schuler *et al.*, 2005). Three studies describe comprehensive preventive programs, which included expanded respiratory protection, dermal protection, and improved control of beryllium dust migration, that substantially reduced the rate of beryllium sensitization among new hires (Cummings *et al.*, 2007; Thomas *et al.*, 2009; Bailey *et al.*, 2010; Schuler *et al.*, 2012).

Some of the epidemiological studies presented in this review suffer from challenges common to many published epidemiological studies: Limitations in study design (particularly cross-sectional); small sample size; lack of personal and/or short-term exposure data, particularly those published before the late 1990s; and incomplete information regarding specific chemical form and/or particle characterization. Challenges that are specific to beryllium epidemiological studies include: uncertainty regarding the contribution of dermal exposure; use of various BeLPT protocols; a variety of case definitions for determining CBD; and use of various exposure sampling/assessment methods (*e.g.*, daily weighted average (DWA), lapel sampling). Even with these limitations, the epidemiological evidence presented in this section clearly demonstrates that beryllium sensitization and CBD are continuing to occur from present-day exposures below OSHA's PEL. The available literature also indicates that the rate of BeS can be substantially lowered by reducing inhalation exposure and minimizing dermal contact.

##### a. Studies Conducted Prior to the BeLPT

First reports of CBD came from studies performed by Hardy and Tabershaw (1946). Cases were observed in industrial plants that were refining and manufacturing beryllium metal and beryllium alloys and in plants manufacturing fluorescent light bulbs (NAS, 2008). From the late 1940s through the 1960s, clusters of non-occupational CBD cases were identified around beryllium refineries in Ohio and Pennsylvania, and outbreaks in family members of beryllium factory workers were assumed to be from exposure to contaminated clothes (Hardy, 1980). It had been established that the risk of disease among beryllium workers was variable and generally rose with the levels of airborne concentrations (Machle *et al.*, 1948). And while there was a relationship between air concentrations of beryllium and risk of developing disease both in and surrounding these plants, the disease rates outside the plants were higher than expected and not very different from the rate of CBD within the plants (Eisenbud *et al.*, 1949; Lieben and Metzner, 1959). There remained considerable uncertainty regarding diagnosis due to lack of well-defined cohorts, modern diagnostic methods, or inadequate follow-up. In fact, many patients with CBD may have been misdiagnosed with sarcoidosis (NAS, 2008).

The difficulties in distinguishing lung disease caused by beryllium from other lung diseases led to the establishment of the BCR in 1952 to identify and track cases of ABD and CBD. A uniform diagnostic criterion was introduced in 1959 as a way to delineate CBD from sarcoidosis. Patient entry into the BCR required either: documented past exposure to beryllium or the presence of beryllium in lung tissue as well as clinical evidence of beryllium disease (Hardy *et al.*, 1967); or any three of the six criteria listed below (Hasan and Kazemi, 1974). Patients identified using the above criteria were registered and added to the BCR from 1952 through 1983 (Eisenbud and Lisson, 1983).

The BCR listed the following criteria for diagnosing CBD (Eisenbud and Lisson, 1983):

- (1) Establishment of significant beryllium exposure based on sound epidemiologic history;
- (2) Objective evidence of lower respiratory tract disease and clinical course consistent with beryllium disease;
- (3) Chest X-ray films with radiologic evidence of interstitial fibronodular disease;
- (4) Evidence of restrictive or obstructive defect with diminished carbon monoxide diffusing capacity ( $\text{DL}_{\text{CO}}$ ) by physiologic studies of lung function;
- (5) Pathologic changes consistent with beryllium disease on examination of lung tissue; and
- (6) Presence of beryllium in lung tissue or thoracic lymph nodes.

Prevalence of CBD in workers during the time period between the 1940s and 1950s was estimated to be between 1–10% (Eisenbud and Lisson, 1983). In a 1969 study, Stoeckle *et al.* presented 60 case histories with a selective literature review utilizing the above criteria except that urinary beryllium was substituted for lung beryllium to demonstrate beryllium exposure. Stoeckle *et al.* (1969) were able to demonstrate corticosteroids as a successful treatment option in one case of confirmed CBD. This study also presented a 28 percent mortality rate from complications of CBD at the time of publication. However, even with the improved methodology for determining CBD based on the BCR criteria, these studies suffered from lack of well-defined cohorts, modern diagnostic techniques or adequate follow-up.

##### b. Criteria for Beryllium Sensitization and CBD Case Definition Following the Development of the BeLPT

The criteria for diagnosis of CBD have evolved over time as more advanced

diagnostic technology, such as the (blood) BeLPT and BAL BeLPT, has become available. More recent diagnostic criteria have both higher specificity than earlier methods and higher sensitivity, identifying subclinical effects. Recent studies typically use the following criteria (Newman *et al.*, 1989; Pappas and Newman, 1993; Maier *et al.*, 1999):

- (1) History of beryllium exposure;
- (2) Histopathological evidence of noncaseating granulomas or mononuclear cell infiltrates in the absence of infection; and
- (3) Positive blood or BAL BeLPT (Newman *et al.*, 1989).

The availability of transbronchial lung biopsy facilitates the evaluation of the second criterion, by making histopathological confirmation possible in almost all cases.

A significant component for the identification of CBD is the demonstration of a confirmed abnormal BeLPT result in a blood or BAL sample (Newman, 1996). Since the development of the BeLPT in the 1980s, it has been used to screen beryllium-exposed workers for sensitization in a number of studies to be discussed below. The BeLPT is a non-invasive *in vitro* blood test which measures the beryllium antigen-specific T-cell mediated immune response and is the most commonly available diagnostic tool for identifying beryllium sensitization. The BeLPT measures the degree to which beryllium stimulates lymphocyte proliferation under a specific set of conditions, and is interpreted based upon the number of stimulation indices that exceed the normal value. The 'cut-off' is based on the mean value of the peak stimulation index among controls plus 2 or 3 standard deviations. This methodology was modeled into a statistical method known as the "least absolute values" or "statistical-biological positive" method and relies on natural log modeling of the median stimulation index values (DOE, 2001; Frome, 2003). In most applications, two or more stimulation indices that exceed the cut-off constitute an abnormal test.

Early versions of the BeLPT test had high variability, but the use of tritiated thymidine to identify proliferating cells has led to a more reliable test (Mroz *et al.*, 1991; Rossmann *et al.*, 2001). In recent years, the peripheral blood test has been found to be as sensitive as the BAL assay, although larger abnormal responses have been observed with the BAL assay (Kreiss *et al.*, 1993; Pappas and Newman, 1993). False negative results have also been observed with the BAL BeLPT in cigarette smokers who have marked excess of alveolar

macrophages in lavage fluid (Kreiss *et al.*, 1993). The BeLPT has also been a useful tool in animal studies to identify those species with a beryllium-specific immune response (Haley *et al.*, 1994).

Screenings for beryllium sensitization have been conducted using the BeLPT in several occupational surveys and surveillance programs, including nuclear weapons facilities operated by the Department of Energy (Viet *et al.*, 2000; Strange *et al.*, 2001; DOE/HSS Report, 2006), a beryllium ceramics plant in Arizona (Kreiss *et al.*, 1996; Henneberger *et al.*, 2001; Cummings *et al.*, 2007), a beryllium production plant in Ohio (Kreiss *et al.*, 1997; Kent *et al.*, 2001), a beryllium machining facility in Alabama (Kelleher *et al.*, 2001; Madl *et al.*, 2007), a beryllium alloy plant (Schuler *et al.*, 2005; Thomas *et al.*, 2009), and another beryllium processing plant (Rosenman *et al.*, 2005) in Pennsylvania. In most of these studies, individuals with an abnormal BeLPT result were retested and were identified as sensitized (*i.e.*, confirmed positive) if the abnormal result was repeated.

There has been criticism regarding the reliability and specificity of the BeLPT as a screening tool (Borak *et al.*, 2006). Stange *et al.* (2004) studied the reliability and laboratory variability of the BeLPT by splitting blood samples and sending samples to two laboratories simultaneously for BeLPT analysis. Stange *et al.* found the range of agreement on abnormal (positive BeLPT) results was 26.2–61.8 percent depending upon the labs tested (Stange *et al.*, 2004). Borak *et al.* (2006) contended that the positive predictive value (PPV) (PPV is the portion of patients with positive test result correctly diagnosed) is not high enough to meet the criteria of a good screening tool. Middleton *et al.* (2008) used the data from the Stange *et al.* (2004) study to estimate the PPV and determined that the PPV of the BeLPT could be improved from 0.383 to 0.968 when an abnormal BeLPT result is confirmed with a second abnormal result (Middleton *et al.*, 2008). However, an apparent false positive can occur in people not occupationally exposed to beryllium (NAS, 2008). An analysis of survey data from the general workforce and new employees at a beryllium manufacturer was performed to assess the reliability of the BeLPT (Donovan *et al.*, 2007). Donovan *et al.* analyzed more than 10,000 test results from nearly 2400 participants over a 12-year period. Donovan *et al.* found that approximately 2 percent of new employees had at least one positive BeLPT at the time of hire and 1 percent of new hires with no known occupational exposure were

confirmed positive at the time of hire with two BeLPTs. Since there are currently no alternatives to the BeLPT in a screening program many programs rely on a second test to confirm a positive result (NAS, 2008).

The epidemiological studies presented in this section utilized the BeLPT as either a surveillance tool or a screening tool for determining sensitization status and/or sensitization/CBD prevalence in workers for inclusion in the published studies. Most epidemiological studies have reported rates of sensitization and disease based on a single screening of a working population ('cross-sectional' or 'population prevalence' rates). Studies of workers in a beryllium machining plant and a nuclear weapons facility have included follow-up of the population originally screened, resulting in the detection of additional cases of sensitization over several years (Newman *et al.*, 2001; Stange *et al.*, 2001). OSHA regards the BeLPT as a reliable medical surveillance tool. The BeLPT is discussed in more detail in Non-Mandatory Appendix A to the proposed standard, Immunological Testing for the Determination of Beryllium Sensitization.

### c. Beryllium Mining and Extraction

Mining and extraction of beryllium usually involves the two major beryllium minerals, beryl (an aluminosilicate containing up to 4 percent beryllium) and bertrandite (a beryllium silicate hydrate containing generally less than 1 percent beryllium) (WHO, 2001). The United States is the world leader in beryllium extraction and also leads the world in production and use of beryllium and its alloys (WHO, 2001). Most exposures from mining and extraction come in the form of beryllium ore, beryllium salts, beryllium hydroxide (NAS 2008) or beryllium oxide (Stefaniak *et al.*, 2008).

Deubner *et al.* published a study of 75 workers employed at a beryllium mining and extraction facility in Delta, UT (Deubner *et al.*, 2001b). Of the 75 workers surveyed for sensitization with the BeLPT, three were identified as sensitized by an abnormal BeLPT result. One of those found to be sensitized was diagnosed with CBD. Exposures at the facility included primarily beryllium ore and salts. General area (GA), breathing zone (BZ), and personal lapel (LP) exposure samples were collected from 1970 to 1999. Jobs involving beryllium hydrolysis and wet-grinding activities had the highest air concentrations, with an annual median GA concentration ranging from 0.1 to 0.4  $\mu\text{g}/\text{m}^3$ . Median BZ concentrations

were higher than either LP or GA. The average duration of exposure for beryllium sensitized workers was 21.3 years (27.7 years for the worker with CBD), compared to an average duration for all workers of 14.9 years. However, these exposures were less than either the Elmore, OH, or Tucson, AZ, facilities described below, which also had higher reported rates of BeS and CBD. A study by Stefaniak *et al.* (2008) demonstrated that beryllium was present at the mill in three forms: mineral, poorly crystalline oxide, and hydroxide.

There was no sensitization or CBD among those who worked only at the mine where exposure to beryllium resulted solely from working with bertrandite ore. The authors concluded that the results of this study indicated that beryllium ore and salts may pose less of a hazard than beryllium metal and beryllium hydroxide. These results are consistent with the previously discussed animal studies examining solubility and particle size.

#### d. Beryllium Metal Processing and Alloy Production

Kreiss *et al.* (1997) conducted a study of workers at a beryllium production facility in Elmore, OH. The plant, which opened in 1953 and initially specialized in production of beryllium-copper alloy, later expanded its operations to include beryllium metal, beryllium oxide, and beryllium-aluminum alloy production; beryllium and beryllium alloy machining; and beryllium ceramics production, which was moved to a different factory in the early 1980s. Production operations included a wide variety of jobs and processes, such as work in arc furnaces and furnace rebuilding, alloy melting and casting, beryllium powder processing, and work in the pebble plant. Non-production work included jobs in the analytical laboratory, engineering research and development, maintenance, laundry, production-area management, and office-area administration. While the publication refers to the use of respiratory protection in some areas, such as the pebble plant, the extent of its use across all jobs or time periods was not reported. Use of dermal PPE was not reported.

The authors characterized exposures at the plant using industrial hygiene (IH) samples collected between 1980 and 1993. The exposure samples and the plant's formulas for estimating workers' DWA exposures were used, together with study participants' work histories, to estimate their cumulative and average beryllium exposure levels. Exposure concentrations reflected the

high exposures found historically in beryllium production and processing. Short-term BZ measurements had a median of 1.4, with 18.5 percent of samples exceeding OSHA's STEL of 5.0  $\mu\text{g}/\text{m}^3$ . Particularly high beryllium concentrations were reported in the areas of beryllium powder production, laundry, alloy arc furnace (approximately 40 percent of DWA estimates over 2.0  $\mu\text{g}/\text{m}^3$ ) and furnace rebuild (28.6 percent of short-term BZ samples over the OSHA STEL of 5  $\mu\text{g}/\text{m}^3$ ). LP samples ( $n = 179$ ), which were available from 1990 to 1992, had a median value of 1  $\mu\text{g}/\text{m}^3$ .

Of 655 workers employed at the time of the study, 627 underwent BeLPT screening. Blood samples were divided and split between two labs for analysis, with repeat testing for results that were abnormal or indeterminate. Thirty-one workers had an abnormal blood test upon initial testing and at least one of two subsequent tests was classified as sensitized. These workers, together with 19 workers who had an initial abnormal result and one subsequent indeterminate result, were offered clinical evaluation for CBD including the BAL-BeLPT and transbronchial lung biopsy. Nine with an initial abnormal test followed by two subsequent normal tests were not clinically evaluated, although four were found to be sensitized upon retesting in 1995. Of 47 workers who proceeded with evaluation for CBD (3 of the 50 initial workers with abnormal results declined to participate), 24 workers were diagnosed with CBD based on evidence of granulomas on lung biopsy (20 workers) or on other findings consistent with CBD (4 workers) (Kreiss *et al.*, 1997). After including five workers who had been diagnosed prior to the study, a total of 29 (4.6 percent) current workers were found to have CBD. In addition, the plant medical department identified 24 former workers diagnosed with CBD before the study.

Kreiss *et al.* reported that the highest prevalence of sensitization and CBD occurred among workers employed in beryllium metal production, even though the highest airborne total mass concentrations of beryllium were generally among employees operating the beryllium alloy furnaces in a different area of the plant (Kreiss *et al.*, 1997). Preliminary follow-up investigations of particle size-specific sampling at five furnace sites within the plant determined that the highest respirable (*e.g.*, particles  $<10 \mu\text{m}$  in diameter as defined by the authors) and alveolar-deposited (*e.g.*, particles  $<1 \mu\text{m}$  in diameter as defined by the authors) beryllium mass and particle number

concentrations, as collected by a general area impactor device, were measured at the beryllium metal production furnaces rather than the beryllium alloy furnaces (Kent *et al.*, 2001; McCawley *et al.*, 2001). A statistically significant linear trend was reported between the above alveolar-deposited particle mass concentration and prevalence of CBD and sensitization in the furnace production areas. The authors concluded that alveolar-deposited particles may be a more relevant exposure metric for predicting the incidence of CBD or sensitization than the total mass concentration of airborne beryllium.

Bailey *et al.* (2010) evaluated the effectiveness of a workplace preventive program in lowering BeS at the beryllium metal, oxide, and alloy production plant studied by Kreiss *et al.* (1997). The preventive program included use of administrative and PPE controls (*e.g.*, improved training, skin protection and other PPE, half-mask or air-purified respirators, medical surveillance, improved housekeeping standards, clean uniforms) as well as engineering controls (*e.g.*, migration controls, physical separation of administrative offices from production facilities) implemented over the course of five years.

In a cross-sectional/longitudinal hybrid study, Bailey *et al.* compared rates of sensitization in pre-program workers to those hired after the preventive program began. Pre-program workers were surveyed cross-sectionally in 1993–1994, and again in 1999 using the BeLPT to determine sensitization and CBD prevalence rates. The 1999 cross-sectional survey was conducted to determine if improvements in engineering and administrative controls were successful, however, results indicated no improvement in reducing rates of sensitization or CBD.

An enhanced preventive program including particle migration control, respiratory and dermal protection, and process enclosure was implemented in 2000, with continuing improvements made to the program in 2001, 2002–2004, and 2005. Workers hired during this period were longitudinally surveyed for sensitization using the BeLPT. Both the pre-program and program survey of worker sensitization status utilized split-sample testing to verify positive test results using the BeLPT. Of the total 660 workers employed at the production plant, 258 workers participated from the pre-program group while 290 participated from the program group (206 partial program, 84 full program). Prevalence comparisons of the pre-program and

program groups (partial and full) were performed by calculating prevalence ratios. A 95 percent confidence interval (95 percent CI) was derived using a cohort study method that accounted for the variance in survey techniques (cross-sectional versus longitudinal) (Bailey *et al.*, 2010). The sensitization prevalence of the pre-program group was 3.8 times higher (95 percent CI, 1.5–9.3) than the program group, 4.0 times higher (95 percent CI, 1.4–11.6) than the partial program subgroup, and 3.3 times higher (95 percent CI, 0.8–13.7) than the full program subgroup indicating that a comprehensive preventive program can reduce, but not eliminate, occurrence of sensitization among non-sensitized workers (Bailey *et al.*, 2010).

Rosenman *et al.* (2005) studied a group of several hundred workers who had been employed at a beryllium production and processing facility that operated in eastern Pennsylvania between 1957 and 1978. Of 715 former workers located, 577 were screened for BeS with the BLPT and 544 underwent chest radiography to identify cases of BeS and CBD. Workers were reported to have exposure to beryllium dust and fume in a variety of chemical forms including beryl ore, beryllium metal, beryllium fluoride, beryllium hydroxide, and beryllium oxide.

Rosenman *et al.* used the plant's DWA formulas to assess workers' full-shift exposure levels, based on IH data collected between 1957–1962 and 1971–1976, to calculate exposure metrics including cumulative, average, and peak for each worker in the study. The DWA was calculated based on air monitoring that consisted of GA and short-term task-based BZ samples. Workers' exposures to specific chemical and physical forms of beryllium were assessed, including insoluble beryllium (metal and oxide), soluble beryllium (fluoride and hydroxide), mixed soluble and insoluble beryllium, beryllium dust (metal, hydroxide, or oxide), fume (fluoride), and mixed dust and fume. Use of respiratory or dermal protection by workers was not reported. Exposures in the plant were high overall. Representative task-based IH samples ranged from 0.9  $\mu\text{g}/\text{m}^3$  to 84  $\mu\text{g}/\text{m}^3$  in the 1960s, falling to a range of 0.5–16.7  $\mu\text{g}/\text{m}^3$  in the 1970s. A large number of workers' mean DWA estimates (25 percent) were above the OSHA PEL of 2.0  $\mu\text{g}/\text{m}^3$ , while most workers had mean DWA exposures between 0.2 and 2.0  $\mu\text{g}/\text{m}^3$  (74 percent) or below 0.02  $\mu\text{g}/\text{m}^3$  (1 percent) (Rosenman *et al.*, Table 11; revised erratum April, 2006).

Blood samples for the BeLPT were collected from the former workers between 1996 and 2001 and were

evaluated at a single laboratory. Individuals with an abnormal test result were offered repeat testing, and were classified as sensitized if the second test was also abnormal. Sixty workers with two positive BeLPTs and 50 additional workers with chest radiography suggestive of disease were offered clinical evaluation, including bronchoscopy with bronchial biopsy and BAL-BeLPT. Seven workers met both criteria. Only 56 (51 percent) of these workers proceeded with clinical evaluation, including 57 percent of those referred on the basis of confirmed abnormal BeLPT and 47 percent of those with abnormal radiographs.

Of those workers who underwent bronchoscopy, 32 (5.5 percent) with evidence of granulomas were classified as "definite" CBD cases. Twelve (2.1 percent) additional workers with positive BAL-BeLPT or confirmed positive BeLPT and radiographic evidence of upper lobe fibrosis were classified as "probable" CBD cases. Forty workers (6.9 percent) without upper lobe fibrosis who had confirmed abnormal BeLPT, but who were not biopsied or who underwent biopsy with no evidence of granuloma, were classified as sensitized without disease. It is not clear how many of the 40 workers underwent biopsy. Another 12 (2.1 percent) workers with upper lobe fibrosis and negative or unconfirmed positive BeLPT were classified as "possible" CBD cases. Nine additional workers who were diagnosed with CBD before the screening were included in some parts of the authors' analysis.

The authors reported a total prevalence of 14.5 percent for CBD (definite and probable) and sensitization. This rate, considerably higher than the overall prevalence of sensitization and disease in several other worker cohorts as described earlier in this section, reflects in part the very high exposures experienced by many workers during the plant's operation in the 1950s, 1960s and 1970s. A total of 115 workers had mean DWAs above the OSHA PEL of 2  $\mu\text{g}/\text{m}^3$ . Of those, 7 (6.0 percent) had definite or probable CBD and another 13 (11 percent) were classified as sensitized without disease. The true prevalence of CBD in the group may be higher than reported, due to the low rate of clinical evaluation among sensitized workers.

Although most of the workers in this study had high exposures, sensitization and CBD also were observed within the small subgroup of participants believed to have relatively low beryllium exposures. Thirty-three cases of CBD and 24 additional cases of sensitization occurred among 339 workers with mean

DWA exposures below OSHA's PEL of 2.0  $\mu\text{g}/\text{m}^3$  (Rosenman *et al.*, Table 11, erratum 2006). Ten cases of sensitization and five cases of CBD were found among office and clerical workers, who were believed to have low exposures (levels not reported).

Follow-up time for sensitization screening of workers in this study who became sensitized during their employment had a minimum of 20 years to develop CBD prior to screening. In this sense the cohort is especially well suited to compare the exposure patterns of workers with CBD and those sensitized without disease, in contrast to several other studies of workers with only recent beryllium exposures. Rosenman *et al.* characterized and compared the exposures of workers with definite and probable CBD, sensitization only, and no disease or sensitization using chi-squared tests for discrete outcomes and analysis of variance (ANOVA) for continuous variables (cumulative, mean, and peak exposure levels). Exposure-response relationships were further examined with logistic regression analysis, adjusting for potential confounders including smoking, age, and beryllium exposure from outside of the plant. The authors found that cumulative, peak, and duration of exposure were significantly higher for workers with CBD than for sensitized workers without disease ( $p < 0.05$ ), suggesting that the risk of progressing from sensitization to CBD is related to the level or extent of exposure a worker experiences. The risk of developing CBD following sensitization appeared strongly related to exposure to insoluble forms of beryllium, which are cleared slowly from the lung and increase beryllium lung burden more rapidly than quickly mobilized soluble forms. Individuals with CBD had higher exposures to insoluble beryllium than those classified as sensitized without disease, while exposure to soluble beryllium was higher among sensitized individuals than those with CBD.

Cumulative, mean, peak, and duration of exposure were found to be comparable for workers with CBD and workers without sensitization or CBD ("normal" workers). Cumulative, peak, and duration of exposure were significantly lower for sensitized workers without disease than for normal workers. Rosenman *et al.* suggested that genetic predisposition to sensitization and CBD may have obscured an exposure-response relationship in this study, and plan to control for genetic risk factors in future studies. Exposure misclassification from the 1950s and 1960s may have been another limitation in this study, introducing bias that

could have influenced the lack of exposure response. It is also unknown if the 25 percent who died from CBD-related conditions may have had higher exposures.

A follow-up was conducted of the cross-sectional study of a population of workers first evaluated by Kreiss *et al.* (1997) and Rosenman *et al.* (2005) at a beryllium production and processing facility in eastern Pennsylvania by Schuler *et al.* (2012), and in a companion study by Virji *et al.* (2012). Schuler *et al.* evaluated the worker population employed in 1999 with six years or less work tenure in a cross-sectional study. The investigators evaluated the worker population by administering a work history questionnaire with a follow-up examination for sensitization and CBD. A job-exposure matrix (JEM) was combined with work histories to create individual estimates of average, cumulative, and highest-job-related exposure for total, respirable, and sub-micron beryllium mass concentration. Of the 291 eligible workers, 90.7 percent (264) participated in the study. Sensitization prevalence was 9.8 percent (26/264) with CBD prevalence of 2.3 percent (6/264). The investigators found a general pattern of increasing sensitization prevalence as the exposure quartile increased indicating an exposure-response relationship. The investigators found positive associations with both total and respirable mass concentration with sensitization (average and highest job) and CBD (cumulative). Increased sensitization prevalence was observed with metal oxide production alloy melting and casting, and maintenance. CBD was associated with melting and casting. The investigators summarized that both total and respirable mass concentration were relevant predictors of risk (Schuler *et al.*, 2012).

In the companion study by Virji *et al.* (2012), the investigators reconstructed historical exposure from 1994 to 1999 utilizing the personal sampling data collected in 1999 as baseline exposure estimates (BEE). The study evaluated techniques for reconstructing historical data to evaluate exposure-response relationships for epidemiological studies. The investigators constructed JEMs using the BEE and estimates of annual changes in exposure for 25 different process areas. The investigators concluded these reconstructed JEMs could be used to evaluate a range of exposure parameters from total, respirable and submicron mass concentration including cumulative, average, and highest exposure. These two studies

demonstrate that high-quality exposure estimates can be developed both for total mass and respirable mass concentrations.

#### e. Beryllium Machining Operations

Newman *et al.* (2001) and Kelleher *et al.* (2001) studied a group of 235 workers at a beryllium metal machining plant. Since the plant opened in 1969, its primary operations have been machining and polishing beryllium metal and high-beryllium content composite materials, with occasional machining of beryllium oxide/metal matrix ('E-metal'), and beryllium alloys. Other functions include machining of metals other than beryllium; receipt and inspection of materials; acid etching; final inspection, quality control, and shipping of finished materials; tool making; and engineering, maintenance, administrative and supervisory functions (Newman *et al.*, 2001; Madl *et al.*, 2007). Machining operations, including milling, grinding, lapping, deburring, lathing, and electrical discharge machining (EDM), were performed in an open-floor plan production area. Most non-machining jobs were located in a separate, adjacent area; however, non-production employees had access to the machining area.

Engineering and administrative measures, rather than PPE, were primarily used to control beryllium exposures at the plant (Madl *et al.*, 2007). Based on interviews with long-standing employees of the plant, Kelleher *et al.* reported that work practices were relatively stable until 1994, when a worker was diagnosed with CBD and a new exposure control program was initiated. Between 1995 and 1999 new engineering and work practice controls were implemented, including removal of pressurized air hoses and discouragement of dry sweeping (1995), enclosure of deburring processes (1996), mandatory uniforms (1997), and installation or updating of local exhaust ventilation (LEV) in EDM, lapping, deburring, and grinding processes (1998) (Madl *et al.*, 2007). Throughout the plant's history, respiratory protection was used mainly for "unusually large, anticipated exposures" to beryllium (Kelleher *et al.*, 2001), and was not routinely used otherwise (Newman *et al.*, 2001).

All workers at the plant participated in a beryllium disease surveillance program initiated in 1994, and were screened for beryllium sensitization with the BeLPT beginning in 1995. A BeLPT result was considered abnormal if two or more of six stimulation indices exceeded the normal range (see section

on BeLPT testing above), and was considered borderline if one of the indices exceeded the normal range. A repeat BeLPT was conducted for workers with abnormal or borderline initial results. Workers were identified as beryllium sensitized and referred for a clinical evaluation, including bronchoalveolar lavage (BAL) and transbronchial lung biopsy, if the repeat test was abnormal. CBD was diagnosed upon evidence of sensitization with granulomas or mononuclear cell infiltrates in the lung tissue (Newman *et al.*, 2001). Following the initial plant-wide screening, plant employees were offered BeLPT testing at two-year intervals. Workers hired after the initial screening were offered a BeLPT within 3 months of their hire date, and at 2-year intervals thereafter (Madl *et al.*, 2007).

Kelleher *et al.* performed a nested case-control study of the 235 workers evaluated in Newman *et al.* (2001) to evaluate the relationship between beryllium exposure levels and risk of sensitization and CBD (Kelleher *et al.*, 2001). The authors evaluated exposures at the plant using IH samples they had collected between 1996 and 1999, using personal cascade impactors designed to measure the mass of beryllium particles less than 6  $\mu\text{m}$ , particles less than 1  $\mu\text{m}$  in diameter, and total mass. The great majority of workers' exposures were below the OSHA PEL of 2  $\mu\text{g}/\text{m}^3$ . However, a few higher levels were observed in machining jobs including deburring, lathing, lapping, and grinding. Based on a statistical comparison between their samples and historical data provided by the plant, the authors concluded that worker beryllium exposures across all time periods could be approximated using the 1996–1999 data. They estimated workers' cumulative and 'lifetime weighted' (LTW) beryllium exposure based on the exposure samples they collected for each job in 1996–1999 and company records of each worker's job history.

Twenty workers with beryllium sensitization or CBD (cases) were compared to 206 workers (controls) for the case-control analysis from the study evaluating workers originally conducted by Newman *et al.* Thirteen workers were diagnosed with CBD based on lung biopsy evidence of granulomas and/or mononuclear cell infiltrates (11) or positive BAL results with evidence of lymphocytosis (2). Seven were evaluated for CBD and found to be sensitized only, thus twenty composing the case group. Nine of the remaining 215 workers first identified in original study (Newman *et al.*, 2001) were

excluded due to incomplete job history information, leaving 206 workers in the control group.

Kelleher *et al.*'s analysis included comparisons of the case and control groups' median exposure levels; calculation of odds ratios for workers in high, medium, and low exposure groups; and logistic regression testing of the association of sensitization or CBD with exposure level and other variables. Median cumulative exposures for total mass, particles <6  $\mu\text{m}$ , and particles <1  $\mu\text{m}$  were approximately three times higher among the cases than controls, although the relationships observed were not statistically significant (p values ~ 0.2). No clear difference between cases and controls was observed for the median LTW exposures. Odds ratios with sensitization and CBD as outcomes were elevated in high (upper third) and intermediate exposure groups relative to low (lowest third) exposure groups for both cumulative and LTW exposure, though the results were not statistically significant (p > 0.1). In the logistic regression analysis, only machinist work history was a significant predictor of case status in the final model. Quantitative exposure measures were not significant predictors of sensitization or disease risk.

Citing an 11.5 percent prevalence of beryllium sensitization or CBD among machinists as compared with 2.9 percent prevalence among workers with no machinist work history, the authors concluded that the risk of sensitization and CBD is increased among workers who machine beryllium. Although differences between cases and controls in median cumulative exposure did not achieve conventional thresholds for statistical significance, the authors noted that cumulative exposures were consistently higher among cases than controls for all categories of exposure estimates and for all particle sizes, suggesting an effect of cumulative exposure on risk. The levels at which workers developed CBD and sensitization were predominantly below OSHA's current PEL of 2  $\mu\text{g}/\text{m}^3$ , and no cases of sensitization or CBD were observed among workers with LTW exposure <0.02  $\mu\text{g}/\text{m}^3$ . Twelve (60 percent) of the 20 sensitized workers had LTW exposures > 0.20  $\mu\text{g}/\text{m}^3$ .

In 2007, Madl *et al.* published an additional study of 27 workers at the machining plant who were found to be sensitized or diagnosed with CBD between the start of medical surveillance in 1995 and 2005. As previously described, workers were offered a BeLPT in the initial 1995 screening (or within 3 months of their

hire date if hired after 1995) and at 2-year intervals after their first screening. Workers with two positive BeLPTs were identified as sensitized and offered clinical evaluation for CBD, including bronchoscopy with BAL and transbronchial lung biopsy. The criteria for CBD in this study were somewhat stricter than those used in the Newman *et al.* study, requiring evidence of granulomas on lung biopsy or detection of X-ray or pulmonary function changes associated with CBD, in combination with two positive BeLPTs or one positive BAL-BeLPT.

Based on the history of the plant's control efforts and their analysis of historical IH data, Madl *et al.* identified three "exposure control eras": A relatively uncontrolled period from 1980–1995; a transitional period from 1996 to 1999; and a relatively well-controlled "modern" period from 2000–2005. They found that the engineering and work practice controls instituted in the mid-1990s reduced workers' exposures substantially, with nearly a 15-fold difference in reported exposure levels between the pre-control and the modern period (Madl *et al.*, 2007). Madl *et al.* estimated workers' exposures using LP samples collected between 1980 and 2005, including those collected by Kelleher *et al.*, and work histories provided by the plant. As described more fully in the study, they used a variety of approaches to describe individual workers' exposures, including approaches designed to characterize the highest exposures workers were likely to have experienced. Their exposure-response analysis was based primarily on an exposure metric they derived by identifying the year and job of each worker's pre-diagnosis work history with the highest reported exposures. They used the upper 95th percentile of the LP samples collected in that job and year (in some cases supplemented with data from other years) to characterize the worker's upper-level exposures.

Based on their estimates of workers' upper level exposures, Madl *et al.* concluded that workers with sensitization or CBD were likely to have been exposed to airborne beryllium levels greater than 0.2  $\mu\text{g}/\text{m}^3$  as an 8-hour TWA at some point in their history of employment in the plant. They also concluded that most sensitization and CBD cases were likely to have been exposed to levels greater than 0.4  $\mu\text{g}/\text{m}^3$  at some point in their work at the plant. Madl *et al.* did not reconstruct exposures for workers at the plant who did not have sensitization or CBD and therefore could not determine whether non-cases had upper-bound exposures

lower than these levels. They found that upper-bound exposure estimates were generally higher for workers with CBD than for those who were sensitized but not diagnosed with CBD at the conclusion of the study (Madl *et al.*, 2007). Because CBD is an immunological disease and beryllium sensitization has been shown to occur within a year of exposure for some workers, Madl *et al.* argued that their estimates of workers' short-term upper-bound exposures may better capture the exposure levels that led to sensitization and disease than estimates of long-term cumulative or average exposures such as the LTW exposure measure constructed by Kelleher *et al.* (Madl *et al.*, 2007).

#### f. Beryllium Oxide Ceramics

Kreiss *et al.* (1993) conducted a screening of current and former workers at a plant that manufactured beryllium ceramics from beryllium oxide between 1958 and 1975, and then transitioned to metalizing circuitry onto beryllium ceramics produced elsewhere. Of the plant's 1,316 current and 350 retired workers, 505 participated who had not previously been diagnosed with CBD or sarcoidosis, including 377 current and 128 former workers. Although beryllium exposure was not estimated quantitatively in this survey, the authors conducted a questionnaire to assess study participants' exposures qualitatively. Results showed that 55 percent of participants reported working in jobs with exposure to beryllium dust. Close to 25 percent of participants did not know if they had exposure to beryllium, and just over 20 percent believed they had not been exposed.

BeLPT tests were administered to all 505 participants in the 1989–1990 screening period and evaluated at a single lab. Seven workers had confirmed abnormal BeLPT results and were identified as sensitized; these workers were also diagnosed with CBD based on findings of granulomas upon clinical evaluation. Radiograph screening led to clinical evaluation and diagnosis of two additional CBD cases, who were among three participants with initially abnormal BeLPT results that could not be confirmed on repeat testing. In addition, nine workers had been previously diagnosed with CBD, and another five were diagnosed shortly after the screening period, in 1991–1992.

Eight (3.7 percent of the screening population) of the nine CBD cases identified in the screening population were hired before the plant stopped producing beryllium ceramics in 1975, and were among the 216 participants who had reported having been near or



exposed to beryllium dust. Particularly high CBD rates of 11.1–15.8 percent were found among screening participants who had worked in process development/engineering, dry pressing, and ventilation maintenance jobs believed to have high or uncontrolled dust exposure. One case (0.6 percent) of CBD was diagnosed among the 171 study participants who had been hired after the plant stopped producing beryllium ceramics. Although this worker was hired eight years after the end of ceramics production, he had worked in an area later found to be contaminated with beryllium dust. The authors concluded that the study results suggested an exposure-response relationship between beryllium exposure and CBD, and recommended beryllium exposure control to reduce workers' risk of CBD.

Kreiss *et al.* later published a study of workers at a second ceramics plant located in Tucson, AZ (Kreiss *et al.*, 1996), which since 1980 had produced beryllium ceramics from beryllium oxide powder manufactured elsewhere. IH measurements collected between 1981 and 1992, primarily GA or short-term BZ samples and a few (<100) LP samples, were available from the plant. Airborne beryllium exposures were generally low. The majority of area samples were below the analytical detection limit of 0.1  $\mu\text{g}/\text{m}^3$ , while LP and short-term BZ samples had medians of 0.3  $\mu\text{g}/\text{m}^3$ . However, 3.6 percent of short-term BZ samples and 0.7 percent of GA samples exceeded 5.0  $\mu\text{g}/\text{m}^3$ , while LP samples ranged from 0.1 to 1.8  $\mu\text{g}/\text{m}^3$ . Machining jobs had the highest beryllium exposure levels among job tasks, with short-term BZ samples significantly higher for machining jobs than for non-machining jobs (median 0.6  $\mu\text{g}/\text{m}^3$  vs. 0.3  $\mu\text{g}/\text{m}^3$ ,  $p = 0.0001$ ). The authors used DWA formulas provided by the plant to estimate workers' full-shift exposure levels, and to calculate cumulative and average beryllium exposures for each worker in the study. The median cumulative exposure was 591.7 mg-days/ $\text{m}^3$  and the median average exposure was 0.35  $\mu\text{g}/\text{m}^3$ .

One hundred thirty-six of the 139 workers employed at the plant at the time of the Kreiss *et al.* (1996) study underwent BeLPT screening and chest radiographs in 1992. Blood samples were split between two laboratories. If one or both test results were abnormal, an additional sample was collected and split between the labs. Seven workers with an abnormal result on two draws were initially identified as sensitized. Those with confirmed abnormal BeLPTs or abnormal chest X-rays were offered

clinical evaluation for CBD, including transbronchial lung biopsy and BAL BeLPT. CBD was diagnosed based on observation of granulomas on lung biopsy, in five of the six sensitized workers who accepted evaluation. An eighth case of sensitization and sixth case of CBD were diagnosed in one worker hired in October 1991 whose initial BeLPT was normal, but who was confirmed as sensitized and found to have lung granulomas less than two years later, after sustaining a beryllium-contaminated skin wound. The plant medical department reported 11 additional cases of CBD among former workers (Kreiss *et al.*, 1996). The overall prevalence of sensitization in the plant was 5.9 percent, with a 4.4 percent prevalence of CBD.

Kreiss *et al.* reported that six (75 percent) of the eight sensitized workers were exposed as machinists during or before the period October 1985–March 1988, when measurements were first available for machining jobs. The authors reported that 14.3 percent of machinists were sensitized, compared to 1.2 percent of workers who had never been machinists ( $p < 0.01$ ). Workers' estimated cumulative and average beryllium exposures did not differ significantly for machinists and non-machinists, or for cases and non-cases. As in the previous study of the same ceramics plant published by Kreiss *et al.* in 1993, one case of CBD was diagnosed in a worker who had never been employed in a production job. This worker was employed in administration, a job with a median DWA of 0.1  $\mu\text{g}/\text{m}^3$  (range 0.1–0.3).

In 1998, Henneberger *et al.* conducted a follow-up cross-sectional survey of 151 employees employed at the beryllium ceramics plant studied by Kreiss *et al.* (1996) (Henneberger *et al.*, 2001). Employees were eligible who either had not participated in the Kreiss *et al.* survey ("short-term workers"—74 of those studied by Henneberger *et al.*), or who had participated and were not found to have sensitization or disease ("long-term workers"—77 of those studied by Henneberger *et al.*).

The authors estimated workers' cumulative, average, and peak beryllium exposures based on the plant's formulas for estimating job-specific DWA exposures, participants' work histories, and area and short-term task-specific BZ samples collected from the start of full production at the plant in 1981 to 1998. The long-term workers, who were hired before the 1992 study was conducted, had generally higher estimated exposures (median of average exposures—0.39  $\mu\text{g}/\text{m}^3$ ; mean—14.9  $\mu\text{g}/\text{m}^3$ ) than the short-term workers, who

were hired after 1992 (median 0.28  $\mu\text{g}/\text{m}^3$ , mean 6.1  $\mu\text{g}/\text{m}^3$ ).

Fifteen cases of sensitization were found, including eight among short-term and seven among long-term workers. Eight of the 15 workers were found to have CBD. Of the workers diagnosed with CBD, seven (88 percent) were long-term workers. One non-sensitized long-term worker and one sensitized long-term worker declined clinical examination.

Henneberger *et al.* reported a higher prevalence of sensitization among long-term workers with "high" (greater than median) peak exposures compared to long-term workers with "low" exposures; however, this relationship was not statistically significant. No association was observed for average or cumulative exposures. The authors reported higher prevalence of sensitization (but not statistically significant) among short-term workers with "high" (greater than median) average, cumulative, and peak exposures compared to short-term workers with "low" exposures of each type.

The cumulative incidence of sensitization and CBD was investigated in a cohort of 136 workers at the beryllium ceramics plant previously studied by the Kreiss and Henneberger groups (Schuler *et al.*, 2008). The study cohort consisted of those who participated in the plant-wide BeLPT screening in 1992. Both current and former workers from this group were invited to participate in follow-up BeLPT screenings in 1998, 2000, and 2002–03. A total of 106 of the 128 non-sensitized individuals in 1992 participated in the 11-year follow-up. Sensitization was defined as a confirmed abnormal BeLPT based on the split blood sample-dual laboratory protocol described earlier. CBD was diagnosed in sensitized individuals based on pathological findings from transbronchial biopsy and BAL fluid analysis. The 11-year crude cumulative incidence of sensitization and CBD was 13 percent (14 of 106) and 8 percent (9 of 106) respectively. The cumulative prevalence was about triple the point prevalences determined in the initial 1992 cross-sectional survey. The corrected cumulative prevalences for those that ever worked in machining were nearly twice that for non-machinists. The data illustrate the value of longitudinal medical screening over time to obtain a more accurate estimate of the occurrence of sensitization and CBD among an exposed working population.

Following the 1998 survey, the company continued efforts to reduce

exposures and risk of sensitization and CBD by implementing additional engineering, administrative, and PPE measures (Cummings *et al.*, 2007). Respirator use was required in production areas beginning in 1999, and latex gloves were required beginning in 2000. The lapping area was enclosed in 2000, and enclosures were installed for all mechanical presses in 2001. Between 2000 and 2003, water-resistant or water-proof garments, shoe covers, and taped gloves were incorporated to keep beryllium-containing fluids from wet machining processes off the skin. The new engineering measures did not appear to substantially reduce airborne beryllium levels in the plant. LP samples collected between 2000 and 2003 had a median of 0.18  $\mu\text{g}/\text{m}^3$ , similar to the 1994–1999 samples. However, respiratory protection requirements to control workers' airborne beryllium exposures were instituted prior to the 2000 sample collections.

To test the efficacy of the new measures instituted after 1998, in January 2000 the company began screening new workers for sensitization at the time of hire and at 3, 6, 12, 24, and 48 months of employment. These more stringent measures appear to have substantially reduced the risk of sensitization among new employees. Of 126 workers hired between 2000 and 2004, 93 completed BeLPT testing at hire and at least one additional test at 3 months of employment. One case of sensitization was identified at 24 months of employment (1 percent). This worker had experienced a rash after an incident of dermal exposure to lapping fluid through a gap between his glove and uniform sleeve, indicating that he may have become sensitized via the skin. He was tested again at 48 months of employment, with an abnormal result.

A second worker in the 2000–2004 group had two abnormal BeLPT tests at the time of hire, and a third had one abnormal test at hire and a second abnormal test at 3 months. Both had normal BeLPTs at 6 months, and were not tested thereafter. A fourth worker had one abnormal BeLPT result at the time of hire, a normal result at 3 months, an abnormal result at 6 months, and a normal result at 12 months. Four additional workers had one abnormal result during surveillance, which could not be confirmed upon repeat testing.

Cummings *et al.* calculated two sensitization rates based on these screening results: (1) a rate using only the sensitized worker identified at 24 months, and (2) a rate including all four workers who had repeated abnormal

results. They reported a sensitization incidence rate (IR) of 0.7 per 1,000 person-months to 2.7 per 1,000 person-months for the workers hired between 2000 and 2004, using the sum of sensitization-free months of employment among all 93 workers as the denominator.

The authors also estimated an incidence rate (IR) of 5.6 per 1,000 person-months for workers hired between 1993 and the 1998 survey. This estimated IR was based on one BeLPT screening, rather than BeLPTs conducted throughout the workers' employment. The denominator in this case was the total months of employment until the 1998 screening. Because sensitized workers may have been sensitized prior to the screening, the denominator may overestimate sensitization-free time in the legacy group, and the actual sensitization IR for legacy workers may be somewhat higher than 5.6 per 1,000 person-months. Based on comparison of the IRs, the authors concluded that the addition of respirator use, dermal protection, and housekeeping improvements appeared to have reduced the risk of sensitization among workers at the plant, even though airborne beryllium levels in some areas of the plant had not changed significantly since the 1998 survey.

#### g. Copper-Beryllium Alloy Processing and Distribution

Schuler *et al.* (2005) studied a group of 152 workers at a facility processing copper-beryllium alloys and small quantities of nickel-beryllium alloys, and converting semi-finished alloy strip and wire into finished strip, wire and rod. Production activities included annealing, drawing, straightening, point and chamfer, rod and wire packing, die grinding, pickling, slitting, and degreasing. Periodically in the plant's history, they also did salt baths, cadmium plating, welding and deburring. Since the late 1980s, rod and wire production processes were physically segregated from strip metal production. Production support jobs included mechanical maintenance, quality assurance, shipping and receiving, inspection, and wastewater treatment. Administration was divided into staff primarily working within the plant and personnel who mostly worked in office areas (Schuler, *et al.*, 2005). Workers' respirator use was limited, mostly to occasional tasks where high exposures were anticipated.

Following the 1999 diagnosis of a worker with CBD, the company surveyed the workforce, offering all current employees BeLPT testing in 2000 and offering sensitized workers

clinical evaluation for CBD, including BAL and transbronchial biopsy. Of the facility's 185 employees, 152 participated in the BeLPT screening. Samples were split between two laboratories, with additional draws and testing for confirmation if conflicting tests resulted in the initial draw. Ten participants (7 percent) had at least two abnormal BeLPT results. The results of nine workers who had abnormal BeLPT results from only one laboratory were not included because the authors believed it was experiencing technical problems with the test (Schuler *et al.*, 2005). CBD was diagnosed in six workers (4 percent) on evidence of pathogenic abnormalities (*e.g.*, granulomas) or evidence of clinical abnormalities consistent with CBD based on pulmonary function testing, pulmonary exercise testing, and/or chest radiography. One worker diagnosed with CBD had been exposed to beryllium during previous work at another copper-beryllium processing facility.

Schuler *et al.* evaluated airborne beryllium levels at the plant using IH samples collected between 1969 and 2000, including 4,524 GA samples, 650 LP samples and 815 short-duration (3–5 min) high volume (SD–HV) BZ task-specific samples. Occupational exposures to airborne beryllium were generally low. Ninety-nine percent of all LP measurements were below the current OSHA PEL of 2.0  $\mu\text{g}/\text{m}^3$  (8-hr TWA); 93 percent were below the DOE action level of 0.2  $\mu\text{g}/\text{m}^3$ ; and the median value was 0.02  $\mu\text{g}/\text{m}^3$ . The SD–HV BZ samples had a median value of 0.44  $\mu\text{g}/\text{m}^3$ , with 90 percent below the OSHA Short-Term Exposure Limit (STEL) of 5.0  $\mu\text{g}/\text{m}^3$ . The highest levels of beryllium were found in rod and wire production, particularly in wire annealing and pickling, the only production job with a median personal sample measurement greater than 0.1  $\mu\text{g}/\text{m}^3$  (median 0.12  $\mu\text{g}/\text{m}^3$ ; range 0.01–7.8  $\mu\text{g}/\text{m}^3$ ) (Schuler *et al.*, Table 4). These concentrations were significantly higher than the exposure levels in the strip metal area (median 0.02, range 0.01–0.72  $\mu\text{g}/\text{m}^3$ ), in production support jobs (median 0.02, range <0.01–0.33  $\mu\text{g}/\text{m}^3$ ), plant administration (median 0.02, range <0.01–0.11  $\mu\text{g}/\text{m}^3$ ), and office administration jobs (median 0.01, range <0.01–0.06  $\mu\text{g}/\text{m}^3$ ).

The authors reported that eight of the ten sensitized employees, including all six CBD cases, had worked in both major production areas during their tenure with the plant. The 7 percent prevalence (6 of 81 workers) of CBD among employees who had ever worked in rod and wire was statistically

significantly elevated compared with employees who had never worked in rod and wire ( $p < 0.05$ ), while the 6 percent prevalence (6 of 94 workers) among those who had worked in strip metal was not significantly elevated compared to non-strip metal workers ( $p > 0.1$ ). Based on these results, together with the higher exposure levels reported for the rod and wire production area, Schuler *et al.* concluded that work in rod and wire was a key risk factor for CBD in this population. Schuler *et al.* also found a high prevalence (13 percent) of sensitization among workers who had been exposed to beryllium for less than a year at the time of the screening, a rate similar to that found by Henneberger *et al.* among beryllium ceramics workers exposed for one year or less (16 percent, Henneberger *et al.*, 2001). All four workers who were sensitized without disease had been exposed 5 years or less; conversely, all six of the workers with CBD had first been exposed to beryllium at least five years prior to the screening (Schuler *et al.*, Table 2).

As has been seen in other studies, beryllium sensitization and CBD were found among workers who were typically exposed to low time-weighted average airborne concentrations of beryllium. While jobs in the rod and wire area had the highest exposure levels in the plant, the median personal sample value was only  $0.12 \mu\text{g}/\text{m}^3$ . However, workers may have occasionally been exposed to higher beryllium levels for short periods during specific tasks. A small fraction of personal samples recorded in rod and wire were above the OSHA PEL of  $2.0 \mu\text{g}/\text{m}^3$ , and half of workers with sensitization or CBD reported that they had experienced a "high-exposure incident" at some point in their work history (Schuler *et al.*, 2005). The only group of workers with no cases of sensitization or CBD, a group of 26 office administration workers, was the group with the lowest recorded exposures (median personal sample  $0.01 \mu\text{g}/\text{m}^3$ , range  $< 0.01$ – $0.06 \mu\text{g}/\text{m}^3$ ).

After the BeLPT screening was conducted in 2000, the company began implementing new measures to further reduce workers' exposure to beryllium (Thomas *et al.*, 2009). Requirements designed to minimize dermal contact with beryllium, including long-sleeve facility uniforms and polymer gloves, were instituted in production areas in 2000. In 2001 the company installed LEV in die grinding and polishing. LP samples collected between June 2000 and December 2001 show reduced exposures plant-wide. Of 2,211 exposure samples collected, 98 percent

were below  $0.2 \mu\text{g}/\text{m}^3$ , and 59 percent below the limit of detection (LOD), which was either  $0.02 \mu\text{g}/\text{m}^3$  or  $0.2 \mu\text{g}/\text{m}^3$  depending on the method of sample analysis (Thomas *et al.*, 2009). Median values below  $0.03 \mu\text{g}/\text{m}^3$  were reported for all processes except the wire annealing and pickling process. Samples for this process remained somewhat elevated, with a median of  $0.1 \mu\text{g}/\text{m}^3$ . In January 2002, the plant enclosed the wire annealing and pickling process in a restricted access zone (RAZ), requiring respiratory PPE in the RAZ and implementing stringent measures to minimize the potential for skin contact and beryllium transfer out of the zone. While exposure samples collected by the facility were sparse following the enclosure, they suggest exposure levels comparable to the 2000–01 samples in areas other than the RAZ. Within the RAZ, required use of powered air-purifying respirators indicates that respiratory exposure was negligible.

To test the efficacy of the new measures in preventing sensitization and CBD, in June 2000 the facility began an intensive BeLPT screening program for all new workers. The company screened workers at the time of hire; at intervals of 3, 6, 12, 24, and 48 months; and at 3-year intervals thereafter. Among 82 workers hired after 1999, three (3.7 percent) cases of sensitization were found. Two (5.4 percent) of 37 workers hired prior to enclosure of the wire annealing and pickling process were found to be sensitized within 3 and 6 months of beginning work at the plant. One (2.2 percent) of 45 workers hired after the enclosure was confirmed as sensitized.

Thomas *et al.* calculated a sensitization IR of 1.9 per 1,000 person-months for the workers hired after the exposure control program was initiated in 2000 ("program workers"), using the sum of sensitization-free months of employment among all 82 workers as the denominator (Thomas *et al.*, 2009). They calculated an estimated IR of 3.8 per 1,000 person-months for 43 workers hired between 1993 and 2000 who had participated in the 2000 BeLPT screening ("legacy workers"). This estimated IR was based on one BeLPT screening, rather than BeLPTs conducted throughout the legacy workers' employment. The denominator in this case is the total months of employment until the 2000 screening. Because sensitized workers may have been sensitized prior to the screening, the denominator may overestimate sensitization-free time in the legacy group, and the actual sensitization IR for legacy workers may be somewhat higher

than 3.8 per 1,000 person-months. Based on comparison of the IRs and the prevalence rates discussed previously, the authors concluded that the combination of dermal protection, respiratory protection, housekeeping improvements and engineering controls implemented beginning in 2000 appeared to have reduced the risk of sensitization among workers at the plant. However, they noted that the small size of the study population and the short follow-up time for the program workers suggested that further research is needed to confirm the program's efficacy (Thomas *et al.*, 2009).

Stanton *et al.* (2006) conducted a study of workers in three different copper-beryllium alloy distribution centers in the United States. The distribution centers, including one bulk products center established in 1963 and strip metal centers established in 1968 and 1972, sell products received from beryllium production and finishing facilities and small quantities of copper-beryllium, aluminum-beryllium, and nickel-beryllium alloy materials. Work at distribution centers does not require large-scale heat treatment or manipulation of material typical of beryllium processing and machining plants, but involves final processing steps that can generate airborne beryllium. Slitting, the main production activity at the two strip product distribution centers, generates low levels of airborne beryllium particles, while operations such as tensioning and welding used more frequently at the bulk products center can generate somewhat higher levels. Non-production jobs at all three centers included shipping and receiving, palletizing and wrapping, production-area administrative work, and office-area administrative work.

The authors estimated workers' beryllium exposures using IH data from company records and job history information collected through interviews conducted by a company occupational health nurse. Stanton *et al.* evaluated airborne beryllium levels in various jobs based on 393 full-shift LP samples collected from 1996 to 2004. Airborne beryllium levels at the plant were generally very low, with 54 percent of all samples at or below the LOD, which ranged from  $0.02$  to  $0.1 \mu\text{g}/\text{m}^3$ . The authors reported a median of  $0.03 \mu\text{g}/\text{m}^3$  and an arithmetic mean of  $0.05 \mu\text{g}/\text{m}^3$  for the 393 full-shift LP samples, where samples below the LOD were assigned a value of half the applicable LOD. Median and geometric mean values for specific jobs ranged from  $0.01$ – $0.07$  and  $0.02$ – $0.07 \mu\text{g}/\text{m}^3$ , respectively. All measurements were

below the OSHA PEL of 2.0  $\mu\text{g}/\text{m}^3$  and 97 percent were below the DOE action level of 0.2  $\mu\text{g}/\text{m}^3$ . The paper does not report use of respiratory or skin protection. Exposure conditions may have changed somewhat over the history of the plant due to changes in exposure control measures, including improvements to product and container cleaning practices instituted during the 1990s.

Eighty-eight of the 100 workers (88 percent) employed at the three centers at the time of the study participated in screening for beryllium sensitization. Blood samples were collected between November 2000 and March 2001 by the company's medical staff. Samples collected from employees of the strip metal centers were split and evaluated at two laboratories, while samples from the bulk product center workers were evaluated at a single laboratory. Participants were considered to be "sensitized" to beryllium if two or more BeLPT results, from two laboratories or from repeat testing at the same laboratory, were found to be abnormal. One individual was found to be sensitized and was offered clinical evaluation, including BAL and fiberoptic bronchoscopy. He was found to have lung granulomas and was diagnosed with CBD.

The worker diagnosed with CBD had been employed at a strip metal distribution center from 1978 to 2000 as a shipper and receiver, loading and unloading trucks delivering materials from a beryllium production facility and to the distribution center's customers. Although the LP samples collected for his job between 1996 and 2000 were generally low ( $n = 35$ , median 0.01, range < 0.02–0.13  $\mu\text{g}/\text{m}^3$ ), it is not clear whether these samples adequately characterize his exposure conditions over the course of his work history. He reported that early in his work history, containers of beryllium oxide powder were transported on the trucks he entered. While he did not recall seeing any breaks or leaks in the beryllium oxide containers, some containers were known to have been punctured by forklifts on trailers used by the company during the period of his employment, and could have contaminated trucks he entered. With 22 years of employment at the facility, this worker had begun beryllium-related work earlier and performed it longer than about 90 percent of the study population (Stanton *et al.*, 2006).

#### h. Nuclear Weapons Production Facilities & Cleanup of Former Facilities

Primary exposure from nuclear weapons production facilities comes

from beryllium metal and beryllium alloys. A study conducted by Kreiss *et al.* (1989) documented sensitization and CBD among beryllium-exposed workers in the nuclear industry. A company medical department identified 58 workers with beryllium exposure among a work force of 500, of whom 51 (88 percent) participated in the study. Twenty-four workers were involved in research and development (R&D), while the remaining 27 were production workers. The R&D workers had a longer tenure with a mean time from first exposure of 21.2 years, compared to a mean time since first exposure of 5 years among the production workers. The number of workers with abnormal BeLPT readings was 6, with 4 being diagnosed with CBD. This resulted in an estimated 11.8 percent prevalence of sensitization.

Kreiss *et al.* (1993) expanded the work of Kreiss *et al.* (1989) by performing a cross-sectional study of 895 (current and former) beryllium workers in the same nuclear weapons plant. Participants were placed in qualitative exposure groups ("no exposure," "minimal exposure," "intermittent exposure," and "consistent exposure") based on questionnaire responses. The number of workers with abnormal BeLPT totaled 18 with 12 being diagnosed with CBD. Three additional workers with sensitization developed CBD over the next 2 years. Sensitization occurred in all of the qualitatively defined exposure groups. Individuals who had worked as machinists were statistically overrepresented among beryllium-sensitized cases, compared with non-cases. Cases were more likely than non-cases to report having had a measured overexposure to beryllium ( $p = 0.009$ ), a factor which proved to be a significant predictor of sensitization in logistic regression analyses, as was exposure to beryllium prior to 1970. Beryllium sensitized cases were also significantly more likely to report having had cuts that were delayed in healing ( $p = 0.02$ ). The authors concluded that individual variability and susceptibility along with exposure circumstances are important factors in developing beryllium sensitization and CBD.

In 1991, the Beryllium Health Surveillance Program (BHSP) was established at the Rocky Flats Nuclear Weapons Facility to offer BLPT screening to current and former employees who may have been exposed to beryllium (Stange *et al.*, 1996). Participants received an initial BeLPT and follow-ups at one and three years. Based on histologic evidence of pulmonary granulomas and a positive BAL-BeLPT, Stange *et al.* published a

study of 4,397 BHSP participants tested from June 1991 to March 1995, including current employees (42.8 percent) and former employees (57.2 percent). Twenty-nine cases of CBD and 76 cases of sensitization were identified. The sensitization rate for the population was 2.43 percent. Available exposure data included fixed airhead (FAH) exposure samples collected between 1970 and 1988 (mean concentration 0.016  $\mu\text{g}/\text{m}^3$ ) and personal samples collected between 1984 and 1987 (mean concentration 1.04  $\mu\text{g}/\text{m}^3$ ). Cases of CBD and sensitization were noted in individuals in all jobs classifications, including those believed to involve minimal exposure to beryllium. The authors recommended ongoing surveillance for workers in all jobs with potential for beryllium exposure.

Stange *et al.* (2001) extended the previous study, evaluating 5,173 participants in the Rocky Flats BHSP who were tested between June 1991 and December 1997. Three-year serial testing was offered to employees who had not been tested for three years or more and did not show beryllium sensitization during the previous study. This resulted in 2,891 employees being tested. Of the 5,173 workers participating in the study, 172 were found to have abnormal BeLPT. Ninety-eight (3.33 percent) of the workers were found to be sensitized (confirmed abnormal BeLPT results) in the initial screening, conducted in 1991. Of these workers 74 were diagnosed with CBD (history of beryllium exposure, evidence of non-caseating granulomas or mononuclear cell infiltrates on lung biopsy, and a positive BeLPT or BAL-BeLPT). A follow-up survey of 2,891 workers three years later identified an additional 56 sensitized workers and an additional seven cases of CBD. Sensitization and CBD rates were analyzed with respect to gender, building work locations, and length of employment. Historical employee data included hire date, termination date, leave of absences, and job title changes. Exposure to beryllium was determined by job categories and building or work area codes. Personal beryllium air monitoring results were used, when available, from employees with the same job title or similar job. However, no quantitative information was presented in the study. The authors conclude that for some individuals, exposure to beryllium at levels less than the OSHA PEL could cause sensitization and CBD.

Viet *et al.* (2001) conducted a case-control study of the Rocky Flats worker population studied by Stange *et al.* (1996 and 2001) to examine the relationship between estimated

beryllium exposure level and risk of sensitization or CBD. The worker population included 74 beryllium-sensitized workers and 50 workers diagnosed with CBD. Beryllium exposure levels were estimated based on FAH airhead samples from one building, the beryllium machine shop. These were collected away from the BZ of the machine operator and likely underestimated exposure. To estimate levels in other locations, these air sample concentrations were used to construct a job exposure matrix that included the determination of the Building 444 exposure estimates for a 30-year period; each subject's work history by job location, task, and time period; and assignment of exposure estimates to each combination of job location, task, and time period as compared to Building 444 machinists. The authors adjusted the levels observed in the machine shop by factors based on interviews with former workers. Workers' estimated mean exposure concentrations ranged from 0.083  $\mu\text{g}/\text{m}^3$  to 0.622  $\mu\text{g}/\text{m}^3$ . Estimated maximum air concentrations ranged from 0.54  $\mu\text{g}/\text{m}^3$  to 36.8  $\mu\text{g}/\text{m}^3$ . Cases were matched to controls of the same age, race, gender, and smoking status (Viet *et al.*, 2001).

Estimated mean and cumulative exposure levels and duration of employment were found to be significantly higher for CBD cases than for controls. Estimated mean exposure levels were significantly higher for sensitization cases than for controls. No significant difference was observed for estimated cumulative exposure or duration of exposure. Similar results were found using logistic regression analysis, which identified statistically significant relationships between CBD and both cumulative and mean estimated exposure, but did not find significant relationships between estimated exposure levels and sensitization without CBD. Comparing CBD with sensitization cases, Viet *et al.* found that workers with CBD had significantly higher estimated cumulative and mean beryllium exposure levels than workers who were sensitized, but did not have CBD.

Johnson *et al.* (2001) conducted a review of personal sampling records and medical surveillance reports at an atomic weapons establishment in Cardiff, United Kingdom. The study evaluated airborne samples collected over the 36-year period of operation for the plant. Data included 367,757 area samples and 217,681 personal lapel samples from 194 workers over the time period from 1981–1997. Data was available prior to this time period but

was not analyzed since this data was not available electronically. The authors estimated that over the 17 years of measurement data analyzed, airborne beryllium concentrations did exceed 2.0  $\mu\text{g}/\text{m}^3$ , however, due to the limitations with regard to collection times it is difficult to assess the full reliability of this estimate. The authors noted that in the entire plant's history, only one case of CBD had been diagnosed. It was also noted that BeLPT has not been routinely conducted among any of the workers at this facility.

Armojandi *et al.* (2010) conducted a cross-sectional study of workers at a nuclear weapons research and development (R&D) facility to determine the risk of developing CBD in sensitized workers at facilities with exposures much lower than production plants. Of the 1875 current or former workers at the R&D facility, 59 were determined to be sensitized based on at least two positive BeLPTs (*i.e.*, samples drawn on two separate occasions or on split samples tested in two separate DOE-approved laboratories) for a sensitization rate of 3.1 percent. Workers found to have positive BeLPTs were further evaluated in an Occupational Medicine Clinic between 1999 through 2005. Armojandi *et al.* (2010) evaluated 50 of the sensitized workers who also had medical and occupational histories, physical examination, chest imaging with high-resolution computed tomography (HRCT) (N = 49), and pulmonary function testing (nine of the 59 workers refused physical examinations so were not included in this study). Forty of the 50 workers chosen for this study underwent bronchoscopy for bronchoalveolar lavage and transbronchial biopsies in addition to the other testing. Five of the 49 workers had CBD at the time of evaluation (based on histology or high-resolution computed tomography); three others had evidence of probable CBD; however, none of these cases were classified as severe at the time of evaluation. The rate of CBD at the time of study among sensitized individuals was 12.5 percent (5/40) for those using pathologic review of lung tissue, and 10.2 percent (5/49) for those using HRCT as a criteria for diagnosis. The rate of CBD among the entire population (5/1875) was 0.3 percent.

The mean duration of employment at the facility was 18 years, and the mean latency period (from first possible exposure) to time of evaluation and diagnosis was 32 years. There was no available exposure monitoring in the breathing zone of workers at the facility but the beryllium levels were believed

to be relatively low (possibly less than 0.1  $\mu\text{g}/\text{m}^3$  for most jobs). There was not an apparent exposure-response relationship for sensitization or CBD. The sensitization prevalence was similar and the CBD prevalence higher among workers with the lower-exposure jobs. The authors concluded that these sensitized workers, who were subjected to an extended duration of low potential beryllium exposures over a long latency period, had a low prevalence of CBD (Armojandi *et al.*, 2010).

#### i. Aluminum Smelting

Bauxite ore, the primary source of aluminum, contains naturally occurring beryllium. Worker exposure to beryllium can occur at aluminum smelting facilities where aluminum extraction occurs via electrolytic reduction of aluminum oxide into aluminum metal. Characterization of beryllium exposures and sensitization prevalence rates were examined by Taiwo *et al.* (2010) in a study of nine aluminum smelting facilities from four different companies in the U.S., Canada, Italy and Norway.

Of the 3,185 workers determined to be potentially exposed to beryllium, 1,932 agreed to participate in a medical surveillance program between 2000 and 2006 (60 percent participation rate). The medical surveillance program included serum BeLPT analysis, confirmation of an abnormal BeLPT with a second BeLPT, and follow-up of all confirmed positive responses by a pulmonary physician to evaluate for progression to CBD.

Eight-hour TWAs were assessed utilizing 1,345 personal samples collected from the 9 smelters. The personal beryllium samples obtained showed a range of 0.01–13.00  $\mu\text{g}/\text{m}^3$  time-weighted average with an arithmetic mean of 0.25  $\mu\text{g}/\text{m}^3$  and geometric mean of 0.06  $\mu\text{g}/\text{m}^3$ . Exposure levels to beryllium observed in aluminum smelters are similar to those seen in other industries that utilize beryllium. Of the 1,932 workers surveyed by BeLPT, nine workers were diagnosed with sensitization (prevalence rate of 0.47 percent, 95% confidence interval = 0.21–0.88 percent) with 2 of these workers diagnosed with probable CBD after additional medical evaluations.

The authors concluded that compared with beryllium-exposed workers in other industries, the rate of sensitization among aluminum smelter workers appears lower. The authors speculated that this lower observed rate could be related to a more soluble form of beryllium found in the aluminum smelting work environment as well as

the consistent use of respiratory protection. However, the authors also speculated that the 60 percent participation rate may have underestimated the sensitization rate in this worker population.

A study by Nilsen *et al.* (2010) also found a low rate of sensitization among aluminum workers in Norway. Three-hundred sixty-two workers and thirty-one control individuals were tested for beryllium sensitization based on the BeLPT. The results found that one (0.28%) of the smelter workers had been sensitized. No borderline results were reported. The exposure estimated in this plant was 0.1  $\mu\text{g}/\text{m}^3$  to 0.31  $\mu\text{g}/\text{m}^3$  (Nilsen *et al.*, 2010).

#### 6. Animal Models of CBD

This section reviews the relevant animal studies supporting the mechanisms outlined above. Researchers have attempted to identify animal models with which to further investigate the mechanisms underlying the development of CBD. A suitable animal model should exhibit major characteristics of CBD, including the demonstration of a beryllium-specific immune response, the formation of immune granulomas following inhalation exposure to beryllium, and mimicking the progressive nature of the human disease. While exposure to beryllium has been shown to cause chronic granulomatous inflammation of the lung in animal studies using a variety of species, most of the granulomatous lesions were formed by foreign-body reactions, which result from persistent irritation and consist predominantly of macrophages and monocytes, and small numbers of lymphocytes. Foreign-body granulomas are distinct from the immune granulomas of CBD, which are caused by antigenic stimulation of the immune system and contain large numbers of lymphocytes. Animal studies have been useful in providing biological plausibility for the role of immunological alterations and lung inflammation and in clarifying certain specific mechanistic aspects of beryllium disease. However, the lack of a dependable animal model that mimics all facets of the human response combined with study limitations in terms of single dose experiments, few animals, or abbreviated observation periods have limited the utility of the data. Currently, no single model has completely mimicked the disease process as it progresses in humans. The following is a discussion of the most relevant animal studies regarding the mechanisms of sensitization and CBD development in humans. Table A.2 in

the Appendix summarizes species, route, chemical form of beryllium, dose levels, and pathological findings of the key studies.

Harmsen *et al.* performed a study to assess whether the beagle dog could provide an adequate model for the study of beryllium-induced lung diseases (Harmsen *et al.*, 1986). One group of dogs served as a control group (air inhalation only) and four other groups received high (approximately 50  $\mu\text{g}/\text{kg}$ ) and low (approximately 20  $\mu\text{g}/\text{kg}$ ) doses of beryllium oxide calcined at 500 °C or 1,000 °C, administered as aerosols in a single exposure. As discussed above, calcining temperature controls the solubility and SSA of beryllium particles. Those particles calcined at higher temperatures (*e.g.*, 1,000 °C) are less soluble and have lower SSA than particles calcined at lower temperatures (*e.g.*, 500 °C). Solubility and SSA are factors in determining the toxic potential of beryllium compounds or materials.

Cells were collected from the dogs by BAL at 30, 60, 90, 180, and 210 days after exposure, and the percentages of neutrophils and lymphocytes were determined. In addition, the mitogenic responses of blood lymphocytes and lavage cells collected at 210 days were determined with either phytohemagglutinin or beryllium sulfate as mitogen. The percentage of neutrophils in the lavage fluid was significantly elevated only at 30 days with exposure to either dose of 500 °C beryllium oxide. The percentage of lymphocytes in the fluid was significantly elevated in samples across all times with exposure to the high dose of this beryllium oxide form. Beryllium oxide calcined at 1,000 °C elevated lavage lymphocytes only in high dose at 30 days. No significant effect of 1,000 °C beryllium oxide exposure on mitogenic response of any lymphocytes was seen. In contrast, peripheral blood lymphocytes from the 500 °C beryllium oxide exposed groups were significantly stimulated by beryllium sulfate compared with the phytohemagglutinin exposed cells. The investigators in this study were able to replicate some of the same findings as those observed in human studies—specifically, that beryllium in soluble and insoluble forms can be mitogenic to immune cells, an important finding for progression of sensitization and proliferation of immune cells to developing full-blown CBD.

In another beagle study Haley *et al.* also found that the beagle dog appears to model some aspects of human CBD (Haley *et al.*, 1989). The authors monitored lung pathologic effects,

particle clearance, and immune sensitization of peripheral blood leukocytes following a single exposure to beryllium oxide aerosol generated from beryllium oxide calcined at 500 °C or 1,000 °C. The aerosol was administered to the dogs perinasally to attain initial lung burdens of 6 or 18  $\mu\text{g}$  beryllium/kg body weight. Granulomatous lesions and lung lymphocyte responses consistent with those observed in humans with CBD were observed, including perivascular and peribronchiolar infiltrates of lymphocytes and macrophages, progressing to microgranulomas with areas of granulomatous pneumonia and interstitial fibrosis. Beryllium specificity of the immune response was demonstrated by positive results in the BeLPT, although there was considerable inter-animal variation. The lesions declined in severity after 64 days post-exposure. Thus, while this model was able to mimic the formation of Be-specific immune granulomas, it was not able to mimic the progressive nature of disease.

This study also provided an opportunity to compare the effects of beryllium oxide calcination temperature on granulomatous disease in the beagle respiratory system. Haley *et al.* found an increase in the percentage and numbers of lymphocytes in BAL fluid at 3 months post-exposure in dogs exposed to either dose of beryllium oxide calcined at 500 °C, but not in dogs exposed to the material calcined at the higher temperature. Although there was considerable inter-animal variation, lesions were generally more severe in the dogs exposed to material calcined at 500 °C. Positive BeLPT results were observed with BAL lymphocytes only in the group with a high initial lung burden of the material calcined at 500 °C, but positive results with peripheral blood lymphocytes were observed at both doses with material calcined at both temperatures.

The histologic and immunologic responses of canine lungs to aerosolized beryllium oxide were investigated in another Haley *et al.* (1989) study. Beagle-dogs were exposed in a single exposure to high dose (50  $\mu\text{g}/\text{kg}$  of body weight) or low dose (17  $\mu\text{g}/\text{kg}$ ) levels of beryllium oxide calcined at either 500° or 1000° C. One group of dogs was examined up to 365 days after exposure for lung histology and biochemical assay to determine the fate of inhaled beryllium oxide. A second group underwent BAL for lung lymphocyte analysis for up to 22 months after exposure. Histopathologic examination revealed peribronchiolar and perivascular lymphocytic histiocytic

inflammation, peaking at 64 days after beryllium oxide exposure. Lymphocytes were initially well differentiated, but progressed to lymphoblastic cells and aggregated in lymphofollicular nodules or microgranulomas over time. Alveolar macrophages were large, and filled with intracytoplasmic material. Cortical and paracortical lymphoid hyperplasia of the tracheobronchial nodes was found. Lung lymphocyte concentrations were increased at 3 months and returned to normal in both dose groups given 500 °C treated beryllium chloride. No significant elevations in lymphocyte concentrations were found in dogs given 1,000° C treated beryllium oxide. Lung retention was higher in the 500 °C treated beryllium oxide group. The lesions found in dog lungs closely resembled those found in humans with CBD: severe granulomas, lymphoblast transformation, increased pulmonary lymphocyte concentrations and variation in beryllium sensitivity. It was concluded that the canine model for berylliosis may provide insight into this disease.

In a follow-up experiment, control dogs and those exposed to beryllium oxide calcined at 500 °C were allowed to rest for 2.5 years, and then re-exposed to filtered air (controls) or beryllium oxide calcined at 500 °C for an initial lung burden (ILB) target of 50 µg beryllium oxide/kg body weight (Haley *et al.*, 1992). Immune responses of blood and BAL lymphocytes, and lung lesions in dogs sacrificed 210 days post-exposure, were compared with results following the initial exposure. The severity of lung lesions was comparable under both conditions, suggesting that a 2.5-year interval was sufficient to prevent cumulative pathologic effects. Conradi *et al.* (1971) found no exposure-related histological alterations in the lungs of six beagle dogs exposed to a range of 3,300–4,380 µg Be/m<sup>3</sup> as beryllium oxide calcined at 1,400° C for 30 min, once per month for 3 months. Because the dogs were sacrificed 2 years post-exposure, the long time period between exposure and response may have allowed for the reversal of any beryllium-induced changes (EPA, 1998).

A 1994 study by Haley *et al.* showed that intra-bronchiolar instillation of beryllium induced immune granulomas and sensitization in monkeys. Haley *et al.* (1994) exposed male cynomolgus monkeys to either beryllium metal or beryllium oxide calcined at 500 °C by intrabronchiolar instillation as a saline suspension. Lymphocyte counts in BAL fluid were observed, and were found to be significantly increased in monkeys exposed to beryllium metal on post-exposure days 14 to 90, and on post-

exposure day 60 in monkeys exposed to beryllium oxide. The lungs of monkeys exposed to beryllium metal had lesions characterized by interstitial fibrosis, Type II cell hyperplasia, and lymphocyte infiltration. Some monkeys also exhibited immune granulomas. Similar lesions were observed in monkeys exposed to beryllium oxide, but the incidence and severity were much less. BAL lymphocytes from monkeys exposed to beryllium metal, but not from monkeys exposed to beryllium oxide, proliferated in response to beryllium sulfate in the BeLPT (EPA, 1998).

In an experiment similar to the one conducted with dogs, Conradi *et al.* (1971) found no effect in monkeys (*Macaca irus*) exposed via whole-body inhalation for three 30-minute monthly exposures to a range of 3,300–4,380 µg Be/m<sup>3</sup> as beryllium oxide calcined at 1,400° C. The lack of effect may have been related to the long period (2 years) between exposure and sacrifice, or to low toxicity of beryllium oxide calcined at such a high temperature.

As discussed earlier in this Health Effects section, at the cellular level, beryllium dissolution must occur for either a dendritic cell or a macrophage to present beryllium as an antigen to induce the cell-mediated CBD immune reactions (Stefaniak *et al.*, 2006). Several studies have shown that low-fired beryllium oxide, which is predominantly made up of poorly crystallized small particles, is more immunologically reactive than beryllium oxide calcined at higher firing temperatures that result in less reactivity due to increasing crystal size. As discussed previously, Haley *et al.* (1989a) found more severe lung lesions and a stronger immune response in beagle dogs receiving a single inhalation exposure to beryllium oxide calcined at 500 °C than in dogs receiving an equivalent initial lung burden of beryllium oxide calcined at 1,000° C. Haley *et al.* found that beryllium oxide calcined at 1,000° C elicited little local pulmonary immune response, whereas the much more soluble beryllium oxide calcined at 500 °C produced a beryllium-specific, cell-mediated immune response in dogs (Haley *et al.*, 1991).

In a later study, beryllium metal appeared to induce a greater toxic response than beryllium oxide following intrabronchiolar instillation in cynomolgus monkeys, as evidenced by more severe lung lesions, a larger effect on BAL lymphocyte counts, and a positive response in the BeLPT with BAL lymphocytes only after exposure to beryllium metal (Haley *et al.*, 1994).

Because an oxide layer may form on beryllium-metal surfaces after exposure to air (Mueller and Adolphson, 1979; Harmsen *et al.*, 1986) dissolution of small amounts of poorly soluble beryllium compounds in the lungs might be sufficient to allow persistent low-level beryllium presentation to the immune system (NAS, 2008).

Genetic studies in humans led to the creation of an animal model containing different human HLA–DP alleles inserted into FVB/N mice for mechanistic studies of CBD. Three strains of genetically engineered mice (transgenic mice) were created that conferred different risks for developing CBD based on human studies (Weston *et al.*, 2005; Snyder *et al.*, 2008): (1) the HLDPB1\*401 transgenic strain, where the transgene codes for lysine residue at the 69th position of the B-chain conferred low risk of CBD; (2) the HLA–DPB1\*201 mice, where the transgene codes for glutamic acid residue at the 69th position of the B-chain and glycine residues at positions 84 and 85 conferred medium risk of CBD; and (3) the HLA–DPB1\*1701 mice, where the transgene codes for glutamic acid at the 69th position of the B-chain and aspartic acid and glutamic acid residues at positions 84 and 85, respectively, conferred high risk of CBD (Tarantino-Hutchinson *et al.*, 2009).

In order to validate the transgenic model, Tarantino-Hutchinson *et al.* challenged the transgenic mice along with seven different inbred mouse strains to determine the susceptibility and sensitivity to beryllium exposure. Mice were dermally exposed with either saline or beryllium, then challenged with either saline or beryllium (as beryllium sulfate) using the MEST protocol (mouse ear-swelling test). The authors determined that the high risk HLA–DPB1\*1701 transgenic strain responded 4 times greater (as measured via ear swelling) than control mice and at least 2 times greater than other strains of mice. The findings correspond to epidemiological study results reporting an enhanced CBD odds ratio for the HLA–DPB1\*1701 in humans (Weston *et al.*, 2005; Snyder *et al.*, 2008). Transgenic mice with the genes corresponding to the low and medium odds ratio study did not respond significantly over the control group. The authors concluded that while HLA–DPB1\*1701 is important to beryllium sensitization and progression to CBD, other genetic and environmental factors contribute to the disease process as well.

## 7. Preliminary Beryllium Sensitization and CBD Conclusions

It is well-established that skin and inhalation exposure to beryllium may lead to sensitization and that inhalation exposure, or skin exposure coupled with inhalation exposure, may lead to the onset and progression of CBD. This is supported by extensive human studies. While all facets of the biological mechanism for this complex disease have yet to be fully elucidated, many of the key events in the disease sequence have been identified and described in the previous sections. Sensitization is a necessary first step to the onset of CBD (NAS, 2008). Sensitization is the process by which the immune system recognizes beryllium as a foreign substance and responds in a manner that may lead to development of CBD. It has been documented that a substantial proportion of sensitized workers exposed to airborne beryllium progress to CBD (Rosenman *et al.*, 2005; NAS, 2008; Mroz *et al.*, 2009). Animal studies, particularly in dogs and monkeys, have provided supporting evidence for T-cell lymphocyte proliferation in the development of granulomatous lung lesions after exposure to beryllium (Harmsen *et al.*, 1986; Haley *et al.*, 1989, 1992, 1994). The animal studies have also provided important insights into the roles of chemical form, genetic susceptibility, and residual lung burden in the development of beryllium lung disease (Harmsen *et al.*, 1986; Haley *et al.*, 1992; Tarantino-Hutchison *et al.*, 2009). OSHA has made a preliminary determination to consider sensitization and CBD to be adverse events along the pathological continuum in the disease process, with sensitization being the necessary first step in the progression to CBD.

The epidemiological evidence presented in this section demonstrates that sensitization and CBD are continuing to occur from present-day exposures below OSHA's PEL (Rosenman, 2005 with erratum published 2006). The available literature discussed above shows that disease prevalence can be reduced by reducing inhalation exposure (Thomas *et al.*, 2009). However, the available epidemiological studies also indicate that it may be necessary to minimize skin exposure to further reduce the incidence of sensitization (Bailey *et al.*, 2010). The preliminary risk assessment further discusses the effectiveness of interventions to reduce beryllium exposures and the risk of sensitization and CBD (see section VI, Preliminary Risk Assessment).

Studies have demonstrated there remains a prevalence of sensitization and CBD in facilities with exposure levels below the current OSHA PEL (Rosenman *et al.*, 2005; Thomas *et al.*, 2009), that risk of sensitization and CBD appears to vary across industries and processes (Deubner *et al.*, 2001; Kreiss *et al.*, 1997; Newman *et al.*, 2001; Henneberger *et al.*, 2001; Schuler *et al.*, 2005; Stange *et al.*, 2001; Taiwo *et al.*, 2010), and that efforts to reduce exposure have succeeded in reducing the frequency of beryllium sensitization and CBD (Bailey *et al.*, 2010) (See Table A-1 in the Appendix).

Of workers who were found to be sensitized and underwent clinical evaluation, 20–49 percent were diagnosed with CBD (Kreiss *et al.*, 1993; Newman, 1996, 2005 and 2007; Stange *et al.*, 2001). Overall prevalence of CBD in cross-sectional screenings ranges from 0.6 to 8 percent (Kreiss *et al.*, 2007). A study by Newman (2005) estimated from ongoing surveillance of sensitized individuals, with an average follow-up time of 6 years, that 31 percent of beryllium-exposed employees progressed to CBD (Newman, 2005). However, Newman (2005) went on to suggest that if follow-up times were increased the rate of progression from sensitization to CBD could be much higher. A study of nuclear weapons facility employees enrolled in an ongoing medical surveillance program found that only about 20 percent of sensitized individuals employed less than five years eventually were diagnosed with CBD, while 40 percent of sensitized employees employed ten years or more developed CBD (Stange *et al.*, 2001) indicating length of exposure may play a role in further development of the disease. In addition, Mroz *et al.* (2009) conducted a longitudinal study of individuals clinically evaluated at National Jewish Health (between 1982 and 2002) who were identified as having sensitization and CBD through workforce medical surveillance. The authors identified 171 cases of CBD and 229 cases of sensitization; all individuals were identified through workplace screening using the BeLPT (Mroz *et al.*, 2009). Over the 20-year study period, 8.8 percent (*i.e.*, 22 cases out of 251 sensitized) of individuals with sensitization went on to develop CBD. The findings from this study indicated that on the average span of time from initial beryllium exposure to CBD diagnosis was 24 years (Mroz *et al.*, 2009).

### E. Beryllium Lung Cancer Section

Beryllium exposure has been associated with a variety of adverse

health effects including lung cancer. The potential for beryllium and its compounds to cause cancer has been previously assessed by various other agencies (EPA, ATSDR, NAS, NIEHS, and NIOSH) with each agency identifying beryllium as a potential carcinogen. In addition, the International Agency for Research on Cancer (IARC) did an extensive evaluation in 1993 and reevaluation in April 2009 (IARC, 2012). In brief, IARC determined beryllium and its compounds to be carcinogenic to humans (Group 1 category), while EPA considers beryllium to be a probable human carcinogen (EPA, 1998), and the National Toxicology Program (NTP) has determined beryllium and its compounds to be known carcinogens (NTP, 2014). OSHA has conducted an independent evaluation of the carcinogenic potential of beryllium and these compounds as well. The following is a summary of the studies used to support the Agency findings that beryllium and its compounds are human carcinogens.

#### 1. Genotoxicity Studies

Genotoxicity can be an important indicator for screening the potential of a material to induce cancer and an important mechanism leading to tumor formation and carcinogenesis. In a review conducted by the National Academy of Science, beryllium and its compounds have tested positively in nearly 50 percent of the genotoxicity studies conducted without exogenous metabolic activity. However, they were found to be non-genotoxic in most bacterial assays (NAS, 2008).

Gene mutations have been observed in mammalian cells cultured with beryllium chloride in a limited number of studies (EPA, 1998; ATSDR, 2002; Gordon and Bowser, 2003). Culturing mammalian cells with beryllium chloride, beryllium sulfate, or beryllium nitrate has resulted in clastogenic alterations. However, most studies have found that beryllium chloride, beryllium nitrate, beryllium sulfate, and beryllium oxide did not induce gene mutations in bacterial assays with or without metabolic activation. In the case of beryllium sulfate, all mutagenicity studies (Ames (Simmon, 1979; Dunkel *et al.*, 1984; Arlauskas *et al.*, 1985; Ashby *et al.*, 1990); *E. coli pol A* (Rosenkranz and Poirer, 1979); *E. coli WP2 uvr A* (Dunkel *et al.*, 1984) and *Saccharomyces cerevisiae* (Simmon, 1979)) were negative with the exception of results reported for *Bacillus subtilis rec* assay (Kada *et al.*, 1980; Kanematsu *et al.*, 1980; EPA, 1998). Beryllium sulfate did not induce unscheduled



DNA synthesis in primary rat hepatocytes and was not mutagenic when injected intraperitoneally in adult mice in a host-mediated assay using *Salmonella typhimurium* (Williams *et al.*, 1982).

Beryllium nitrate was negative in the Ames assay (Tso and Fung, 1981; Kuroda *et al.*, 1991) but positive in a *Bacillus subtilis rec* assay (Kuroda *et al.*, 1991). Beryllium chloride was negative in a variety of studies (Ames (Ogawa *et al.*, 1987; Kuroda *et al.*, 1991); *E. coli* WP2 uvr A (Rossman and Molina, 1984); and *Bacillus subtilis rec* assay (Nishioka, 1975)). In addition, beryllium chloride failed to induce SOS DNA repair in *E. coli* (Rossman *et al.*, 1984). However, positive results were reported for *Bacillus subtilis rec* assay using spores (Kuroda *et al.*, 1991), *E. coli* KMBL 3835; *lacI* gene (Zakour and Glickman, 1984), and *hprt* locus in Chinese hamster lung V79 cells (Miyaki *et al.*, 1979). Beryllium oxide was negative in the Ames assay and *Bacillus subtilis rec* assays (Kuroda *et al.*, 1991; EPA, 1998).

Gene mutations have been observed in mammalian cells (V79 and CHO) cultured with beryllium chloride (Miyaki *et al.*, 1979; Hsie *et al.*, 1979a, b), and culturing of mammalian cells with beryllium chloride (Vegni-Talluri and Guiggiani, 1967), and beryllium sulfate (Brooks *et al.*, 1989; Larramendy *et al.*, 1981) has resulted in clastogenic alterations—producing breakage or disrupting chromosomes (EPA, 1998). Beryllium chloride evaluated in a mouse model indicated increased DNA strand breaks and the formation of micronuclei in bone marrow (Attia *et al.*, 2013).

Data on the *in vivo* genotoxicity of beryllium are limited to a single study that found beryllium sulfate (1.4 and 2.3 g/kg, 50 percent and 80 percent of median lethal dose) administered by gavage did not induce micronuclei in the bone marrow of CBA mice. However, a marked depression of erythropoiesis (red blood cell production) was suggestive of bone marrow toxicity which was evident 24 hours after dosing. No mutations were seen in *p53* or *c-raf-1* and only weak mutations were detected in *K-ras* in lung carcinomas from F344/N rats given a single nose-only exposure to beryllium metal (Nickell-Brady *et al.*, 1994). The authors concluded that the mechanisms for the development of lung carcinomas from inhaled beryllium in the rat do not involve gene dysfunctions commonly associated with human non-small-cell lung cancer (EPA, 1998).

## 2. Human Epidemiological Studies

This section reviews in greater detail the studies used to support the mechanistic findings for beryllium-induced cancer. Table A.3 in the Appendix summarizes the important features and characteristics of each study.

### a. Beryllium Case Registry (BCR).

Two studies evaluated participants in the BCR (Infante *et al.*, 1980; Steenland and Ward, 1991). Infante *et al.* (1980) evaluated the mortality patterns of white male participants in the BCR diagnosed with non-neoplastic respiratory symptoms of beryllium disease. Of the 421 cases evaluated, 7 of the participants had died of lung cancer. Six of the deaths occurred more than 15 years after initial beryllium exposure. The duration of exposure for 5 of the 7 participants with lung cancer was less than 1 year, with the time since initial exposure ranging from 12 to 29 years. One of the participants was exposed for 4 years with a 26-year interval since the initial exposure. Exposure duration for one participant diagnosed with pulmonary fibrosis could not be determined; however, it had been 32 years since the initial exposure. Based on BCR records, the participants were classified as being in the acute respiratory group (*i.e.*, those diagnosed with acute respiratory illness at the time of entry in the registry) or the chronic respiratory group (*i.e.*, those diagnosed with pulmonary fibrosis or some other chronic lung condition at the time of entry into the BCR). The 7 participants with lung cancer were in the BCR because of diagnoses of acute respiratory illness. For only one of those individuals was initial beryllium exposure less than 15 years prior. Only 1 of the 6 (with greater than 15 years since initial exposure to beryllium) had been diagnosed with chronic respiratory disease. The study did not report exposure concentrations or smoking habits. The authors concluded that the results of this cohort agreed with previous animal studies and with epidemiological studies demonstrating an increased risk of lung cancer in workers exposed to beryllium.

Steenland and Ward (1991) extended the work of Infante *et al.* (1980) to include females and to include 13 additional years of follow-up. At the time of entry in the BCR, 93 percent of the women in the study, but only 50 percent of the men, had been diagnosed with CBD. In addition, 61 percent of the women had worked in the fluorescent tube industry and 50 percent of the men had worked in the basic manufacturing industry. A total of 22 males and 6

females died of lung cancer. Of the 28 total deaths from lung cancer, 17 had been exposed to beryllium for less than 4 years and 11 had been exposed for greater than 4 years. The study did not report exposure concentrations. Survey data collected in 1965 provided information on smoking habits for 223 cohort members (32 percent), on the basis of which the authors suggested that the rate of smoking among workers in the cohort may have been lower than U.S. rates. The authors concluded that there was evidence of increased risk of lung cancer in workers exposed to beryllium and diagnosed with beryllium disease.

### b. Beryllium Manufacturing and/or Processing Plants (Extraction, Fabrication, and Processing)

Several epidemiological cohort studies have reported excess lung cancer mortality among workers employed in U.S. beryllium production and processing plants during the 1930s to 1960s. The largest and most comprehensive study investigated the mortality experience of 9,225 workers employed in seven different beryllium processing plants over a 30-year period (Ward *et al.*, 1992). The workers at the two oldest facilities (*i.e.*, Lorain, OH, and Reading, PA) were found to have significant excess lung cancer mortality relative to the U.S. population. Of the seven plants in the study, these two plants were believed to have the highest exposure levels to beryllium. A different analysis of the lung cancer mortality in this cohort using various local reference populations and alternate adjustments for smoking generally found smaller, non-significant rates of excess mortality among the beryllium employees (Levy *et al.*, 2002). Both cohort studies are limited by a lack of job history and air monitoring data that would allow investigation of mortality trends with beryllium exposure. The majority of employees at the Lorain, OH, and Reading, PA, facilities were employed for a relatively short period of less than one year.

Bayliss *et al.* (1971) performed a nested cohort study of more than 7,000 former workers from the beryllium processing industry employed from 1942–1967. Information for the workers was collected from the personnel files of participating companies. Of the more than 7,000 employees, a cause of death was known for 753 male workers. The number of observed lung cancer deaths was 36 compared to 34.06 expected for a standardized mortality ratio (SMR) of 1.06. When evaluated by the number of years of employment, 24 of the 36 men were employed for less than 1 year in

the industry (SMR = 1.24), 8 were employed for 1 to 5 years (SMR 1.40), and 4 were employed for more than 5 years (SMR = 0.54). Half of the workers who died from lung cancer began employment in the beryllium production industry prior to 1947. When grouped by job classification, over two thirds of the workers with lung cancer were in production-related jobs while the rest were classified as office workers. The authors concluded that while the lung cancer mortality rates were the highest of all other mortality rates, the SMR for lung cancer was still within range of the expected based on death rates in the United States. The limitations of this study included the lack of information regarding exposure concentrations, smoking habits, and the age and race of the participants.

Mancuso (1970, 1979, 1980) and Mancuso and El-Attar (1969) performed a series of occupational cohort studies on a group of over 3,685 workers (primarily white males) employed in the beryllium manufacturing industry during 1937–1948.<sup>3</sup> The beryllium production facilities were located in Ohio and Pennsylvania and the records for the employees, including periods of employment, were obtained from the Social Security Administration. These studies did not include analyses of mortality by job title or exposure category. In addition, there were no exposure concentrations estimated or adjustments for smoking. The estimated duration of employment ranged from less than 1 year to greater than 5 years. In the most recent study (Mancuso, 1980), employees from the viscose rayon industry served as a comparison population. There was a significant excess of lung cancer deaths based on the total number of 80 observed lung cancer mortalities at the end of 1976 compared to an expected number of 57.06 based on the comparison population resulting in an SMR of 1.40 ( $p < 0.01$ ) (Mancuso, 1980). There was a statistically significant excess in lung cancer deaths for the shortest duration of employment ( $< 12$  months,  $p < 0.05$ ) and the longest duration of employment ( $\leq 49$  months,  $p < 0.01$ ). Based on the results of this study, the author concluded that the ability of beryllium to induce cancer in workers does not require continuous exposure and that it is reasonable to assume that the amount of exposure required to produce lung cancer can occur within a few months

of exposure regardless of the length of employment.

Wagoner *et al.* (1980) expanded the work of Mancuso (1970; 1979; 1980) using a cohort of 3,055 white males from the beryllium extraction, processing, and fabrication facility located in Reading, Pennsylvania. The men included in the study worked at the facility sometime between 1942 and 1968, and were followed through 1976. The study accounted for length of employment. Other factors accounted for included age, smoking history, and regional lung cancer mortality. Forty-seven members of the cohort died of lung cancer compared to an expected 34.29 based on U.S. white male lung cancer mortality rates ( $p < .05$ ). The results of this cohort showed an excess risk of lung cancer in beryllium-exposed workers at each duration of employment ( $< 5$  years and  $\geq 5$  years), with a statistically significant excess noted at  $< 5$  years durations of employment and a  $\geq 25$ -year interval since the beginning of employment ( $p < 0.05$ ). The study was criticized by several epidemiologists (MacMahon, 1978, 1979; Roth, 1983), by a CDC Review Committee appointed to evaluate the study, and by one of the study's coauthors (Bayliss, 1980) for inadequate discussion of possible alternative explanations of excess lung cancer in the cohort. The specific issues identified include the use of 1965–1967 U.S. white male lung cancer mortality rates to generate expected numbers of lung cancers in the period 1968–1975 and inadequate adjustment for smoking.

Ward *et al.* (1992) performed a retrospective mortality cohort study of 9,225 male workers employed at seven beryllium processing facilities, including the Ohio and Pennsylvania facilities studied by Mancuso and El-Attar (1969), Mancuso (1970; 1979; 1980), and Wagoner *et al.* (1980). The men were employed for no less than 2 days between January 1940 and December 1988. At the end of the study 61.1 percent of the cohort was known to be living and 35.1 percent was known to be deceased. The duration of employment ranged from 1 year or less to greater than 10 years with the largest percentage of the cohort (49.7 percent) employed for less than one year, followed by 1 to 5 years of employment (23.4 percent), greater than 10 years (19.1 percent), and 5 to 10 years (7.9 percent). Of the 3,240 deaths, 280 observed deaths were caused by lung cancer compared to 221.5 expected deaths, yielding a statistically significant SMR of 1.26 ( $p < 0.01$ ). Information on the smoking habits of 15.9 percent of the cohort members, obtained from a 1968 Public Health

Service survey conducted at four of the plants, was used to calculate a smoking-adjusted SMR of 1.12, which was not statistically significant. The number of deaths from lung cancer was also examined by decade of hire. The authors reported a relationship between earlier decades of hire and increased lung cancer risk.

The EPA Integrated Risk Information System (IRIS), IARC, and California EPA Office of Environmental Health Hazard Assessment (OEHHA) have all based their cancer assessment on the Ward *et al.* 1992 study, with supporting data concerning exposure concentrations from Eisenbud and Lisson (1983) and NIOSH (1972), who estimated that the lower-bound estimate of the median exposure concentration exceeded  $100 \mu\text{g}/\text{m}^3$  and found that concentrations in excess of  $1,000 \mu\text{g}/\text{m}^3$  were common. The IRIS cancer risk assessment recalculated expected lung cancers based on U.S. white male lung cancer rates (including the period 1968–1975) and used an alternative adjustment for smoking. In addition, one individual with lung cancer, who had not worked at the plant, was removed from the cohort. After these adjustments were made, an elevated rate of lung cancer was still observed in the overall cohort (46 cases vs. 41.9 expected cases). However, based on duration of employment or interval since beginning of employment, neither the total cohort nor any of the subgroups had a statistically significant excess in lung cancer (EPA, 1987). Based on their evaluation of this and other epidemiological studies, the EPA characterized the human carcinogenicity data then available as “limited” but “suggestive of a causal relationship between beryllium exposure and an increased risk of lung cancer” (IRIS database). This report includes quantitative estimates of risk that were derived using the information presented in Wagoner *et al.* (1980), the expected lung cancers recalculated by the EPA, and bounds on presumed exposure levels.

Levy *et al.* (2002) questioned the results of Ward *et al.* (1992) and performed a reanalysis of the Ward *et al.* data. The Levy *et al.* reanalysis differed from the Ward *et al.* analysis in the following significant ways. First, Levy *et al.* (2002) examined two alternative adjustments for smoking, which were based on (1) a different analysis of the American Cancer Society (ACS) data used by Ward *et al.* (1992) for their smoking adjustment, or (2) results from a smoking/lung cancer study of veterans (Levy and Marimont, 1998). Second, Levy *et al.* (2002) also examined the

<sup>3</sup> The third study (Mancuso *et al.*, 1979) restricted the cohort to workers employed between 1942 and 1948.

impact of computing different reference rates derived from information about the lung cancer rates in the cities in which most of the workers at two of the plants lived. Finally, Levy *et al.* (2002) considered a meta-analytical approach to combining the results across beryllium facilities. For all of the alternatives Levy *et al.* (2002) considered, except the meta-analysis, the facility-specific and combined SMRs derived were lower than those reported by Ward *et al.* (1992). Only the SMR for the Lorain, OH, facility remained statistically significantly elevated in some reanalyses. The SMR obtained when combining over the plants was not statistically significant in eight of the nine approaches they examined, leading Levy *et al.* (2002) to conclude that there was little evidence of statistically significant elevated SMRs in those plants.

One occupational nested case-control study evaluated lung cancer mortality in a cohort of 3,569 male workers employed at a beryllium alloy production plant in Reading, PA, from 1940 to 1969 and followed through 1992 (Sanderson *et al.*, 2001). There were a total of 142 known lung cancer cases and 710 controls. For each lung cancer death, 5 age- and race-matched controls were selected by incidence density sampling. Confounding effects of smoking were evaluated. Job history and historical air measurements at the plant were used to estimate job-specific beryllium exposures from the 1930s to 1990s. Calendar-time-specific beryllium exposure estimates were made for every job and used to estimate workers' cumulative, average, and maximum exposure. Because of the long period of time required for the onset of lung cancer, an "exposure lag" was employed to discount recent exposures less likely to contribute to the disease.

The cumulative, average, and maximum beryllium exposure concentration estimates for the 142 known lung cancer cases were  $46.06 \pm 9.3 \mu\text{g}/\text{m}^3\text{-days}$ ,  $22.8 \pm 3.4 \mu\text{g}/\text{m}^3$ , and  $32.4 \pm 13.8 \mu\text{g}/\text{m}^3$ , respectively. The lung cancer mortality rate was 1.22 (95 percent CI = 1.03 – 1.43). Exposure estimates were lagged by 10 and 20 years in order to account for exposures that did not contribute to lung cancer because they occurred after the induction of cancer. In the 10- and 20-year lagged exposures the geometric mean tenures and cumulative exposures of the lung cancer mortality cases were higher than the controls. In addition, the geometric mean and maximum exposures of the workers were significantly higher than controls when

the exposure estimates were lagged 10 and 20 years ( $p < 0.01$ ).

Results of a conditional logistic regression analysis indicated that there was an increased risk of lung cancer in workers with higher exposures when dose estimates were lagged by 10 and 20 years. There was also a lack of evidence that confounding factors such as smoking affected the results of the regression analysis. The authors noted that there was considerable uncertainty in the estimation of exposure in the 1940's and 1950's and the shape of the dose-response curve for lung cancer. Another analysis of the study data using a different statistical method did not find a significantly greater relative risk of lung cancer with increasing beryllium exposures (Levy *et al.*, 2007). The average beryllium air levels for the lung cancer cases were estimated to be an order of magnitude above the current 8-hour OSHA TWA PEL ( $2 \mu\text{g}/\text{m}^3$ ) and roughly two orders of magnitude higher than the typical air levels in workplaces where beryllium sensitization and pathological evidence of CBD have been observed. IARC evaluated this reanalysis in 2012 and found the study introduced a downward bias into risk estimates (IARC, 2012).

Schubauer-Berigan *et al.* reanalyzed data from the nested case-control study of 142 lung cancer cases in the Reading, PA, beryllium processing plant (Schubauer-Berigan *et al.*, 2008). This dataset was reanalyzed using conditional (stratified by case age) logistic regression. Independent adjustments were made for potential confounders of birth year and hire age. Average and cumulative exposures were analyzed using the values reported in the original study. The objective of the reanalysis was to correct for the known differences in smoking rates by birth year. In addition, the authors evaluated the effects of age at hire to determine differences observed by Sanderson *et al.* in 2001. The effect of birth cohort adjustment on lung cancer rates in beryllium-exposed workers was evaluated by adjusting in a multivariable model for indicator variables for the birth cohort quartiles.

Unadjusted analyses showed little evidence of lung cancer risk associated with beryllium occupational exposure using cumulative exposure until a 20-year lag was used. Adjusting for either birth cohort or hire age attenuated the risk for lung cancer associated with cumulative exposure. Using a 10- or 20-year lag in workers born after 1900 also showed little evidence of lung cancer risk, while those born prior to 1900 did show a slight elevation in risk. Unlagged and lagged analysis for average exposure

showed an increase in lung cancer risk associated with occupational exposure to beryllium. The finding was consistent for either workers adjusted or unadjusted for birth cohort or hire age. Using a 10-year lag for average exposure showed a significant effect by birth cohort.

The authors stated that the reanalysis indicated that differences in the hire ages among cases and controls, first noted by Deubner *et al.* (2001) and Levy *et al.* (2007), were primarily due to the fact that birth years were earlier among controls than among cases, resulting from much lower baseline risk of lung cancer for men born prior to 1900 (Schubauer-Berigan *et al.*, 2008). The authors went on to state that the reanalysis of the previous NIOSH case-control study suggested the relationship observed previously between cumulative beryllium exposure and lung cancer was greatly attenuated by birth cohort adjustment.

Hollins *et al.* (2009) re-examined the weight of evidence of beryllium as a lung carcinogen in a recent publication (Hollins *et al.*, 2009). Citing more than 50 relevant papers, the authors noted the methodological shortcomings examined above, including lack of well-characterized historical occupational exposures and inadequacy of the availability of smoking history for workers. They concluded that the increase in potential risk of lung cancer was observed among those exposed to very high levels of beryllium and that beryllium's carcinogenic potential in humans at these very high exposure levels were not relevant to today's industrial settings. IARC performed a similar re-evaluation in 2009 (IARC, 2012) and found that the weight of evidence for beryllium lung carcinogenicity, including the animal studies described below, still warranted a Group I classification, and that beryllium should be considered carcinogenic to humans.

Schubauer-Berigan *et al.* (2010) extended their analysis from a previous study estimating associations between mortality risk and beryllium exposure to include workers at 7 beryllium processing plants. The study (Schubauer-Berigan *et al.*, 2010) followed the mortality incidences of 9,199 workers from 1940 through 2005 at the 7 beryllium plants. JEMs were developed for three plants in the cohort: The Reading plant, the Hazleton plant, and the Elmore plant. The last is described in Couch *et al.* 2010. Including these JEMs substantially improved the evidence base for evaluating the carcinogenicity of beryllium and, and this change

represents more than an update of the beryllium cohort. Standardized mortality ratios (SMRs) were estimated based on US population comparisons for lung, nervous system and urinary tract cancers, chronic obstructive pulmonary disease (COPD), chronic kidney disease, and categories containing chronic beryllium disease (CBD) and cor pulmonale. Associations with maximum and cumulative exposure were calculated for a subset of the workers.

Overall mortality in the cohort compared with the US population was elevated for lung cancer (SMR 1.17; 95% CI 1.08 to 1.28), COPD (SMR 1.23; 95% CI 1.13 to 1.32), and the categories containing CBD (SMR 7.80; 95% CI 6.26 to 9.60) and cor pulmonale (SMR 1.17; 95% CI 1.08 to 1.26). Mortality rates for most diseases of interest increased with time-since-hire. For the category including CBD, rates were substantially elevated compared to the US population across all exposure groups. Workers whose maximum beryllium exposure was  $\geq 10 \mu\text{g}/\text{m}^3$  had higher rates of lung cancer, urinary tract cancer, COPD and the category containing cor pulmonale than workers with lower exposure. These studies showed strong associations for cumulative exposure (when short-term workers were excluded), maximum exposure or both. Significant positive trends with cumulative exposure were observed for nervous system cancers ( $p = 0.0006$ ) and, when short-term workers were excluded, lung cancer ( $p = 0.01$ ), urinary tract cancer ( $p = 0.003$ ) and COPD ( $p < 0.0001$ ).

The authors concluded the findings from this reanalysis reaffirmed that lung cancer and CBD are related to beryllium exposure. The authors went on to suggest that beryllium exposures may be associated with nervous system and urinary tract cancers and that cigarette smoking and other lung carcinogens were unlikely to explain the increased incidences in these cancers. The study corrected an error that was discovered in the indirect smoking adjustment initially conducted by Ward *et al.*, concluding that cigarette smoking rates did not differ between the cohort and the general U.S. population. No association was found between cigarette smoking and either cumulative or maximum beryllium exposure, making it very unlikely that smoking was a substantial confounder in this study (Schubauer-Berigan *et al.*, 2010).

### 3. Animal Cancer Studies

This section reviews the animal literature used to support the findings for beryllium-induced lung cancer. Lung

tumors have been induced via inhalation and intratracheal administration of beryllium to rats and monkeys, and osteosarcomas have been induced via intravenous and intramedullary (inside the bone) injection of beryllium in rabbits and possibly in mice. The chronic oral studies did not report increased incidences of tumors in rodents, but these were conducted at doses below the maximum tolerated dose (MTD) (EPA, 1998).

Early animal studies revealed that some beryllium compounds are carcinogenic when inhaled (ATSDR, 2002). Animal experiments have shown consistent increases in lung cancers in rats, mice and rabbits chronically exposed to beryllium and beryllium compounds by inhalation or intratracheal instillation. In addition to lung cancer, osteosarcomas have been produced in mice and rabbits exposed to various beryllium salts by intravenous injection or implantation into the bone (NTP, 1999).

In an inhalation study assessing the potential tumorigenicity of beryllium, Schepers *et al.* (1957) exposed 115 albino Sherman and Wistar rats (male and female) via inhalation to  $0.0357 \text{ mg beryllium}/\text{m}^3$  ( $1 \gamma \text{ beryllium}/\text{ft}^3$ )<sup>4</sup> as an aqueous aerosol of beryllium sulfate for 44 hours/week for 6 months, and observed the rats for 18 months after exposure. Three to four control rats were killed every two months for comparison purposes. Seventy-six lung neoplasms,<sup>5</sup> including adenomas, squamous-cell carcinomas, acinous adenocarcinomas, papillary adenocarcinomas, and alveolar-cell adenocarcinomas, were observed in 52 rats exposed to beryllium sulfate aerosol. Adenocarcinoma were the most numerous. Pulmonary metastases tended to localize in areas with foam cell clustering and granulomatosis. No neoplasia was observed in any of the control rats. The incidence of lung tumors in exposed rats is presented in the following Table 2:

TABLE 2—NEOPLASM ANALYSIS

Neoplasm	Number	Metastases
Adenoma .....	18	

<sup>4</sup> Schepers *et al.* (1957) reported concentrations in  $\gamma \text{ Be}/\text{ft}^3$ ; however,  $\gamma/\text{ft}^3$  is no longer a common unit. Therefore, the concentration was converted to  $\text{mg}/\text{m}^3$ .

<sup>5</sup> While a total of 89 tumors were observed or palpated at the time of autopsy in the  $\text{BeSO}_4$ -exposed animals, only 76 tumors are listed as histologically neoplastic. Only the new growths identified in single midcoronal sections of both lungs were recorded.

TABLE 2—NEOPLASM ANALYSIS—  
Continued

Neoplasm	Number	Metastases
Squamous carcinoma .....	5	1
Acinous adenocarcinoma .....	24	2
Papillary adenocarcinoma .....	11	1
Alveolar-cell adenocarcinoma .....	7	
Mucigenous tumor ..	7	1
Endothelioma .....	1	
Retesarcoma .....	3	3
Total .....	76	8

Schepers (1962) reviewed 38 existing beryllium studies that evaluated seven beryllium compounds and seven mammalian species. Beryllium sulfate, beryllium fluoride, beryllium phosphate, beryllium alloy ( $\text{BeZnMnSiO}_4$ ), and beryllium oxide were proven to be carcinogenic and have remarkable pleomorphic neoplasia proclivities. Ten varieties of tumors were observed, with adenocarcinoma being the most common variety.

In another study, Vorwald and Reeves (1959) exposed Sherman albino rats via the inhalation route to aerosols of  $0.006 \text{ mg beryllium}/\text{m}^3$  as beryllium oxide and  $0.0547 \text{ mg beryllium}/\text{m}^3$  as beryllium sulfate for 6 hours/day, 5 days/week for an unspecified duration. Lung tumors (single or multifocal) were observed in the animals sacrificed following 9 months of daily inhalation exposure. The histologic pattern of the cancer was primarily adenomatous; however, epidermoid and squamous cell cancers were also observed. Infiltrative, vascular, and lymphogenous extensions often developed with secondary metastatic growth in the tracheobronchial lymph nodes, the mediastinal connective tissue, the parietal pleura, and the diaphragm.

In the first of two articles, Reeves *et al.* (1967a) investigated the carcinogenic process in lungs resulting from chronic (up to 72 weeks) beryllium sulfate inhalation. One hundred fifty male and female Sprague Dawley C.D. strain rats were exposed to beryllium sulfate aerosol at a mean atmospheric concentration of  $34.25 \mu\text{g beryllium}/\text{m}^3$  (with an average particle diameter of  $0.12 \mu\text{m}$ ). Prior to initial exposure and again during the 67–68 and 75–76 weeks of life, the animals received prophylactic treatments of tetracycline-HCl to combat recurrent pulmonary infections.

The animals entered the exposure chamber at 6 weeks of age and were

exposed 7 hours per day/5 days per week for up to 2,400 hours of total exposure time. An equal number of unexposed controls were held in a separate chamber. Three male and three female rats were sacrificed monthly during the 72-week exposure period. Mortality due to respiratory or other infections did not appear until 55 weeks of age, and 87 percent of all animals survived until their scheduled sacrifices.

Average lung weight towards the end of exposure was 4.25 times normal with progressively increasing differences between control and exposed animals. The increase in lung weight was accompanied by notable changes in tissue texture with two distinct pathological processes—inflammatory and proliferative. The inflammatory response was characterized by marked accumulation of histiocytic elements forming clusters of macrophages in the alveolar spaces. The proliferative response progressed from early epithelial hyperplasia of the alveolar surfaces, through metaplasia (after 20–22 weeks of exposure), anaplasia (cellular dedifferentiation) (after 32–40 weeks of exposure), and finally to lung tumors.

Although the initial proliferative response occurred early in the exposure period, tumor development required considerable time. Tumors were first identified after nine months of beryllium sulfate exposure, with rapidly increasing rates of incidence until tumors were observed in 100 percent of exposed animals by 13 months. The 9- to-13-month interval is consistent with earlier studies. The tumors showed a high degree of local invasiveness. No tumors were observed in control rats. All 56 tumors studied appeared to be alveolar adenocarcinomas and 3 “fast-

growing” tumors that reached a very large size comparatively early. About one-third of the tumors showed small foci where the histologic pattern differed. Most of the early tumor foci appeared to be alveolar rather than bronchiolar, which is consistent with the expected pathogenesis, since permanent deposition of beryllium was more likely on the alveolar epithelium rather than on the bronchiolar epithelium. Female rats appeared to have an increased susceptibility to beryllium exposure. Not only did they have a higher mortality (control males [n = 8], exposed males [n = 9] versus control females [n = 4], exposed females [n = 17]) and body weight loss than male rats, but the three “fast-growing” tumors only occurred in females.

In the second article, Reeves *et al.* (1967b) described the rate of accumulation and clearance of beryllium sulfate aerosol from the same experiment (Reeves *et al.*, 1967a). At the time of the monthly sacrifice, beryllium assays were performed on the lungs, tracheobronchial lymph nodes, and blood of the exposed rats. The pulmonary beryllium levels of rats showed a rate of accumulation which decreased during continuing exposure and reached a plateau (defined as equilibrium between deposition and clearance) of about 13.5 µg beryllium for males and 9 µg beryllium for females in whole lungs after approximately 36 weeks. Females were notably less efficient than males in utilizing the lymphatic route as a method of clearance, resulting in slower removal of pulmonary beryllium deposits, lower accumulation of the inhaled material in the tracheobronchial lymph nodes, and higher morbidity and mortality.

There was no apparent correlation between the extent and severity of

pulmonary pathology and total lung load. However, when the beryllium content of the excised tumors was compared with that of surrounding nonmalignant pulmonary tissues, the former showed a notable decrease (0.50 ± 0.35 µg beryllium/gram versus 1.50 ± 0.55 µg beryllium/gram). This was believed to be largely a result of the dilution factor operating in the rapidly growing tumor tissue. However, other factors, such as lack of continued local deposition due to impaired respiratory function and enhanced clearance due to high vascularity of the tumor, may also have played a role. The portion of inhaled beryllium retained in the lungs for a longer duration, which is in the range of one-half of the original pulmonary load, may have significance for pulmonary carcinogenesis. This pulmonary beryllium burden becomes localized in the cell nuclei and may be an important factor in eliciting the carcinogenic response associated with beryllium inhalation.

Groth *et al.* (1980) conducted a series of experiments to assess the carcinogenic effects of beryllium, beryllium hydroxide, and various beryllium alloys. For the beryllium metal/alloys experiment, 12 groups of 3-month-old female Wistar rats (35 rats/group) were used. All rats in each group received a single intratracheal injection of either 2.5 or 0.5 mg of one of the beryllium metals or beryllium alloys as described in Table 3 below. These materials were suspended in 0.4 cc of isotonic saline followed by 0.2 cc of saline. Forty control rats were injected with 0.6 cc of saline. The geometric mean particle sizes varied from 1 to 2 µm. Rats were sacrificed and autopsied at various intervals ranging from 1 to 18 months post-injection.

TABLE 3—SUMMARY OF BERYLLIUM DOSE FROM GROTH ET AL. (1980)

Form of Be	Percent Be	Percent other compounds	Total No. rats autopsied	Compound dose (mg)	Be dose (mg)
Be metal	100	None	16	2.5	2.5
Passivated Be metal	99	0.26% Chromium	21	0.5	0.5
			26	2.5	2.5
			20	0.5	0.5
BeAl alloy	62	38% Aluminum	24	2.5	1.55
			21	0.5	0.3
BeCu alloy	4	96% Copper	28	2.5	0.1
			24	0.5	0.02
BeCuCo alloy	2.4	0.4% Cobalt	33	2.5	0.06
		96% Copper	30	0.5	0.012
BeNi alloy	2.2	97.8% Nickel	28	2.5	0.056
			27	0.5	0.011

Lung tumors were observed only in rats exposed to beryllium metal,

passivated beryllium metal, and beryllium-aluminum alloy. Passivation

refers to the process of removing iron contamination from the surface of

beryllium metal. As discussed, metal alloys may have a different toxicity than beryllium alone. Rats exposed to 100 percent beryllium exhibited relatively high mortality rates, especially in the groups where lung tumors were observed. Nodules varying from 1 to 10 mm in diameter were also observed in the lungs of rats exposed to beryllium metal, passivated beryllium metal, and beryllium-aluminum alloy. These nodules were suspected of being malignant.

To test this hypothesis, transplantation experiments involving the suspicious nodules were conducted in nine rats. Seven of the nine suspected tumors grew upon transplantation. All transplanted tumor types metastasized to the lungs of their hosts. Lung tumors were observed in rats injected with both the high and low doses of beryllium metal, passivated beryllium metal, and beryllium-aluminum alloy. No lung tumors were observed in rats injected with the other compounds. From a total of 32 lung tumors detected, most were adenocarcinomas and adenomas; however, two epidermoid carcinomas and at least one poorly differentiated carcinoma were observed. Bronchiolar alveolar cell tumors were frequently observed in rats injected with beryllium metal, passivated beryllium metal, and

beryllium-aluminum alloy. All stages of cuboidal, columnar, and squamous cell metaplasia were observed on the alveolar walls in the lungs of rats injected with beryllium metal, passivated beryllium metal, and beryllium-aluminum alloy. These lesions were generally reduced in size and number or absent from the lungs of animals injected with the other alloys (BeCu, BeCuCo, BeNi).

The extent of alveolar metaplasia could be correlated with the incidence of lung cancer. The incidences of lung tumors in the rats that received 2.5 mg of beryllium metal, and 2.5 and 0.5 mg of passivated beryllium metal, were significantly different ( $p \leq 0.008$ ) from controls. When autopsies were performed at the 16-to-19-month interval, the incidence (2/6) of lung tumors in rats exposed to 2.5 mg of beryllium-aluminum alloy was statistically significant ( $p = 0.004$ ) when compared to the lung tumor incidence (0/84) in rats exposed to BeCu, BeNi, and BeCuCo alloys, which contained much lower concentrations of Be (Groth *et al.*, 1980).

Finch *et al.* (1998b) investigated the carcinogenic effects of inhaled beryllium on heterozygous TSG-p53 knockout mice ( $p53^{+/-}$ ) and wild-type ( $p53^{+/+}$ ) mice. Knockout mice can be

valuable tools in determining the role of specific genes on the toxicity of a material of interest, in this case, beryllium. Equal numbers of approximately 10-week-old male and female mice were used for this study. Two exposure groups were used to provide dose-response information on lung carcinogenicity. The maximum initial lung burden (ILB) target of 60  $\mu\text{g}$  beryllium was based on previous acute inhalation exposure studies in mice. The lower exposure target level of 15  $\mu\text{g}$  was selected to provide a lung burden significantly less than the high-level group, but high enough to yield carcinogenic responses. Mice were exposed in groups to beryllium metal or to filtered air (controls) via nose-only inhalation. The specific exposure parameters are presented in Table 4 below. Mice were sacrificed 7 days post exposure for ILB analysis, and either at 6 months post exposure ( $n = 4-5$  mice per group per gender) or when 10 percent or less of the original population remained (19 months post exposure for  $p53^{+/-}$  knockout and 22.5 months post exposure for  $p53^{+/+}$  wild-type mice). The sacrifice time was extended in the study because a significant number of lung tumors were not observed at 6 months post exposure.

TABLE 4—SUMMARY OF ANIMAL DATA FROM FINCH ET AL., 1998 b

Mouse strain	Mean exposure concentration ( $\mu\text{g}$ Be/L)	Target be lung burden ( $\mu\text{g}$ )	Number of mice	Mean daily exposure duration (minutes)	Mean ILB ( $\mu\text{g}$ )	Number of mice with 1 or more lung tumors/total number examined
Knockout ( $p53^{+/-}$ )	34	15	30	112 (single)	NA	0/29
	36	60	30	139‡	NA	4/28
Wild-type ( $p53^{+/+}$ )	34	15	6*	112 (single)	12 $\pm$ 4	NA
	36	60	36†	139‡	54 $\pm$ 6	0/28
Knockout ( $p53^{+/-}$ )	NA (air)	Control	30	60–180 (single)	NA	0/30

ILB = initial lung burden; NA = not applicable

Median aerodynamic diameter of Be aerosol = 1.4  $\mu\text{m}$  ( $\sigma_g = 1.8$ )

\* Wild-type mice in the low exposure group were not evaluated for carcinogenic effects; however ILB was analyzed in six wild-type mice.

† Thirty wild-type mice were analyzed for carcinogenic effects; six wild-type mice were analyzed for ILB.

‡ Mice were exposed for 2.3 hours/day for three consecutive days.

Lung burdens of beryllium measured in wild-type mice at 7 days post exposure were approximately 70–90 percent of target levels. No exposure-related effects on body weight were observed in mice; however, lung weights and lung-to-body-weight ratios were somewhat elevated in 60  $\mu\text{g}$  target ILB  $p53^{+/-}$  knockout mice compared to controls ( $0.05 < p < 0.10$ ). In general,  $p53^{+/+}$  wild-type mice survived longer than  $p53^{+/-}$  knockout mice and beryllium exposure tended to decrease survival time in both groups. The incidence of beryllium-induced lung tumors was marginally higher in the 60

$\mu\text{g}$  target ILB  $p53^{+/-}$  knockout mice compared to 60  $\mu\text{g}$  target ILB  $p53^{+/+}$  wild-type mice ( $p = 0.056$ ). The incidence of lung tumors in the 60  $\mu\text{g}$  target ILB  $p53^{+/-}$  knockout mice was also significantly higher than controls ( $p = 0.048$ ). No tumors developed in the control mice, 15  $\mu\text{g}$  target ILB  $p53^{+/-}$  knockout mice, or 60  $\mu\text{g}$  target ILB  $p53^{+/+}$  wild-type mice throughout the length of the study. Most lung tumors in beryllium-exposed mice were squamous cell carcinomas, three of four of which were poorly circumscribed and all were associated with at least some degree of granulomatous pneumonia. The study

results suggest that having an inactivated  $p53$  allele is associated with lung tumor progression in  $p53^{+/-}$  knockout mice. This is based on the significant difference seen in the incidence of beryllium-induced lung neoplasms for the  $p53^{+/-}$  knockout mice compared with the  $p53^{+/+}$  wild-type mice. The authors conclude that since there was a relatively late onset of tumors in the beryllium-exposed  $p53^{+/-}$  knockout mice, a 6-month bioassay in this mouse strain might not be an appropriate model for lung carcinogenesis (Finch *et al.*, 1998b).

Nickell-Brady *et al.* (1994) investigated the development of lung tumors in 12-week-old F344/N rats after a single nose-only inhalation exposure to beryllium aerosol, and evaluated whether beryllium lung tumor induction involves alterations in the *K-ras*, *p53*, and *c-raf-1* genes. Four groups of rats (30 males and 30 females per group) were exposed to different mass concentrations of beryllium (Group 1: 500 mg/m<sup>3</sup> for 8 min; Group 2: 410 mg/m<sup>3</sup> for 30 min; Group 3: 830 mg/m<sup>3</sup> for 48 min; Group 4: 980 mg/m<sup>3</sup> for 39 min). The beryllium mass median aerodynamic diameter was 1.4 μm ( $\sigma_g = 1.9$ ). The mean beryllium lung burdens for each exposure group were 40, 110, 360, and 430 μg, respectively.

To examine genetic alterations, DNA isolation and sequencing techniques (PCR amplification and direct DNA sequence analysis) were performed on wild-type rat lung tissue (*i.e.*, control samples) along with two mouse lung tumor cell lines containing known *K-ras* mutations, 12 carcinomas induced by beryllium (*i.e.*, experimental samples), and 12 other formalin-fixed specimens. Tumors appeared in beryllium-exposed rats by 14 months, and 64 percent of exposed rats developed lung tumors during their lifetime. Lungs frequently contained multiple tumor sites, with some of the tumors greater than 1 cm. A total of 24 tumors were observed. Most of the tumors ( $n = 22$ ) were adenocarcinomas exhibiting a papillary pattern characterized by cuboidal or columnar cells, although a few had a tubular or solid pattern. Fewer than 10 percent of the tumors were adenosquamous ( $n = 1$ ) or squamous cell ( $n = 1$ ) carcinomas.

No transforming mutations of the *K-ras* gene (codons 12, 13, or 61) were detected by direct sequence analysis in any of the lung tumors induced by beryllium. However, using a more sensitive sequencing technique (PCR enrichment restriction fragment length polymorphism (RFLP) analysis) resulted in the detection of *K-ras* codon 12 GGT to GTT transversions in 2 of 12 beryllium-induced adenocarcinomas. No *p53* and *c-raf-1* alterations were observed in any of the tumors induced by beryllium exposure (*i.e.*, no differences observed between beryllium-exposed and control rat tissues). The authors note that the results suggest that activation of the *K-ras* proto-oncogene is both a rare and late event, possibly caused by genomic instability during the progression of beryllium-induced rat pulmonary adenocarcinomas. It is unlikely that the *K-ras* gene plays a role in the carcinogenicity of beryllium. The results also indicate that *p53* mutation

is unlikely to play a role in tumor development in rats exposed to beryllium.

Belinsky *et al.* (1997) reviewed the findings by Nickell-Brady *et al.* (1994) to further examine the role of the *K-ras* and *p53* genes in lung tumors induced in the F344 rat by non-mutagenic (non-genotoxic) exposures to beryllium. Their findings are discussed along with the results of other genomic studies that look at carcinogenic agents that are either similarly non-mutagenic or, in other cases, mutagenic. The authors conclude that the identification of non-*ras* transforming genes in rat lung tumors induced by non-mutagenic exposures, such as beryllium, as well as mutagenic exposures will help define some of the mechanisms underlying cancer induction by different types of DNA damage.

The inactivation of the *p16<sup>INK4a</sup>* (*p16*) gene is a contributing factor in disrupting control of the normal cell cycle and may be an important mechanism of action in beryllium-induced lung tumors. Swafford *et al.* (1997) investigated the aberrant methylation and subsequent inactivation of the *p16* gene in primary lung tumors induced in F344/N rats exposed to known carcinogens via inhalation. The research involved a total of 18 primary lung tumors that developed after exposing rats to five agents, one of which was beryllium. In this study, only one of the 18 lung tumors was induced by beryllium exposure; the majority of the other tumors were induced by radiation (x-rays or plutonium-239 oxide). The authors hypothesized that if *p16* inactivation plays a central role in development of non-small-cell lung cancer, then the frequency of gene inactivation in primary tumors should parallel that observed in the corresponding cell lines. To test the hypothesis, a rat model for lung cancer was used to determine the frequency and mechanism for inactivation of *p16* in matched primary lung tumors and derived cell lines. The methylation-specific PCR (MSP) method was used to detect methylation of *p16* alleles. The results showed that the presence of aberrant *p16* methylation in cell lines was strongly correlated with absent or low expression of the gene. The findings also demonstrated that aberrant *p16* CpG island methylation, an important mechanism in gene silencing leading to the loss of *p16* expression, originates in primary tumors.

Building on the rat model for lung cancer and associated findings from Swafford *et al.* (1997), Belinsky *et al.* (2002) conducted experiments in 12-

week-old F344/N rats (male and female) to determine whether beryllium-induced lung tumors involve inactivation of the *p16* gene and estrogen receptor  $\alpha$  (ER) gene. Rats received a single nose-only inhalation exposure to beryllium aerosol at four different exposure levels. The mean lung burdens measured in each exposure group were 40, 110, 360, and 430 μg. The methylation status of the *p16* and ER genes was determined by MSP. A total of 20 tumors detected in beryllium-exposed rats were available for analysis of gene-specific promoter methylation. Three tumors were classified as squamous cell carcinomas and the others were determined to be adenocarcinomas. Methylated *p16* was present in 80 percent (16/20), and methylated ER was present in one-half (10/20), of the lung tumors induced by exposure to beryllium. Additionally, both genes were methylated in 40 percent of the tumors. The authors noted that four tumors from beryllium-exposed rats appeared to be partially methylated at the *p16* locus. Bisulfite sequencing of exon 1 of the ER gene was conducted on normal lung DNA and DNA from three methylated, beryllium-induced tumors to determine the density of methylation within amplified regions of exon 1 (referred to as CpG sites). Two of the three methylated, beryllium-induced lung tumors showed extensive methylation, with more than 80 percent of all CpG sites methylated.

The overall findings of this study suggest that inactivation of the *p16* and ER genes by promoter hypermethylation are likely to contribute to the development of lung tumors in beryllium-exposed rats. The results showed a correlation between changes in *p16* methylation and loss of gene transcription. The authors hypothesize that the mechanism of action for beryllium-induced *p16* gene inactivation in lung tumors may be inflammatory mediators that result in oxidative stress. The oxidative stress damages DNA directly through free radicals or indirectly through the formation of 8-hydroxyguanosine DNA adducts, resulting primarily in a single-strand DNA break.

Wagner *et al.* (1969) studied the development of pulmonary tumors after intermittent daily chronic inhalation exposure to beryllium ores in three groups of male squirrel monkeys. One group was exposed to bertrandite ore, a second to beryl ore, and the third served as unexposed controls. Each of these three exposure groups contained 12 monkeys. Monkeys from each group were sacrificed after 6, 12, or 23 months of exposure. The 12-month sacrificed

monkeys (n = 4 for bertrandite and control groups; n = 2 for beryl group) were replaced by a separate replacement group to maintain a total animal population approximating the original numbers and to provide a source of confirming data for biologic responses that might arise following the ore exposures. Animals were exposed to bertrandite and beryl ore concentrations of 15 mg/m<sup>3</sup>, corresponding to 210 µg beryllium/m<sup>3</sup> and 620 µg beryllium/m<sup>3</sup> in each exposure chamber, respectively. The parent ores were reduced to particles with geometric mean diameters of 0.27 µm (± 2.4) for bertrandite and 0.64 µm (± 2.5) for beryl. Animals were exposed for approximately 6 hours/day, 5 days/week. The histological changes in the lungs of monkeys exposed to bertrandite and beryl ore exhibited a similar pattern. The changes generally consisted of aggregates of dust-laden macrophages, lymphocytes, and plasma cells near respiratory bronchioles and small blood vessels. There were, however, no consistent or significant pulmonary lesions or tumors observed in monkeys exposed to either of the beryllium ores. This is in contrast to the findings in rats exposed to beryl ore and to a lesser extent bertrandite, where atypical cell proliferation and tumors were frequently observed in the lungs. The authors hypothesized that the rats' greater susceptibility may be attributed to the spontaneous lung disease characteristic of rats, which might have interfered with lung clearance.

As previously described, Conradi *et al.* (1971) investigated changes in the lungs of monkeys and dogs two years after intermittent inhalation exposure to beryllium oxide calcined at 1,400 °C. Five adult male and female monkeys (*Macaca irus*) weighing between 3 and 5.75 kg were used in the study. The study included two control monkeys. Beryllium concentrations in the atmosphere of whole-body exposed monkeys varied between 3.30 and 4.38 mg/m<sup>3</sup>. Thirty-minute exposures occurred once a month for three months, with beryllium oxide concentrations increasing at each exposure interval. Lung tissue was investigated using electron microscopy and morphometric methods. Beryllium content in portions of the lungs of five monkeys was measured two years following exposure by emission spectrography. The reported concentrations in monkeys (82.5, 143.0, and 112.7 µg beryllium per 100 gm of wet tissue in the upper lobe, lower lobe, and combined lobes, respectively) were higher than those in dogs. No neoplastic or granulomatous lesions were observed

in the lungs of any exposed animals and there was no evidence of chronic proliferative lung changes after two years.

#### 4. In vitro Studies

The exact mechanism by which beryllium induces pulmonary neoplasms in animals remains unknown (NAS 2008). Keshava *et al.* (2001) performed studies to determine the carcinogenic potential of beryllium sulfate in cultured mammalian cells. Joseph *et al.* (2001) investigated differential gene expression to understand the possible mechanisms of beryllium-induced cell transformation and tumorigenesis. Both investigations used cell transformation assays to study the cellular/molecular mechanisms of beryllium carcinogenesis and assess carcinogenicity. Cell lines were derived from tumors developed in nude mice injected subcutaneously with non-transformed BALB/c-3T3 cells that were morphologically transformed *in vitro* with 50–200 µg beryllium sulfate/ml for 72 hours. The non-transformed cells were used as controls.

Keshava *et al.* (2001) found that beryllium sulfate is capable of inducing morphological cell transformation in mammalian cells and that transformed cells are potentially tumorigenic. A dose-dependent increase (9–41 fold) in transformation frequency was noted. Using differential polymerase chain reaction (PCR), gene amplification was investigated in six proto-oncogenes (*K-ras*, *c-myc*, *c-fos*, *c-jun*, *c-sis*, *erb-B2*) and one tumor suppressor gene (*p53*). Gene amplification was found in *c-jun* and *K-ras*. None of the other genes tested showed amplification. Additionally, Western blot analysis showed no change in gene expression or protein level in any of the genes examined. Genomic instability in both the non-transformed and transformed cell lines was evaluated using random amplified polymorphic DNA fingerprinting (RAPD analysis). Using different primers, 5 of the 10 transformed cell lines showed genomic instability when compared to the non-transformed BALB/c-3T3 cells. The results indicate that beryllium sulfate-induced cell transformation might, in part, involve gene amplification of *K-ras* and *c-jun* and that some transformed cells possess neoplastic potential resulting from genomic instability.

Using the Atlas mouse 1.2 cDNA expression microarrays, Joseph *et al.* (2001) studied the expression profiles of 1,176 genes belonging to several different functional categories. Compared to the control cells, expression of 18 genes belonging to two

functional groups (nine cancer-related genes and nine DNA synthesis, repair, and recombination genes) was found to be consistently and reproducibly different (at least 2-fold) in the tumor cells. Differential gene expression profile was confirmed using reverse transcription-PCR with primers specific to the differentially expressed genes. Two of the differentially expressed genes (*c-fos* and *c-jun*) were used as model genes to demonstrate that the beryllium-induced transcriptional activation of these genes was dependent on pathways of protein kinase C and mitogen-activated protein kinase and independent of reactive oxygen species in the control cells. These results indicate that beryllium-induced cell transformation and tumorigenesis are associated with up-regulated expression of the cancer-related genes (such as *c-fos*, *c-jun*, *c-myc*, and *R-ras*) and down-regulated expression of genes involved in DNA synthesis, repair, and recombination (such as *MCM4*, *MCM5*, *PMS2*, *Rad23*, and *DNA ligase I*).

#### 5. Preliminary Lung Cancer Conclusions

OSHA has preliminarily determined that the weight of evidence indicates that beryllium compounds should be regarded as potential occupational lung carcinogens. Other scientific organizations, including the International Agency for Research on Cancer (IARC), the National Toxicology Program (NTP), the U.S. Environmental Protection Agency (EPA), the National Institute for Occupational Safety and Health (NIOSH), and the American Conference of Governmental Industrial Hygienists (ACGIH) have reached similar conclusions with respect to the carcinogenicity of beryllium.

While some evidence exists for direct-acting genotoxicity as a possible mechanism for beryllium carcinogenesis, the weight of evidence suggests a possible indirect mechanism may be responsible for most tumorigenic activity of beryllium in animal models and possibly humans (EPA, 1998). Inflammation has been postulated to be a key contributor to many different forms of cancer (Jackson *et al.*, 2006; Pikarsky *et al.*, 2004; Greten *et al.*, 2004; Leek, 2002). In fact, chronic inflammation may be a primary factor in the development of up to one-third of all cancers (Ames *et al.*, 1990; NCI, 2010).

In addition to a T-cell mediated response beryllium has been demonstrated to produce an inflammatory response in animal models similar to other particles (Reeves *et al.*, 1967; Swafford *et al.*, 1997; Wagner *et al.*, 1969) possibly



contributing to its carcinogenic potential. Animal studies, as summarized above, have demonstrated a consistent scenario of beryllium exposure resulting in chronic pulmonary inflammation. Studies conducted in rats have demonstrated that chronic inhalation of materials similar in solubility to beryllium result in increased pulmonary inflammation, fibrosis, epithelial hyperplasia, and, in some cases, pulmonary adenomas and carcinomas (Heinrich *et al.*, 1995; Nikula *et al.*, 1995; NTP, 1993; Lee *et al.*, 1985; Warheit *et al.*, 1996). This response is generally referred to as an "overload" response or threshold effect. Substantial data indicate that tumor formation in the rat after exposure to some sparingly soluble particles at doses causing marked, chronic inflammation is due to a secondary mechanism unrelated to the genotoxicity (or lack thereof) of the particle itself.

It has been hypothesized that the recruitment of neutrophils during the inflammatory response and subsequent release of oxidants from these cells have been demonstrated to play an important role in the pathogenesis of rat lung tumors (Borm *et al.*, 2004; Carter and Driscoll, 2001; Carter *et al.*, 2006; Johnston *et al.*, 2000; Knaapen *et al.*, 2004; Mossman, 2000). Inflammatory mediators, as characterized in many of the studies summarized above, have been shown to play a significant role in the recruitment of cells responsible for the release of reactive oxygen and hydrogen species. These species have been determined to be highly mutagenic themselves as well as mitogenic, inducing a proliferative response (Feriola and Nettesheim, 1994; Jetten *et al.*, 1990; Moss *et al.*, 1994; Coussens and Werb, 2002). The resultant effect is an environment rich for neoplastic transformations and the progression of fibrosis and tumor formation. This finding does not imply no risk at levels below an inflammatory response; rather, the overall weight of evidence is suggestive of a mechanism of an indirect carcinogen at levels where inflammation is seen. While tumorigenesis secondary to inflammation is one reasonable mode of action, other plausible modes of action independent of inflammation (*e.g.*, epigenetic, mitogenic, reactive oxygen mediated, indirect genotoxicity, etc.) may also contribute to the lung cancer associated with beryllium exposure.

Epidemiological studies indicate excess risk of lung cancer mortality from occupational beryllium exposure levels at or below the current OSHA PEL

(Schubauer-Berigan *et al.*, 2010; Table 4).

#### F. Other Health Effects

Past studies on other health effects have been thoroughly reviewed by several scientific organizations (NTP, 1999; EPA, 1998; ATSDR, 2002; WHO, 2001; HSDB, 2010). These studies include summaries of animal studies, *in vitro* studies, and human epidemiological studies associated with cardiovascular, hematological, hepatic, renal, endocrine, reproductive, ocular and mucosal, and developmental effects. High-dose exposures to beryllium have been shown to have an adverse effect upon a variety of organs and tissues in the body, particularly the liver. The adverse systemic effects from human exposures mostly occurred prior to the introduction of occupational and environmental standards set in 1970–1972 (OSHA, 1971; ACGIH, 1971; ANSI, 1970) and 1974 (EPA, 1974) and therefore are less relevant today than in the past. The available data is fairly limited. The hepatic, cardiovascular, renal, and ocular and mucosal effects are briefly summarized below. Health effects in other organ systems listed above were only observed in animal studies at very high exposure levels and are, therefore, not discussed here.

##### 1. Hepatic Effects

Beryllium has been shown to accumulate in the liver and a correlation has been demonstrated between beryllium content and hepatic damage. Different compounds have been shown to distribute differently within the hepatic tissues. For example, beryllium phosphate had accumulated almost exclusively within sinusoidal (Kupffer) cells of the liver, while the beryllium derived from beryllium sulfate was found mainly in parenchymal cells. Conversely, beryllium sulphosalicylic acid complexes were rapidly excreted (Skillteter and Paine, 1979).

According to a few autopsies, beryllium-laden liver had central necrosis, mild focal necrosis as well as congestion, and occasionally beryllium granuloma.

Residents near a beryllium plant may have been exposed by inhaling trace amounts of beryllium powder, and different beryllium compounds may have induced different toxicant reactions (Yian and Yin, 1982).

##### 2. Cardiovascular Effects

There is very limited evidence of cardiovascular effects of beryllium and its compounds in humans. Severe cases of chronic beryllium disease can result in cor pulmonale, which is hypertrophy

of the right heart ventricle. In a case history study of 17 individuals exposed to beryllium in a plant that manufactured fluorescent lamps, autopsies revealed right atrial and ventricular hypertrophy (Hardy and Tabershaw, 1946). It is not likely that these cardiac effects were due to direct toxicity to the heart, but rather were a response to impaired lung function. However, an increase in deaths due to heart disease or ischemic heart disease was found in workers at a beryllium manufacturing facility (Ward *et al.*, 1992).

Animal studies performed in monkeys indicate heart enlargement after acute inhalation exposure to 13 mg beryllium/m<sup>3</sup> as beryllium hydrogen phosphate, 0.184 mg beryllium/m<sup>3</sup> as beryllium fluoride, or 0.198 mg beryllium/m<sup>3</sup> as beryllium sulfate (Schepers 1964). Decreased arterial oxygen tension was observed in dogs exposed to 30 mg beryllium/m<sup>3</sup> as beryllium oxide for 15 days (HSDB, 2010), 3.6 mg beryllium/m<sup>3</sup> as beryllium oxide for 40 days (Hall *et al.*, 1950), or 0.04 mg beryllium/m<sup>3</sup> as beryllium sulfate for 100 days (Stokinger *et al.*, 1950). These are expected to be indirect effects on the heart due to pulmonary fibrosis and toxicity which can increase arterial pressure and restrict blood flow.

##### 3. Renal Effects

Renal calculi (stones) were unusually prevalent in severe cases that resulted from high levels of beryllium exposure. Renal stones containing beryllium occurred in about 10 percent of patients affected by high exposures (Barnett, *et al.*, 1961). Kidney stones were observed in 10 percent of the CBD cases collected by the BCR up to 1959 (Hall *et al.*, 1959). In addition, an excess of calcium in the blood and urine has been seen frequently in patients with chronic beryllium disease (ATSDR, 2002).

##### 4. Ocular and Mucosal Effects

Both the soluble, sparingly soluble, and insoluble beryllium compounds have been shown to cause ocular irritation in humans (Van Orstrand *et al.*, 1945; De Nardi *et al.*, 1953; Nishimura, 1966; Epstein, 1990; NIOSH, 1994). In addition, beryllium compounds (soluble, sparingly soluble, or insoluble) have been demonstrated to induce acute conjunctivitis with corneal maculae and diffuse erythema (HSDB, 2010).

The mucosa (mucosal membrane) is the moist lining of certain tissues/organs including the eyes, nose, mouth, lungs, and the urinary and digestive tracts. Soluble beryllium salts have been

shown to be directly irritating to mucous membranes (HSDB, 2010).

### G. Summary of Preliminary Conclusions Regarding Health Effects

Through careful analysis of the current best available scientific information outlined in this Health Effects Section V, OSHA has preliminarily determined that beryllium and beryllium-containing compounds are able to cause sensitization, chronic beryllium disease (CBD) and lung cancer below the current OSHA PEL of 2 µg/m<sup>3</sup>. The Agency has preliminarily determined through the studies outlined in section V.A.2 of this health effects section that skin and inhalation exposure to beryllium can lead to sensitization; and inhalation exposure, or skin exposure coupled with inhalation, can cause onset and progression of CBD. In addition, the Agency has preliminarily determined through studies outlined in section V.E. of this health effects section that inhalation exposure to beryllium and beryllium containing materials causes lung cancer.

#### 1. Beryllium Causes Sensitization Below the Current PEL and Sensitization is a Precursor to CBD

Through the biological and immunological processes outlined in section V.B. of the Health Effects, the Agency believes that the scientific evidence supports the following mechanism for the development of sensitization and CBD.

- Inhaled beryllium and beryllium-containing materials able to be retained and solubilized in the lungs initiate sensitization and facilitate CBD development (Section V.B.5).
- Beryllium compounds that dissolve in biological fluids, such as sweat, can penetrate intact skin and initiate sensitization (section V.A.2; V.B). Phagosomal fluid and lung fluid have been demonstrated to dissolve beryllium compounds in the lung (section V.A.2a).
- Sensitization occurs through a CD4+ T-cell mediated process with both soluble and insoluble beryllium and beryllium-containing compounds through direct antigen presentation or through further antigen processing (section V.D.1) in the skin or lung. T-cell mediated responses, such as sensitization, are generally regarded as long-lasting (e.g., not transient or readily reversible) immune conditions.
- Beryllium sensitization and CBD are adverse events along a pathological

continuum in the disease process with sensitization being the necessary first step in the progression to CBD (section V.D).

- Animal studies have provided supporting evidence for T-cell proliferation in the development of granulomatous lung lesions after beryllium exposure (section V.D.2; V.D.6).
  - Since the pathogenesis of CBD involves a beryllium-specific, cell-mediated immune response, CBD cannot occur in the absence of beryllium sensitization (V.D.1). While no clinical symptoms are associated with sensitization, a sensitized worker is at risk of developing CBD upon subsequent inhalation exposure to beryllium.
  - Epidemiological evidence that covers a wide variety of different beryllium compounds and industrial processes demonstrates that sensitization and CBD are continuing to occur at present-day exposures below OSHA's PEL (section V.D.4; V.D.5).
  - OSHA considers CBD to be a progressive illness with a continuous spectrum of symptoms ranging from its earliest asymptomatic stage following sensitization through to full-blown CBD and death (section V.D.7).
  - Genetic variabilities may enhance risk for developing sensitization and CBD in some groups (section V.D.3).
- In addition, epidemiological studies outlined in section V.D.5 have demonstrated that efforts to reduce exposures have succeeded in reducing the frequency of sensitization and CBD.

#### 2. Evidence Indicates Beryllium is a Human Carcinogen

OSHA has conducted an evaluation of the current available scientific information of the carcinogenic potential of beryllium and beryllium-containing compounds (section V.E). Based on weight of evidence and plausible mechanistic information obtained from *in vitro* and *in vivo* animal studies as well as clinical and epidemiological investigations, the Agency has preliminarily determined that beryllium and beryllium-containing materials should be regarded as human carcinogens. This information is in accordance with findings from IARC, NTP, EPA, NIOSH, and ACGIH (section V.E).

- Lung cancer is an irreversible and frequently fatal disease with an extremely poor 5-year survival rate (NCI, 2009).
- Epidemiological cohort studies have reported statistically significant

excess lung cancer mortality among workers employed in U.S. beryllium production and processing plants during the 1930s to 1970s (Section V.E.2).

- Significant positive associations were found between lung cancer mortality and both average and cumulative beryllium exposures when appropriately adjusted for birth cohort and short-term work status (Section V.E.2).
  - Studies in which large amounts of different beryllium compounds were inhaled or instilled in the respiratory tracts of experimental animals resulted in an increased incidence of lung tumors (Section V.E.3).
  - Authoritative scientific organizations, such as the IARC, NTP, and EPA, have classified beryllium as a known or probable human carcinogen.
- While OSHA has preliminarily determined there is sufficient evidence of beryllium carcinogenicity, the exact tumorigenic mechanism for beryllium is unclear and a number of mechanisms are plausibly involved, including chronic inflammation, genotoxicity, mitogenicity oxidative stress, and epigenetic changes (section V.E.3).

• Studies of beryllium exposed animals have consistently demonstrated chronic pulmonary inflammation after exposure (section V.E.3).

○ Substantial data indicate that tumor formation in certain animal models after inhalation exposure to sparingly soluble particles at doses causing marked, chronic inflammation is due to a secondary mechanism unrelated to the genotoxicity of the particle (section V.E.5).

- A review conducted by the NAS (2008) found that beryllium and beryllium-containing compounds tested positive for genotoxicity in nearly 50 percent of studies without exogenous metabolic activity, suggesting a possible direct-acting mechanism may exist (section V.E.1) as well as the potential for epigenetic changes (section V.E.4).

Other health effects have been summarized in sections F of the Health Effects Section and include hepatic, cardiovascular, renal, ocular, and mucosal effects. The adverse systemic effects from human exposures mostly occurred prior to the introduction of occupational and environmental standards set in 1970–1972 (OSHA, 1971; ACGIH, 1971; ANSI, 1970) and 1974 (EPA, 1974) and therefore are less relevant today than in the past.

APPENDIX

TABLE A.1—SUMMARY OF BERYLLIUM SENSITIZATION AND CHRONIC BERYLLIUM DISEASE EPIDEMIOLOGICAL STUDIES

Reference	Study type	(%) Prevalence		Range of exposure measurements	Exposure-response relationship	Study limitations	Additional comments
		Sensitization	CBD				
<b>Studies Conducted Prior to BeLPT</b>							
Hardy and Tabershaw, 1946.	Case-series .....	N/A .....	N/A .....	N/A .....	N/A .....	Selection bias .....	Small sample size.
Hardy, 1980 .....	Case-series .....	N/A .....	N/A .....	N/A .....	N/A .....	Selection bias .....	Small sample size.
Machle <i>et al.</i> , 1948	Case-series .....	N/A .....	N/A .....	Semi-quantitative ..	Yes .....	Selection bias .....	Small sample size; unreliable exposure data.
Eisenbud <i>et al.</i> , 1949.	Case-series .....	N/A .....	N/A .....	<i>Average concentration: 350–750 ft from plant—0.05–0.15 µg/m<sup>3</sup>; &lt;350 ft from plant—2.1 µg/m<sup>3</sup>.</i>	.....	.....	Non-occupational; ambient air sampling.
Lieben and Metzner, 1959.	.....	N/A .....	.....	N/A .....	.....	No quantitative exposure data.	Family member contact with contaminated clothes.
Hardy <i>et al.</i> , 1967 ...	Case Registry Review.	N/A .....	N/A .....	N/A .....	N/A .....	Incomplete exposure concentration data.	.....
Hasan and Kazemi, 1974.	.....	N/A .....	.....	.....	.....	.....	.....
Eisenbud and Lisson, 1983.	.....	N/A .....	1–10 .....	.....	.....	.....	.....
Stoeckle <i>et al.</i> , 1969	Case-series (60 cases).	N/A .....	.....	.....	No .....	Selection bias .....	Provided information regarding progression and identifying sarcoidosis from CBD.
<b>Studies Conducted Following the Development of the BeLPT</b>							
<i>Beryllium Mining and Extraction</i>							
Deubner <i>et al.</i> , 2001b.	Cross-sectional (75 workers).	4.0 (3 cases).	1.3 (1 case).	<i>Mining, milling—range 0.05–0.8 µg/m<sup>3</sup>; Annual maximum 0.04–165.7 µg/m<sup>3</sup>.</i>	No .....	Small sample size	Personal sampling.
<i>Beryllium Metal Processing and Alloy Production</i>							
Kreiss <i>et al.</i> , 1997 ..	Cross-sectional study of 627 workers.	6.9 (43 cases).	4.6 (29 cases).	Median—1.4 µg/m <sup>3</sup>	No .....	Inconsistent BeLPT results between labs.	Short-term Breathing Zone sampling.
Rosenman <i>et al.</i> , 2005.	Cross-sectional study of 577 workers.	14.5 (83 cases).	5.5 (32 cases).	Mean average range—7.1–8.7 µg/m <sup>3</sup> ; Mean peak range—53–87 µg/m <sup>3</sup> ; Mean cumulative range—100–209 µg/m <sup>3</sup> .	No .....	.....	Daily weighted average: High exposures compared to other studies.
<i>Beryllium Machining Operations</i>							
Newman <i>et al.</i> , 2001.	Longitudinal study of 235 workers.	9.4 (22 cases).	8.5 (20 cases).	.....	No .....	.....	Engineering and administrative controls primarily used to control exposures.

TABLE A.1—SUMMARY OF BERYLLIUM SENSITIZATION AND CHRONIC BERYLLIUM DISEASE EPIDEMIOLOGICAL STUDIES—Continued

Reference	Study type	(%) Prevalence		Range of exposure measurements	Exposure-response relationship	Study limitations	Additional comments
		Sensitization	CBD				
Kelleher <i>et al.</i> , 2001	Case-control study of 20 cases and 206 controls.	11.5 (machinists). 2.9 (non-machinists).	11.5 (machinists). 2.9 (non-machinists).	0.08–0.6 µg/m <sup>3</sup> —lifetime weighted exposures.	Yes .....	.....	Identified 20 workers with Sensitization or CBD.
Madl <i>et al.</i> , 2007 .....	Longitudinal study of 27 cases.	.....	.....	<i>Machining</i> ..... 1980–1995 median—0.33 µg/m <sup>3</sup> ; 1996–1999 median—0.16 µg/m <sup>3</sup> ; 2000–2005 median—0.09 µg/m <sup>3</sup> ; <i>Non-machining</i> 1980–1995 median—0.12 µg/m <sup>3</sup> ; 1996–1999 median—0.08 µg/m <sup>3</sup> ; 2000–2005 median—0.06 µg/m <sup>3</sup> .	Yes .....	.....	Personal sampling: Required evidence of granulomas for CBD diagnosis.
<i>Beryllium Oxide Ceramics</i>							
Kreiss <i>et al.</i> , 1993b	Cross-sectional survey of 505 workers.	3.6 (18 cases).	1.8 (9 cases).	.....	No		
Kreiss <i>et al.</i> , 1996 ..	Cross-sectional survey of 136 workers.	5.9 (8 cases).	4.4 (6 cases).	<i>Machining</i> median—0.6 µg/m <sup>3</sup> ; <i>Other Areas</i> median—<0.3 µg/m <sup>3</sup> ;	No .....	Small study population.	Breathing Zone Sampling.
Henneberger <i>et al.</i> , 2001.	Cross-sectional survey of 151 workers.	9.9 (15 cases).	5.3 (8 cases).	6.4% samples >2 µg/m <sup>3</sup> ; 2.4% samples >5 µg/m <sup>3</sup> ; 0.3% samples >25 µg/m <sup>3</sup> .	Yes .....	Small study population.	Breathing zone sampling.
Cummings <i>et al.</i> , 2007.	Longitudinal study of 93 workers.	0.7–5.6 (4 cases).	0.1–7.9 (3 cases).	<i>Production</i> ..... 1994–1999 median—0.1 µg/m <sup>3</sup> ; 2000–2003 median—0.04 µg/m <sup>3</sup> ; <i>Administrative</i> 1994–1999 median <0.2 µg/m <sup>3</sup> ; 2000–2003 median—0.02 µg/m <sup>3</sup>	Yes .....	Small sample size	Personal sampling was effective in reducing rates of new cases of sensitization.
<i>Copper-Beryllium Alloy Processing and Distribution</i>							
Schuler <i>et al.</i> , 2005	Cross-sectional survey of 153 workers.	7.0 (10 cases).	4.0 (6 cases).	<i>Rod and Wire Production</i> median—0.12 µg/m <sup>3</sup> ; <i>Strip Metal Production</i> median—0.02 µg/m <sup>3</sup> ; <i>Production Support</i> median—0.02 µg/m <sup>3</sup> ; <i>Administration</i> median—0.02 µg/m <sup>3</sup> .	.....	Small study population.	Personal sampling.

TABLE A.1—SUMMARY OF BERYLLIUM SENSITIZATION AND CHRONIC BERYLLIUM DISEASE EPIDEMIOLOGICAL STUDIES—Continued

Reference	Study type	(%) Prevalence		Range of exposure measurements	Exposure-response relationship	Study limitations	Additional comments
		Sensitization	CBD				
Thomas <i>et al.</i> , 2009	Cross-sectional study of 82 workers.	3.8 (3 cases).	1.9 (1 case).	Used exposure profile from Schuler study.	.....	Authors noted workers may have been sensitized prior to available screening, underestimating sensitization rate in legacy workers.	Instituted PPE to reduce dermal exposures.
Stanton <i>et al.</i> , 2006	Cross-sectional study of 88 workers.	1.1 (1 case).	1.1 (1 case).	<i>Bulk Products Production</i> median 0.04 µg/m <sup>3</sup> ; <i>Strip Metal Production</i> median—0.03 µg/m <sup>3</sup> ; <i>Production support</i> median—0.01 µg/m <sup>3</sup> ; <i>Administration</i> median 0.01 µg/m <sup>3</sup> .	.....	Study did not report use of PPE or respirators.	Personal sampling.
Bailey <i>et al.</i> , 2010 ...	Cross-sectional study of 660 total workers (258 partial program, 290 full program).	11.0 .....	14.5 total	.....	.....	Study reported prevalence rates for pre enhanced control-program, partial enhanced control program, and full enhanced control program.	

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Kreiss <i>et al.</i> , 1989 ..	Cross-sectional survey of 51 workers.	11.8 (6 cases).	7.8 (4 cases).	.....	No .....	Small study population	
Kreiss <i>et al.</i> , 1993a	Cross-sectional survey of 895 workers.	1.9 (18 cases).	1.7 (15 cases).	.....	No .....	Study population includes some workers with no reported Be exposure.	
Stange <i>et al.</i> , 1996	Longitudinal Study of 4,397 BHSP participants.	2.4 (76 cases).	0.7 (29 cases).	<i>Annual mean concentration. 1970–1988</i> 0.016 µg/m <sup>3</sup> ; <i>1984–1987</i> 1.04 µg/m <sup>3</sup> .	No .....	.....	Personal sampling.
Stange <i>et al.</i> , 2001	Longitudinal study of 5,173 workers.	4.5 (154 cases).	1.6 (81 cases).	No quantitative information presented in study.	No .....	.....	Personal sampling.
Viet <i>et al.</i> , 2000 .....	Case-control .....	74 workers sensitized.	50 workers CBD.	Mean exposure range: 0.083–0.622 µg/m <sup>3</sup> . Maximum exposures: 0.54–36.8 µg/m <sup>3</sup> .	Yes .....	Likely underestimated exposures.	Fixed airhead sampling away from breathing zone: Matched controls for age, sex, smoking.

N/A = Information not available from study reports.

TABLE A.2—SUMMARY OF MECHANISTIC ANIMAL STUDIES FOR SENSITIZATION AND CBD

Reference	Species	Study length	Dose or exposure concentration	Type of beryllium	Study results	Other information
Intratracheal (intrabroncheal) or Nasal Instillation						
Barna <i>et al.</i> , 1981 ..	Guinea pig.	3 month	10 mg-5µm particle size.	beryllium oxide .....	Granulomas, interstitial infiltrate with fibrosis with thickening of alveolar septae.	
Barna <i>et al.</i> , 1984 ..	Guinea pig.	3 month	5 mg .....	beryllium oxide .....	Granulomatous lesions in strain 2 but not strain 13 indicating a genetic component.	
Benson <i>et al.</i> , 2000	Mouse ....	.....	0, 12.5, 25, 100µg; 0, 2, 8 µg.	beryllium copper alloy; beryllium metal.	Acute pulmonary toxicity associated with beryllium/copper alloy but not beryllium metal.	
Haley <i>et al.</i> , 1994 ...	Cynomolgus monkey.	14, 60, 90 days	0, 1, 50, 150 µg. 0, 2.5, 12.5, 37.5 µg.	Beryllium metal, beryllium oxide.	Beryllium oxide particles were less toxic than the beryllium metal.	
Huang <i>et al.</i> , 1992	Mouse ....	.....	5 µg ..... 1–5 µg ...	Beryllium sulfate immunization; beryllium metal challenge.	Granulomas produced in A/J strain but not BALB/c or C57BL/6.	
Votto <i>et al.</i> , 1987 ....	Rat .....	3 month	2.4 mg ... 8 mg/ml	Beryllium sulfate immunization; beryllium sulfate challenge.	Granulomas, however, no correlation between T-cell subsets in lung and BAL fluid.	
Inhalation—Single Exposure						
Haley <i>et al.</i> , 1989a	Beagle dog.	Chronic—one dose	0, 6 µg/kg, 18 µg/kg.	500 °C; 1000 °C beryllium oxide.	Positive BeLPT results—developed granulomas; low-calcined beryllium oxide more toxic than high-calcined.	Granulomas resolved with time, no full-blown CBD.
Haley <i>et al.</i> , 1989b	Beagle dog.	Chronic—one dose/2 year recovery	0, 17 µg/kg, 50 µg/kg.	500 °C; 1000 °C beryllium oxide.	Granulomas, sensitization, low-fired more toxic than high fired.	Granulomas resolved over time.
Robinson <i>et al.</i> , 1968.	Dog .....	Chronic	0. 115mg/m <sup>3</sup> .	Beryllium oxide, beryllium fluoride, beryllium chloride.	Foreign body reaction in lung.	
Sendelbach <i>et al.</i> , 1989.	Rat .....	2 week	0, 4.05 µg/L.	Beryllium as beryllium sulfate.	Interstitial pneumonitis.	
Sendelbach and Witschi, 1987.	Rat .....	2 week	0, 3.3, 7 µg/L.	Beryllium as beryllium sulfate.	Enzyme changes in BAL fluid.	
Inhalation—Repeat Exposure						
Conradi <i>et al.</i> , 1971	Beagle dog.	Chronic—2 year	0. 3300 µg/m <sup>3</sup> , 4380 µg/m <sup>3</sup> once/month for 3 months.	1400 °C beryllium oxide.	No changes detected.	May have been due to short exposure time followed by long recovery.

TABLE A.2—SUMMARY OF MECHANISTIC ANIMAL STUDIES FOR SENSITIZATION AND CBD—Continued

Reference	Species	Study length	Dose or exposure concentration	Type of beryllium	Study results	Other information
	Macaca irus Monkey.	Chronic—2 year	0. 3300 µg/m <sup>3</sup> , 4380 µg/m <sup>3</sup> once/month for 3 months.	1400 °C beryllium oxide.	No changes detected.	May have been due to short exposure time followed by long recovery.
Haley <i>et al.</i> , 1992 ...	Beagle dog.	Chronic—repeat dose (2.5 year intervals)	17, 50 µg/kg.	500 °C; 1000 °C beryllium oxide.	Granulomatous pneumonitis.	
Harmsen <i>et al.</i> , 1985.	Beagle dog. 5 dogs per group.	Chronic	0, 20 µg/kg, 50 µg/kg.	500°C; 1000 °C beryllium oxide.		
Dermal or Intradermal						
Kang <i>et al.</i> , 1977 ....	Rabbit ....	.....	10mg ....	Beryllium sulfate ....	Skin sensitization and skin granulomas.	
Tinkle <i>et al.</i> , 2003 ..	Mouse ....	3 month	25 µL .... 70 µg ....	Beryllium sulfate .... Beryllium oxide .....	Microgranulomas with some resolution over time of study.	
Intramuscular						
Eskenasy, 1979 .....	Rabbit ....	35 days (injections at 7 day intervals)	10mg/ml	Beryllium sulfate ....	Sensitization, evidence of CBD.	
Intraperitoneal Injection						
Marx and Burrell, 1973.	Guinea pig.	24 weeks (biweekly injections)	2.6 mg + 10 µg dermal injections.	Beryllium sulfate ....	Sensitization.	

TABLE A-3—SUMMARY OF BERYLLIUM LUNG CANCER EPIDEMIOLOGICAL STUDIES

Reference	Study type	Exposure range	Study number	Mortality ratio	Confounding factors	Study limitations	Additional comments
<i>Beryllium Case Registry</i>							
Infante <i>et al.</i> , 1980	Cohort .....	N/D .....	421 cases from the BCR.	SMR 2.12 ..... 7 lung cancer deaths.	Not reported .....	Exposure concentration data or smoking habits not reported.	
Steenland and Ward, 1991.	Cohort .....	N/D .....	689 cases from the BCR.	SMR 2.00 (95% CI 1.33–2.89). 28 lung cancer deaths.	.....	.....	Included women: 93% women diagnosed with CBD; 50% men diagnosed with CBD; SMR 157 for those with CBD and SMR 232 for those with ABD.
<i>Beryllium Manufacturing and/or Processing Plants (Extraction, Fabrication, and Processing)</i>							
Ward <i>et al.</i> , 1992 ..	Retrospective Mortality Cohort.	N/D .....	9,225 males .....	SMR 1.26 ..... (95% CI 1.12–1.42). 280 lung cancer deaths.	.....	Lack of job history and air monitoring data.	Employment period 1940–1969.

TABLE A-3—SUMMARY OF BERYLLIUM LUNG CANCER EPIDEMIOLOGICAL STUDIES—Continued

Reference	Study type	Exposure range	Study number	Mortality ratio	Confounding factors	Study limitations	Additional comments
Levy <i>et al.</i> , 2002 ...	Cohort .....	N/D .....	9225 males .....	Statistically non-significant elevation in lung cancer deaths.	Adjusted for smoking.	Lack of job history and air monitoring data.	Majority of workers studied employed for less than one year
Bayliss <i>et al.</i> , 1971	Nested cohort .....	.....	8,000 workers .....	SMR 1.06 ..... 36 lung cancer deaths.	.....	.....	Employed prior to 1947 for almost half lung cancer deaths.
Mancuso, 1970 .....	Cohort .....	411–43,300 $\mu\text{g}/\text{m}^3$ annual exposure (reported from Zielinsky, 1961).	1,222 workers at OH plant; 2,044 workers at PA plant.	SMR 1.42 ..... (95% CI 1.1–1.8) 80 lung cancer deaths.	Only partial smoking history.	Partial smoking history; No job analysis by title or exposure category.	Employment period from 1937–1948.
Mancuso, 1980 .....	Cohort .....	N/D .....	Same OH and PA plant analysis.	SMR 1.40 .....	No smoking adjustment.	No adjustment by job title or exposure.	Employment period from 1942–1948; Used workers at rayon plant for comparison.
Mancuso and El Attar, 1969.	Cohort .....	N/D .....	3,685 white males	SMR 1.49 .....	Adjusted for age and local.	No job exposure data or smoking adjustment.	Employment history from 1937–1944.
Wagner <i>et al.</i> , 1980.	Cohort .....	N/D .....	3,055 white males PA plant.	SMR 1.25 ..... (95% CI 0.9–1.7) 47 lung cancer deaths.	.....	Inadequately adjusted for smoking; Used national lung-cancer risk for cancer not PA.	Reanalysis using PA lung-cancer rate revealed 19% underestimation of beryllium lung cancer deaths.
Sanderson <i>et al.</i> , 2001.	Nested case-control.	— Average exposure 22.8 $\mu\text{g}/\text{m}^3$ . — Maximum exposure 32.4 $\mu\text{g}/\text{m}^3$ .	3,569 males PA plant.	SMR 1.22 ..... (95% CI 1.03–1.43). 142 lung cancer deaths.	Smoking was found not to be a confounding factor.	May not have adjusted properly for birth-year or age at hire.	Found association with 20 year latency.
Levy <i>et al.</i> , 2007 ...	Nested case-control.	Used log transformed exposure data.	Reanalysis of Sanderson <i>et al.</i> , 2001.	SMR 1.04 ..... (95% CI 0.92–1.17).	Different methodology for smoking adjustment.	.....	Found no association between beryllium exposure and increased risk of lung cancer.
Schubauer-Berigan <i>et al.</i> , 2008.	Nested case-control.	Used exposure data from Sanderson <i>et al.</i> , 2001, Chen 2001, and Couch <i>et al.</i> , 2010.	Reanalysis of Sanderson <i>et al.</i> , 2001.	Used Odds ratio: 1.91 (95% CI 1.06–3.44) unadjusted; 1.29 (95% CI 0.61–2.71) birth-year adjusted; 1.24 (95% CI 0.58–2.65) age-hire adjusted.	Adjusted for smoking, birth cohort, age.	.....	— Controlled for birth-year and age at hire; — Found similar results to Sanderson <i>et al.</i> , 2001; — Found association with 10 year latency — “0” = used minuscule value at start to eliminate the use of 0 in a logarithmic analysis
Schubauer-Berigan <i>et al.</i> , 2010a.	Cohort .....	N/D .....	9199 workers from 7 processing plants.	SMR 1.17 (95%CI 1.08–1.28). 545 deaths .....	Adjusted for smoking.	.....	Male workers employed at least 2 days between 1940 and 1970.
Schubauer-Berigan <i>et al.</i> , 2010b.	Cohort .....	Used exposure data from Sanderson <i>et al.</i> , 2001.	5436 workers OH and PA plants.	Evaluated using hazard ratios and excess absolute risk. 293 deaths .....	Adjusted for age, birth cohort, asbestos exposure, short-term work status.	.....	— Exposure response was found between 0–10 $\mu\text{g}/\text{m}^3$ mean DWA; — Increased with statistical significance at 4 $\mu\text{g}/\text{m}^3$ ; — 1 in 1000 risk at 0.033 $\mu\text{g}/\text{m}^3$ mean DWA.



TABLE A-3—SUMMARY OF BERYLLIUM LUNG CANCER EPIDEMIOLOGICAL STUDIES—Continued

Reference	Study type	Exposure range	Study number	Mortality ratio	Confounding factors	Study limitations	Additional comments
<i>Re-evaluation of Published Studies</i>							
Hollins <i>et al.</i> , 2009	Review .....	Re-examination of weight-of-evidence from more than 50 publications.	.....	.....	.....	.....	Found lung cancer excess risk was associated with higher levels of exposure not relevant in today's industrial settings.
IARC, 2012 .....	Multiple .....	Insufficient exposure concentration. Data .....	.....	Sufficient evidence for carcinogenicity of beryllium.	IARC concluded beryllium lung cancer risk was not associated with smoking.	.....	<ul style="list-style-type: none"> <li>— Greater lung cancer risk in the BCR cohort</li> <li>— Correlation between highest lung cancer rates and highest amounts of ABD or other non-malignant lung diseases</li> <li>— Increased risk with longer latency</li> <li>— Greater excess lung cancers among those hired prior to 1950.</li> </ul>

N/D = information not determined for most studies  
DWA—daily weighted average

**VI. Preliminary Beryllium Risk Assessment**

The Occupational Safety and Health (OSH) Act and court cases arising under it have led OSHA to rely on risk assessment to support the risk determinations required to set a permissible exposure limit (PEL) for a toxic substance in standards under the OSH Act. Section 6(b)(5) of the OSH Act states that “The Secretary [of Labor], 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” (29 U.S.C. 655(b)(5)).

In *Industrial Union Department, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607 (1980) (*Benzene*), the United States Supreme Court ruled that the OSH Act requires that, prior to the issuance of a new standard, a determination must be made 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 Court stated that “before [the Secretary] can promulgate any permanent health or safety standard, the

Secretary is required to make a threshold finding that a place of employment is unsafe—in the sense that significant risks are present and can be eliminated or lessened by a change in practices” (*Id.* at 642). The Court also stated “that the Act does limit the Secretary’s power to requiring the elimination of significant risks” (488 U.S. at 644 n.49), and that “OSHA is not required to support its finding that a significant risk exists with anything approaching scientific certainty” (*Id.* at 656).

OSHA’s approach for the risk assessment incorporates both a review of the recent literature on populations of workers exposed to beryllium below the current Permissible Exposure Limit (PEL) of 2 µg/m<sup>3</sup> and a statistical exposure-response analysis. OSHA evaluated risk at several alternate PELs under consideration by the Agency: 2 µg/m<sup>3</sup>, 1 µg/m<sup>3</sup>, 0.5 µg/m<sup>3</sup>, 0.2 µg/m<sup>3</sup>, and 0.1 µg/m<sup>3</sup>. A number of recently published epidemiological studies evaluate the risk of sensitization and CBD for workers exposed at and below the current PEL and the effectiveness of exposure control programs in reducing risk. OSHA also conducted a statistical analysis of the exposure-response relationship for sensitization and CBD at the current PEL and alternate PELs the Agency is considering. For this analysis, OSHA used data provided by National Jewish Medical and Research Center

(NJMRC) on a population of workers employed at a beryllium machining plant in Cullman, AL. The review of the epidemiological studies and OSHA’s own analysis show substantial risk of sensitization and CBD among workers exposed at and below the current PEL of 2 µg/m<sup>3</sup>. They also show substantial reduction in risk where employers have implemented a combination of controls, including stringent control of airborne beryllium levels and additional measures such as respirators, dermal personal protective equipment (PPE), and strict housekeeping to protect workers against dermal and respiratory beryllium exposure. To evaluate lung cancer risk, OSHA relied primarily on a quantitative risk assessment published in 2011 by NIOSH. This risk assessment was based on an update of the Reading cohort analyzed by Sanderson *et al.*, as well as workers from two smaller plants (Schubauer-Berigan *et al.*, 2011) where workers were exposed to lower levels of beryllium and worked for longer periods than at the Reading plant. The authors found that lung cancer risk was strongly and significantly related to mean, cumulative, and maximum measures of workers’ exposure; they predicted substantial risk of lung cancer at the current PEL, and substantial reductions in risk at the alternate PELs OSHA considered for the proposed rule (Schubauer-Berigan *et al.*, 2011).

### A. Review of Epidemiological Literature on Sensitization and Chronic Beryllium Disease From Occupational Exposure

As discussed in the Health Effects section, studies of beryllium-exposed workers conducted using the beryllium lymphocyte proliferation test (BeLPT) have found high rates of beryllium sensitization and CBD among workers in many industries, including at some facilities where exposures were primarily below OSHA's PEL of  $2 \mu\text{g}/\text{m}^3$  (Kreiss *et al.*, 1993; Henneberger *et al.*, 2001; Schuler *et al.*, 2005; Schuler *et al.*, 2012). In the mid-1990s, some facilities using beryllium began to aggressively monitor and reduce workplace exposures. Four plants where several rounds of BeLPT screening were conducted before and after implementation of new exposure control methods provide the best currently available evidence on the effectiveness of various exposure control measures in reducing the risk of sensitization and CBD. The experiences of these plants—a copper-beryllium processing facility in Reading, PA, a beryllia ceramics facility in Tucson, AZ; a beryllium processing facility in Elmore, OH; and a machining facility in Cullman, AL—show that efforts to prevent sensitization and CBD by using engineering controls to reduce workers' beryllium exposures to median levels at or around  $0.2 \mu\text{g}/\text{m}^3$  and did not emphasize PPE and stringent housekeeping methods, had only limited impact on risk. However, exposure control programs implemented more recently, which drastically reduced respiratory exposure to beryllium via a combination of engineering controls and respiratory protection, controlled dermal contact with beryllium using PPE, and employed stringent housekeeping methods to keep work areas clean and prevent transfer of beryllium between work areas, sharply curtailed new cases of sensitization among newly-hired workers. There is additional, but more limited, information available on the occurrence of sensitization and CBD among aluminum smelter workers with low-level beryllium exposures (Taiwo *et al.*, 2008; Taiwo *et al.*, 2010; Nilsen *et al.*, 2010). A discussion of the experiences at these plants follows.

The Health Effects section also discussed the role of particle characteristics and beryllium compound solubility in the development of sensitization and CBD among beryllium-exposed workers. Respirable particles small enough to reach the deep lung are responsible for CBD. However, larger inhalable particles that deposit in the

upper respiratory tract may lead to sensitization. The weight of evidence indicates that both soluble and insoluble forms of beryllium are able to induce sensitization and CBD. Insoluble forms of beryllium that persist in the lung for longer periods may pose greater risk of CBD while soluble forms may more easily trigger immune sensitization. Although these factors potentially influence the toxicity of beryllium, the available data are too limited to reliably account for solubility and particle size in the Agency estimates of risk. The qualitative impact on conclusions and uncertainties with regard to risk are discussed in a later section.

#### 1. Reading, PA, Plant

Schuler *et al.* conducted a study of workers at a copper-beryllium processing facility in Reading, PA, screening 152 workers with the BeLPT (Schuler *et al.*, 2005). Exposures at this plant were believed to be low throughout its history due to the low percentage of beryllium in the metal alloys used, and the relatively low exposures found in general area samples collected starting in 1969 (sample median  $\leq 0.1 \mu\text{g}/\text{m}^3$ , 97%  $< 0.5 \mu\text{g}/\text{m}^3$ ). The reported prevalences of sensitization (6.5 percent) and CBD (3.9 percent) showed substantial risk at this facility, even though airborne exposures were primarily below OSHA's current PEL of  $2 \mu\text{g}/\text{m}^3$ .

Personal lapel samples were collected in production and production support jobs between 1995 and May 2000. These samples showed primarily very low airborne beryllium levels, with a median of  $0.073 \mu\text{g}/\text{m}^3$ .<sup>6</sup> The wire annealing and pickling process had the highest personal lapel sample values, with a median of  $0.149 \mu\text{g}/\text{m}^3$ . Despite these low exposure levels, cases of sensitization continued to occur among workers whose first exposures to beryllium occurred in the 1990s. Five (11.5 percent) workers of 43 hired after 1992 who had no prior beryllium exposure became sensitized, including four in production work and one in production support (Thomas *et al.*, 2009; evaluation for CBD not reported). Two (13 percent) of these sensitized workers were among 15 workers in this group who had been hired less than a year before the screening.

After the BeLPT screening was conducted in 2000, the company began implementing new measures to further

reduce workers' exposure to beryllium. Requirements designed to minimize dermal contact with beryllium, including long-sleeve facility uniforms and polymer gloves, were instituted in production areas in 2000. In 2001 the company installed local exhaust ventilation (LEV) in die grinding and polishing. Personal lapel samples collected between June 2000 and December 2001 show reduced exposures plant-wide. Of 2,211 exposure samples collected during this "pre-enclosure program" period, 98 percent were below  $0.2 \mu\text{g}/\text{m}^3$  (Thomas *et al.*, 2009, p. 124). Median, arithmetic mean, and geometric mean values  $\leq 0.03 \mu\text{g}/\text{m}^3$  were reported in this period for all processes except the wire annealing and pickling process. Samples for this process remained elevated, with a median of  $0.1 \mu\text{g}/\text{m}^3$  (arithmetic mean of  $0.127 \mu\text{g}/\text{m}^3$ , geometric mean of  $0.083 \mu\text{g}/\text{m}^3$ ). In January 2002, the plant enclosed the wire annealing and pickling process in a restricted access zone (RAZ), required respiratory PPE in the RAZ, and implemented stringent measures to minimize the potential for skin contact and beryllium transfer out of the zone. While exposure samples collected by the facility were sparse following the enclosure, they suggest exposure levels comparable to the 2000–01 samples in areas other than the RAZ. Within the RAZ, required use of powered air-purifying respirators (PAPRs) indicates that respiratory exposure was negligible. A 2009 publication on the facility reported that outside the RAZ, "the vast majority of employees do not wear any form of respiratory protection due to very low airborne beryllium concentrations" (Thomas *et al.*, 2009, p. 122).

To test the efficacy of the new measures in preventing sensitization and CBD, in June 2000 the facility began an intensive BeLPT screening program for all new workers. The company screened workers at the time of hire; at intervals of 3, 6, 12, 24, and 48 months; and at 3-year intervals thereafter. Among 82 workers hired after 1999, three cases of sensitization were found (3.7 percent). Two (5.4 percent) of 37 workers hired prior to enclosure of the wire annealing and pickling process were found to be sensitized within 3 and 6 months of beginning work at the plant. One (2.2 percent) of 45 workers hired after the enclosure was confirmed as sensitized. Among these early results, it appears that the greatest reduction in sensitization risk was achieved after median exposures in all areas of the plant were reduced to below  $0.1 \mu\text{g}/\text{m}^3$

<sup>6</sup> In their publication, Schuler *et al.* presented median values for plant-wide and work-category-specific exposure levels; they did not present arithmetic or geometric mean values for personal samples.

and PPE to prevent dermal contact was instituted.

## 2. Tucson, AZ, Plant

Kreiss *et al.* conducted a study of workers at a beryllia ceramics plant, screening 136 workers with the BeLPT in 1992 (Kreiss *et al.*, 1996). Full-shift area samples collected between 1983 and 1992 showed primarily low airborne beryllium levels at this facility. Of 774 area samples, 76 percent were at or below  $0.1 \mu\text{g}/\text{m}^3$  and less than 1 percent exceeded  $2 \mu\text{g}/\text{m}^3$ . A small set (75) of personal lapel samples collected at the plant beginning in 1991 had a median of  $0.2 \mu\text{g}/\text{m}^3$  and ranged from  $0.1$  to  $1.8 \mu\text{g}/\text{m}^3$  (arithmetic and geometric mean values not reported) (Kreiss *et al.*, 1996, p. 19). However, area samples and short-term breathing zone samples also showed occasional instances of very high beryllium exposure levels, with extreme values of several hundred  $\mu\text{g}/\text{m}^3$  and 3.6 percent of short-term breathing zone samples in excess of  $5 \mu\text{g}/\text{m}^3$ .

Kreiss *et al.* reported that eight (5.9 percent) of 136 workers tested were sensitized, six (4.4 percent) of whom were diagnosed with CBD. Seven of the eight sensitized employees had worked in machining, where general area samples collected between October 1985 and March 1988 had a median of  $0.3 \mu\text{g}/\text{m}^3$ , in contrast to a median value of less than  $0.1 \mu\text{g}/\text{m}^3$  in other areas of the plant (Kreiss *et al.*, 1996, p. 20; mean values not reported). Short-term breathing zone measurements associated with machining had a median of  $0.6 \mu\text{g}/\text{m}^3$ , double the median of  $0.3 \mu\text{g}/\text{m}^3$  for breathing zone measurements associated with other processes (*id.*, p. 20; mean values not reported). One sensitized worker was one of 13 administrative workers screened, and was among those diagnosed with CBD. Exposures of administrative workers were not well-characterized, but were believed to be among the lowest in the plant. Of three personal lapel samples reported for administrative staff during the 1990s, all were below the then detection limit of  $0.2 \mu\text{g}/\text{m}^3$  (Cummings *et al.*, 2007, p.138).

Following the 1992 screening, the facility reduced exposures in machining areas by enclosing machines and installing HEPA filter exhaust systems. Personal samples collected between 1994 and 1999 had a median of  $0.2 \mu\text{g}/\text{m}^3$  in production jobs and  $0.1 \mu\text{g}/\text{m}^3$  in production support (geometric means  $0.21 \mu\text{g}/\text{m}^3$  and  $0.11 \mu\text{g}/\text{m}^3$ , respectively; arithmetic means not reported. Cummings *et al.*, 2007, p. 138). In 1998, a second screening found that 9 percent of tested workers hired after the 1992

screening were sensitized, of whom one was diagnosed with CBD. All of the sensitized workers had been employed at the plant for less than two years (Henneberger *et al.*, 2001).

Following the 1998 screening, the company continued efforts to reduce exposures and risk of sensitization and CBD by implementing additional engineering and administrative controls and PPE. Respirator use was required in production areas beginning in 1999, and latex gloves were required beginning in 2000. The lapping area was enclosed in 2000, and enclosures were installed for all mechanical presses in 2001. Between 2000 and 2003, water-resistant or water-proof garments, shoe covers, and taped gloves were incorporated to keep beryllium-containing fluids from wet machining processes off the skin. The new engineering measures did not appear to substantially reduce airborne beryllium levels in the plant. Personal lapel samples collected in production processes between 2000 and 2003 had a median and geometric mean of  $0.18 \mu\text{g}/\text{m}^3$ , similar to the 1994–1999 samples (Cummings *et al.*, 2007, p. 138). However, respiratory protection requirements were instituted in 2000 to control workers' airborne beryllium exposures.

To test the efficacy of the new measures instituted after 1998, in January 2000 the company began screening new workers for sensitization at the time of hire and at 3, 6, 12, 24, and 48 months of employment (Cummings *et al.*, 2007). These more stringent measures appear to have substantially reduced the risk of sensitization among new employees. Of 97 workers hired between 2000 and 2004, one case of sensitization was identified (1 percent). This worker had experienced a rash after an incident of dermal exposure to lapping fluid through a gap between the glove and uniform sleeve, indicating that sensitization may have occurred via skin exposure.

## 3. Elmore, OH, Plant

Kreiss *et al.*, Schuler *et al.*, and Bailey *et al.* conducted studies of workers at a beryllium metal, alloy, and oxide production plant. Workers participated in BeLPT surveys in 1992 (Kreiss *et al.*, 1997) and in 1997 and 1999 (Schuler *et al.*, 2012). Exposure levels at the plant between 1984 and 1993 were characterized by a mixture of general area, short-term breathing zone, and personal lapel samples. Kreiss *et al.* reported that the median area samples for various work areas ranged from  $0.1$  to  $0.7 \mu\text{g}/\text{m}^3$ , with the highest values in the alloy arc furnace and alloy melting-

casting areas (other measures of central tendency not reported). Personal lapel samples were available from 1990–1992, and showed high exposures overall (median value of  $1.0 \mu\text{g}/\text{m}^3$ ) with very high exposures for some processes. The authors reported median sample values of  $3.8 \mu\text{g}/\text{m}^3$  for beryllium oxide production,  $1.75 \mu\text{g}/\text{m}^3$  for alloy melting and casting, and  $1.75 \mu\text{g}/\text{m}^3$  for the arc furnace.

Kreiss *et al.* reported that 43 (6.9 percent) of 627 workers tested in 1992 were sensitized, six of whom were diagnosed with CBD (4.4 percent). Workers with less than one year tenure at the plant were not tested in this survey (Bailey *et al.*, 2010, p. 511). The work processes that appeared to carry the highest risk for sensitization and CBD (*e.g.*, ceramics) were not those with the highest reported exposure levels (*e.g.*, arc furnace and melting-casting). The authors noted several possible reasons for this, including factors such as solubility, particle size/number, and particle surface area that could not be accounted for in their analysis (Kreiss *et al.*, 1997).

In 1996–1999, the company took steps to reduce workers' beryllium exposures: some high-exposure processes were enclosed, special restricted-access zones were set up, HEPA filters were installed in air handlers, and some ventilation systems were updated. In 1997 workers in the pebble plant restricted access zone were required to wear half-face air-purifying respirators, and beginning in 1999 all new employees were required to wear loose-fitting powered air-purifying respirators (PAPR) in manufacturing buildings (Bailey *et al.*, 2010, p. 506). Skin protection became part of the protection program for new employees in 2000, and glove use was required in production areas and for handling work boots beginning in 2001. Also beginning in 2001, either half-mask respirators or PAPRs were required in the production facility (type determined by airborne beryllium levels), and respiratory protection was required for roof work and during removal of work boots (Bailey *et al.*, 2010, p. 506). Respirator use was reported to be used on about half or less of industrial hygiene sample records for most processes in 1990–1992 (Kreiss *et al.*, 1996).

Beginning in 2000, workers were offered periodic BeLPT testing to evaluate the effectiveness of a new exposure control program implemented by the company. Bailey *et al.* (2010) reported on the results of this surveillance for 290 workers hired between February 21, 2000 and December 18, 2006. They compared the

occurrence of beryllium sensitization and disease among 258 employees who began work at the Elmore plant between January 15, 1993 and August 9, 1999 (the 'pre-program group') and among 290 employees who were hired between February 21, 2000 and December 18, 2006 and were tested at least once after hire (the 'program group'). They found that, as of 1999, 23 (8.9 percent) of the pre-program group were sensitized to beryllium. Six (2.1 percent) of the program group had confirmed abnormal results on their final round of BeLPTs, which occurred in different years for different employees. In addition, another five employees had confirmed abnormal BeLPT results at some point during the testing period, followed by at least one instance of a normal test result. One of these employees had a confirmed abnormal baseline BeLPT at hire, and had two subsequent normal BeLPT results at 6 and 12 months after hire. Four others had confirmed abnormal BeLPT results at 3 or 6 months after hire, later followed by a normal test. Including these four in the count of sensitized workers, there were a total of ten (3.5 percent) workers sensitized after hire in the program group. It is not clear whether the occurrence of a normal result following an abnormal result reflects an error in one of the test results, a change in the presence or level of memory T-cells circulating in the worker's blood, or other possibilities. Because most of the workers in the study had been employed at the facility for less than two years, Bailey *et al.* did not report the incidence of CBD among the sensitized workers (Bailey *et al.*, 2010, p. 511).

In addition, Bailey *et al.* divided the program group into the 'partial program subgroup' (206 employees hired between February 21, 2000 and December 31, 2003) and the 'full program subgroup' (84 employees hired between January 1, 2004 and December 18, 2006) to account for the greater effectiveness of the exposure control program after the first three years of implementation (Bailey *et al.*, pp 506–507). Four (1.9 percent) of the partial program group were found to be sensitized on their final BeLPT (excluding one with a confirmed abnormal BeLPT from their baseline test at hire). Two (2.4 percent) of the full program group were found to be sensitized on their final BeLPT (Bailey *et al.*, 2010, p. 509). An additional three employees in the partial program group and one in the full program group were confirmed sensitized at 3 or 6 months

after hire, then later had a single normal BeLPT (Bailey *et al.*, 2010, p. 509).

Schuler *et al.* (2012) published a study examining beryllium sensitization and CBD among short-term workers at the Elmore, OH plant, using exposure estimates created by Virji *et al.* (2012). The study population included 264 workers employed in 1999 with up to six years tenure at the plant (91 percent of the 291 eligible workers). By including only short-term workers, Virji *et al.* were able to construct participants' exposures with more precision than was possible in studies involving workers exposed for longer durations and in time periods with less exposure sampling. Each participant completed a work history questionnaire and was tested for beryllium sensitization. The overall prevalence of sensitization was 9.8 percent (26/264). Sensitized workers were offered further evaluation for CBD. Twenty-two sensitized workers consented to clinical testing for CBD via transbronchial biopsy. Six of those sensitized were diagnosed with CBD (2.3 percent, 6/264).

Exposure estimates were constructed using two exposure surveys conducted in 1999: a survey of total mass exposures (4022 full-shift personal samples) and a survey of size-separated impactor samples (198 samples). The 1999 exposure surveys and work histories were used to estimate long-term lifetime weighted (LTW) average, cumulative, and highest-job-worked exposure for total, respirable, and submicron beryllium mass concentrations. Schuler *et al.* (2012) found no cases of sensitization among workers with total mass LTW average exposures below 0.09  $\mu\text{g}/\text{m}^3$ , among workers with total mass cumulative exposures below 0.08  $\mu\text{g}/\text{m}^3\text{-yr}$ , or among workers with total mass highest job worked exposures below 0.12  $\mu\text{g}/\text{m}^3$ . Twenty-four percent, 16 percent, and 25 percent of the study population were exposed below those levels, respectively. Both total and respirable beryllium mass concentration estimates were positively associated with sensitization (average and highest job), and CBD (cumulative) in logistic regression models.

#### 4. Cullman, AL, Plant

Newman *et al.* conducted a series of BeLPT screenings of workers at a precision machining facility between 1995 and 1999 (Newman *et al.*, 2001). A small set of personal lapel samples collected in the early 1980s and in 1995 suggests that exposures in the plant varied widely during this time period. In some processes, such as engineering,

lapping, and electrical discharge machining (EDM), exposures were apparently low ( $\leq 0.1 \mu\text{g}/\text{m}^3$ ). Madl *et al.* reported that personal lapel samples from all machining processes combined had a median of 0.33  $\mu\text{g}/\text{m}^3$ , with a much higher arithmetic mean of 1.63  $\mu\text{g}/\text{m}^3$  (Madl *et al.*, 2007, Table IV, p. 457). The majority of these samples were collected in the high-exposure processes of grinding (median of 1.05  $\mu\text{g}/\text{m}^3$ , mean of 8.48  $\mu\text{g}/\text{m}^3$ ), milling (median of 0.3  $\mu\text{g}/\text{m}^3$ , mean of 0.82  $\mu\text{g}/\text{m}^3$ ), and lathing (median of 0.35  $\mu\text{g}/\text{m}^3$ , mean of 0.88  $\mu\text{g}/\text{m}^3$ ) (Madl *et al.*, 2007, Table IV, p. 457). As discussed in greater detail in the background document,<sup>7</sup> the data set of machining exposure measurements included a few extremely high values (41–73  $\mu\text{g}/\text{m}^3$ ) that a NIOSH researcher identified as probable errors, and that appear to be included in Madl *et al.*'s arithmetic mean calculations. Because high single-data point exposure errors influence the arithmetic mean far more than the median value of a data range, OSHA believes the median values reported by Madl *et al.* are more reliable than the arithmetic means they reported.

After a sentinel case of CBD was diagnosed at the plant in 1995, the company began BeLPT screenings to identify workers at increased risk of CBD and implemented engineering and administrative controls and PPE designed to reduce workers' beryllium exposures in machining operations. Newman *et al.* reported 22 (9.4 percent) sensitized workers among 235 tested, 13 of whom were diagnosed with CBD within the study period. Between 1995 and 1997, the company built enclosures and installed or updated local exhaust ventilation (LEV) for several machining departments, removed pressurized air hoses, and required the use of company uniforms. Madl *et al.* reported that historically, engineering and work process controls, rather than personal protective equipment, were used to limit workers' exposure to beryllium; respirators were used only in cases of high exposure, such as during sandblasting (Madl *et al.*, 2007, p. 450). In contrast to the Reading and Tucson plants, gloves were not required at this plant.

Personal lapel samples collected extensively between 1996 and 1999 in machining jobs have an overall median of 0.16  $\mu\text{g}/\text{m}^3$ , showing that the new controls achieved a marked reduction in machinists' exposures during this

<sup>7</sup> When used throughout this section, "background document" refers to a more comprehensive, companion risk-assessment document that can be found at [www.regulations.gov](http://www.regulations.gov) in OSHA Docket No. \_\_\_\_.

period. Nearly half of the samples were collected in milling (median = 0.18 µg/m³). Exposures in other machining processes were also reduced, including grinding (median of 0.18 µg/m³) and lathing (median of 0.13 µg/m³). However, cases of sensitization and CBD continued to occur.

At the time that Newman *et al.* reviewed the results of BeLPT screenings conducted in 1995–1999, a subset of 60 workers had been employed at the plant for less than a year. Four (6.7 percent) of these workers were found to be sensitized, of whom two were diagnosed with CBD and one with probable CBD (Newman *et al.*, 2001). All four had been hired in 1996. Two (one CBD case, one sensitized only) had worked only in milling, and had worked for approximately 3–4 months (0.3–0.4 yrs) at the time of diagnosis. One of those diagnosed with CBD worked only

in EDM, where lapel samples collected between 1996 and 1999 had a median of 0.03 µg/m³. This worker was diagnosed with CBD in the same year that he began work at the plant. The last CBD case worked as a shipper, where exposures in 1996–1999 were similarly low, with a median of 0.09 µg/m³.

Beginning in 2000, exposures in all jobs at the machining facility were reduced to extremely low levels. Personal lapel samples collected in machining processes between 2000 and 2005 had a median of 0.09 µg/m³, where more than a third of samples came from the milling process (n = 765, median of 0.09 µg/m³). A later publication on this plant by Madl *et al.* reported that only one worker hired after 1999 became sensitized. This worker had been employed for 2.7 years in chemical finishing, where exposures were roughly similar to other machining

processes (n = 153, median of 0.12 µg/m³). Madl *et al.* did not report whether this worker was evaluated for CBD.

5. Aluminum Smelting Plants

Taiwo *et al.* (2008) studied a population of 734 employees at four aluminum smelters located in Canada (2), Italy (1), and the United States (1). In 2000, a beryllium exposure limit of 0.2 µg/m³ 8-hour TWA (action level 0.1 µg/m³) and a short-term exposure limit (STEL) of 1.0 µg/m³ (15-minute sample) were instituted at these plants. Sampling to determine compliance with the exposure limit began at all smelters in 2000. Table VI–1 below, adapted from Taiwo *et al.* (2008), shows summary information on samples collected from the start of sampling through 2005.

TABLE VI–1—EXPOSURE SAMPLING DATA BY PLANT—2000–2005

Smelter	Number of samples	Median (µg/m³)	Arithmetic mean (µg/m³)	Geometric mean (µg/m³)
Canadian smelter 1 .....	246	0.03	0.09	0.03
Canadian smelter 2 .....	329	0.11	0.29	0.08
Italian smelter .....	44	0.12	0.14	0.10
U.S. smelter .....	346	0.03	0.26	0.04

Adapted from Taiwo *et al.*, 2008, Table 1.

All employees potentially exposed to beryllium levels at or above the action level for at least 12 days per year, or exposed at or above the STEL 12 or

more times per year, were offered medical surveillance including the BeLPT (Taiwo *et al.*, 2008, p. 158). Table VI–2 below, adapted from Taiwo

*et al.* (2008), shows test results for each facility between 2001 and 2005.

TABLE VI–2—BeLPT RESULTS BY PLANT—2001–2005

Smelter	Employees tested	Normal	Abnormal BeLPT (unconfirmed)	Confirmed Sensitized
Canadian smelter 1 .....	109	107	1	1
Canadian smelter 2 .....	291	290	1	0
Italian smelter .....	64	63	0	1
U.S. smelter .....	270	268	2	0

Adapted from Taiwo *et al.*, 2008, Table 2.

The two workers with confirmed beryllium sensitization were offered further evaluation for CBD. Both were diagnosed with CBD, based on bronchoalveolar lavage (BAL) results in one case and pulmonary function tests, respiratory symptoms, and radiographic evidence in the other.

In 2010, Taiwo *et al.* published a study of beryllium-exposed workers from smelters at four companies,

including some of the workers from the 2008 publication. 3,185 workers were determined to be “significantly exposed” to beryllium and invited to participate in BeLPT screening. Each company used different criteria to determine “significant” exposure, which appeared to vary considerably (p. 570). About 60 percent of invited workers participated in the program

between 2000 and 2006, of whom nine were determined to be sensitized (see Table VI–3 below). The authors state that all nine workers were referred to a respiratory physician for further evaluation for CBD. Two were diagnosed with CBD, as described above (Taiwo *et al.*, 2008). The authors do not report the details of other sensitized workers’ evaluation for CBD.

TABLE VI-3—MEDICAL SURVEILLANCE FOR BeS IN ALUMINUM SMELTERS

Company	Number of smelters	At-risk employees	Employees tested	BeS
A .....	4	1278	734	4
B .....	3	423	328	0
C .....	1	1100	508	4
D .....	1	384	362	1
Total .....	9	3185	1932	9

Adapted from Taiwo *et al.*, 2011, Table 1.

In general, there appeared to be a low level of sensitization and CBD among employees at the aluminum smelters studied by Taiwo *et al.* This is striking in light of the fact that many of the employees tested had worked at the smelters long before the institution of exposure limits for beryllium at some smelters in 2000. However, the authors note that respiratory protection had long been used at these plants to protect workers from other hazards. The results are roughly consistent with the observed prevalence of sensitization following the institution of respiratory protection at the Tucson beryllium ceramics plant discussed previously. A study by Nilsen *et al.* (2010) also found a low rate of sensitization among aluminum workers in Norway. Three-hundred sixty-two workers and thirty-one control individuals received BeLPT testing for beryllium sensitization. The authors found one sensitized worker (0.28 percent). No borderline results were reported. The authors reported that current exposures in this plant ranged from 0.1  $\mu\text{g}/\text{m}^3$  to 0.31  $\mu\text{g}/\text{m}^3$  (Nilsen *et al.*, 2010) and that respiratory protection was in use, as is the case in the smelters studied by Taiwo *et al.* (2008, 2010).

#### B. Preliminary Conclusions

The published literature on beryllium sensitization and CBD shows that risk of both can be substantial in workplaces in compliance with OSHA's current PEL (Kreiss *et al.*, 1993; Schuler *et al.*, 2005). The experiences of several facilities in developing effective industrial hygiene programs have shown that minimizing both airborne and dermal exposure, using a combination of engineering and administrative controls, respiratory protection, and dermal PPE, has substantially lowered workers' risk of beryllium sensitization. In contrast, risk-reduction programs that relied primarily on engineering controls to reduce workers' exposures to median levels in the range of 0.1–0.2  $\mu\text{g}/\text{m}^3$ , such as those implemented in Tucson following the 1992 survey and in Cullman during 1996–1999, had only limited impact on reducing workers' risk of sensitization.

The prevalence of sensitization among workers hired after such controls were installed at the Cullman plant remained high (Newman *et al.* (6.7 percent) and Henneberger *et al.* (9 percent)). A similar prevalence of sensitization was found in the screening conducted in 2000 at the Reading plant, where the available sampling data show median exposure levels of less than 0.2  $\mu\text{g}/\text{m}^3$  (6.5 percent). The risk of sensitization was found to be particularly high among newly-hired workers ( $\leq 1$  year of beryllium exposure) in the Reading 2000 screening (13 percent) and the Tucson 1998 screening (16 percent).

Cases of CBD have also continued to develop among workers in facilities and jobs where exposures were below 0.2  $\mu\text{g}/\text{m}^3$ . One case of CBD was found in the Tucson 1998 screening among nine sensitized workers hired less than two years previously (Henneberger *et al.*, 2001). At the Cullman plant, at least two cases of CBD were found among four sensitized workers screened in 1995–1999 and hired less than a year previously (Newman *et al.*, 2001). These results suggest a substantial risk of progression from sensitization to CBD among workers exposed at levels well below the current PEL, especially considering the extremely short time of exposure and follow-up for these workers. Six of 10 sensitized workers identified at Reading in the 2000 screening were diagnosed with CBD. The four sensitized workers who did not have CBD at their last clinical evaluation had been hired between one and five years previously; therefore, the time may have been too short for CBD to develop.

In contrast, more recent exposure control programs that have used a combination of engineering controls, PPE, and stringent housekeeping measures to reduce workers' airborne and dermal exposures have substantially lowered risk of sensitization among newly-hired workers. Of 97 workers hired between 2000 and 2004 in Tucson, where respiratory and skin protection was instituted for all workers in production

areas, only one (1 percent) worker became sensitized, and in that case the worker's dermal protection had failed during wet-machining work (Thomas *et al.*, 2009). In the aluminum smelters discussed by Taiwo *et al.*, where available exposure samples indicated median beryllium levels of about 0.1  $\mu\text{g}/\text{m}^3$  or below (measured as an 8-hour TWA) and workers used respiratory and dermal protection, confirmed cases of sensitization were rare (zero or one case per location). Sensitization was also rare among workers at a Norwegian aluminum smelter (Nilsen *et al.*, 2010), where estimated exposures in the plant ranged from 0.1  $\mu\text{g}/\text{m}^3$  to 0.3  $\mu\text{g}/\text{m}^3$  and respiratory protection was regularly used. In Reading, where in 2000–2001 airborne exposures in all jobs were reduced to a median of 0.1  $\mu\text{g}/\text{m}^3$  or below (measured as an 8-hour TWA) and dermal protection was required for production-area workers, two (5.4 percent) of 37 newly hired workers became sensitized (Thomas *et al.*, 2009). After the process with the highest exposures (median of 0.1  $\mu\text{g}/\text{m}^3$ ) was enclosed in 2002 and workers in that process were required to use respiratory protection, the remaining jobs had very low exposures (medians  $\sim 0.03 \mu\text{g}/\text{m}^3$ ). Among 45 workers hired after the enclosure, one was found to be sensitized (2.2 percent). In Elmore, where all workers were required to wear respirators and skin PPE in production areas beginning in 2000–2001, the estimated prevalence of sensitization among workers hired after these measures were put in place was around 2–3 percent (Bailey *et al.*, 2010). In addition, Schuler *et al.* (2012) found no cases of sensitization among short-term Elmore workers employed in 1999 who had total mass LTW average exposures below 0.09  $\mu\text{g}/\text{m}^3$ , among workers with total mass cumulative exposures below 0.08  $\mu\text{g}/\text{m}^3\text{-yr}$ , or among workers with total mass highest job worked exposures below 0.12  $\mu\text{g}/\text{m}^3$ .

Madl *et al.* reported one case of sensitization among workers at the Cullman plant hired after 2000. The median personal exposures were about

0.1  $\mu\text{g}/\text{m}^3$  or below for all jobs during this period. Several changes in the facility's exposure control methods were instituted in the late 1990s that were likely to have reduced dermal as well as respiratory exposure to beryllium. For example, the plant installed change/locker rooms for workers entering the production facility, instituted requirements for work uniforms and dedicated work shoes for production workers, implemented annual beryllium hazard awareness training that encouraged glove use, and purchased high efficiency particulate air (HEPA) filter vacuum cleaners for workplace cleanup and decontamination.

The results of the Reading, Tucson, and Elmore studies show that reducing airborne exposures to below 0.1  $\mu\text{g}/\text{m}^3$  and protecting workers from dermal exposure, in combination, have achieved a substantial reduction in sensitization risk among newly-hired workers. Because respirator use, dermal protection, and engineering changes were often implemented concurrently at these plants, it is difficult to attribute the reduced risk to any single control measure. The reduction is particularly evident when comparing newly-hired workers in the most recent Reading screenings (2.2–5.4 percent), and the rate of sensitization found among workers hired within the year before the 2000 screening (13 percent). There is a similarly striking difference between the rate of prevalence found among newly-hired workers in the most recent Tucson study (1 percent) and the rate found among workers hired within the year before the 1998 screening at that plant (16 percent). These results are echoed in the Cullman facility, which combined engineering controls to reduce airborne exposures to below 0.1  $\mu\text{g}/\text{m}^3$  with measures such as housekeeping improvements and worker training to reduce dermal exposure.

The studies on recent programs to reduce workers' risk of sensitization and CBD were conducted on populations with very short exposure and follow-up time. Therefore, they could not address the question of how frequently workers who become sensitized in environments with extremely low airborne exposures (median  $<0.1 \mu\text{g}/\text{m}^3$ ) develop CBD. Clinical evaluation for CBD was not reported for sensitized workers identified in the most recent Tucson, Reading, and Elmore studies. In Cullman, however, two of the workers with CBD had been employed for less than a year and worked in jobs with very low exposures (median 8-hour personal sample values of 0.03–0.09  $\mu\text{g}/\text{m}^3$ ). The body of scientific literature on occupational beryllium disease also

includes case reports of workers with CBD who are known or believed to have experienced minimal beryllium exposure, such as a worker employed only in shipping at a copper-beryllium distribution center (Stanton *et al.*, 2006), and workers employed only in administration at a beryllium ceramics facility (Kreiss *et al.*, 1996).

Arjomandi *et al.* published a study of 50 sensitized workers from a nuclear weapons research and development facility (Arjomandi *et al.*, 2010). Occupational and medical histories including physical examination and chest imaging were available for the great majority (49) of these individuals. Forty underwent testing for CBD via bronchoscopy and transbronchial biopsies. In contrast to the studies of low-exposure populations discussed previously, this group had much longer follow-up time (mean time since first exposure = 32 years) and length of employment at the facility (mean of 18 years). Quantitative exposure estimates for the workers were not presented; however, the authors characterized their probable exposures as “low” (13 workers), “moderate” (28 workers), or “high” (nine workers) based on the jobs they performed at the facility.

Five of the 50 sensitized workers (10 percent) were diagnosed with CBD based on histology or high-resolution computed tomography. An additional three (who had not undergone full clinical evaluation for CBD) were identified as probable CBD cases, bringing the total prevalence of CBD and probable CBD in this group to 16 percent. As discussed in the epidemiology section of the Health Effects chapter, the prevalence of CBD among worker populations regularly exposed at higher levels (*e.g.*, median  $>0.1 \mu\text{g}/\text{m}^3$ ) is typically much greater, approaching 80–100% in several studies. The lower prevalence of CBD in this group of sensitized workers, who were believed to have primarily low exposure levels, suggests that controlling respiratory exposure to beryllium may reduce risk of CBD among sensitized workers as well as reducing risk of CBD via prevention of sensitization. However, it also demonstrates that some workers in low-exposure environments can become sensitized and go on to develop CBD. The next section discusses an additional source of information on low-level beryllium exposure and CBD: studies of community-acquired CBD in residential areas surrounding beryllium production facilities.

### C. Review of Community-Acquired CBD Literature

The literature on community-acquired chronic beryllium disease (CA–CBD) documents cases of CBD among individuals exposed to airborne beryllium at concentrations below the proposed PEL. OSHA notes that these case studies do not provide information on how frequently individuals exposed to very low airborne levels develop CBD and that reconstructed exposure estimates for CA–CBD cases are less reliable than exposure estimates for working populations reviewed in the previous sections. In addition, the cumulative exposure that an occupationally exposed person would accrue at any given exposure concentration is far less than would typically accrue from long-term environmental exposure. The literature on CA–CBD thus has important limitations and is not used as a basis for quantitative risk assessment for CBD from low-level beryllium exposure. Nevertheless, these case reports and the broader CA–CBD literature indicate that individuals exposed to airborne beryllium below the proposed PEL can develop CBD.

Cases of CA–CBD were first reported among residents of Lorain, OH, and Reading, PA, who lived in the vicinity of beryllium plants. More recently, BeLPT screening has been used to identify additional cases of CA–CBD in Reading.

#### 1. Lorain, OH

In 1948, the State of Ohio Department of Public Health conducted an X-ray program surveying more than 6,000 people who lived within 1.5 miles of a Lorain beryllium plant (Eisenbud, 1949; Eisenbud, 1982; Eisenbud, 1998). This survey, together with a later review of all reported cases of CBD in the area, found 13 cases of CBD. All of the residents who developed CBD lived within 0.75 miles of the plant, and none had occupational exposure or lived with beryllium-exposed workers. Among the population of 500 people living within 0.25 miles of the plant, seven residents (1.4 percent) were diagnosed with CBD. Five cases were diagnosed among residents living between 0.25 and 0.5 miles from the plant, one case was diagnosed among residents living between 0.5 and 0.75 miles from the plant, and no cases were found among those living farther than 0.75 miles from the plant (total populations not reported) (Eisenbud, 1998).

Beginning in January 1948, air sampling was conducted using a mobile sampling station to measure

atmospheric beryllium downwind from the plant. An approximate concentration of  $0.2 \mu\text{g}/\text{m}^3$  was measured at 0.25 miles from the plant's exhaust stack, and concentrations decreased with greater distance from the plant, to  $0.003 \mu\text{g}/\text{m}^3$  at a distance of 5 miles (Eisenbud, 1982). A 10-week sampling program was conducted using three fixed monitoring stations within 700 feet of the plant and one station 7,000 feet from the plant. Interpolating the measurements collected at these locations, Eisenbud and colleagues estimated an average airborne beryllium concentration of between 0.004 and  $0.02 \mu\text{g}/\text{m}^3$  at a distance of 0.75 miles from the plant. Accounting for the possibility that previous exposures may have been higher due to production level fluctuations and greater use of rooftop emissions, they concluded that the lowest airborne beryllium level associated with CA-CBD in this community was somewhere between  $0.01 \mu\text{g}/\text{m}^3$  and  $0.1 \mu\text{g}/\text{m}^3$  (Eisenbud, 1982).

## 2. Reading, PA

Thirty-two cases of CA-CBD were reported in a series of papers published in 1959–1969 concerning a beryllium refinery in Reading (Lieben and Metzner, 1959; Metzner and Lieben, 1961; Dattoli *et al.*, 1964; Lieben and Williams, 1969). The plant, which opened in 1935, manufactured beryllium oxide, alloys and metal, and beryllium tools and metal products (Maier *et al.*, 2008; Sanderson *et al.*, 2001b). In a follow-up study, Maier *et al.* presented eight additional cases of CA-CBD who had lived within 1.5 miles of the plant (Maier *et al.*, 2008). Individuals with a history of occupational beryllium exposure and those who had resided with occupationally exposed workers were not classified as having CA-CBD.

The Pennsylvania Department of Health conducted extensive environmental sampling in the area of the plant beginning in 1958. Based on samples collected in 1958, Maier *et al.* stated that most cases identified in their study would typically have been exposed to airborne beryllium at levels between  $0.0155$  and  $0.028 \mu\text{g}/\text{m}^3$  on average, with the potential for some excursions over  $0.35 \mu\text{g}/\text{m}^3$  (Maier *et al.* 2008, p. 1015). To characterize exposures to cases identified in the earlier publications, Lieben and Williams cited a sampling program conducted by the Department of Health between January and July 1962, using nine sampling stations located between 0.2 and 4.8 miles from the plant. They reported that 72 percent of 24-hour

samples collected were below  $0.01 \mu\text{g}/\text{m}^3$ . Of samples that exceeded  $0.01 \mu\text{g}/\text{m}^3$ , most were collected at close proximity to the plant (*e.g.*, 0.2 miles from the plant).

In the early series of publications, cases of CA-CBD were reported among people living both close to the plant (Maier *et al.*, 2008; Dutra, 1948) and up to several miles away. Of new cases identified in the 1968 update, all lived between 3 and 7.5 miles from the plant. Lieben and Williams suggested that some cases of CA-CBD found among more distant residents might have resulted from working or visiting a graveyard closer to the plant (Lieben and Williams, 1969). For example, a milkman who developed CA-CBD had a route in the neighborhood of the plant. Another resident with CA-CBD had worked as a cleaning woman in the area of the plant, and a third worked within a half-mile of the plant.

At the time of the final follow-up study (1968), 11 residents diagnosed with CA-CBD were alive and 21 were deceased. Among those who had died, berylliosis was listed as the cause of death for three, including a 10-year-old girl and two women in their sixties. Fibrosis, granuloma or granulomatosis, and chronic or fibrous pneumonitis were listed as the cause of death for eight more of those deceased. Histologic evidence of CBD was reported for nine of 12 deceased individuals who had been evaluated for it. In addition to showing radiologic abnormalities associated with CBD, all living cases were dyspneic.

Following the 1969 publication by Liebman and Williams, no additional CA-CBD cases were reported in the Reading area until 1999, when a new case was diagnosed. The individual was a 72-year-old woman who had had abnormal chest x-rays for the previous six years (Maier *et al.*, 2008). After the diagnosis of this case, Maier *et al.* reviewed medical records and/or performed medical evaluations, including BeLPT results for 16 community residents who were referred by family members or an attorney.

Among those referred, eight cases of definite or probable CBD were identified between 1999 and 2002. All eight were women who lived between 0.1 and 1.05 miles from the plant, beginning between 1943–1953 and ending between 1956–2001. Five of the women were considered definite cases of CA-CBD, based on an abnormal blood or lavage cell BeLPT and granulomatous inflammation on lung biopsy. Three probable cases of CA-CBD were identified. One had an abnormal BeLPT and radiography consistent with CBD,

but granulomatous disease was not pathologically proven. Two met Beryllium Case Registry epidemiologic criteria for CBD based on radiography, pathology and a clinical course consistent with CBD, but both died before they could be tested for beryllium sensitization. One of the probable cases, who could not be definitively diagnosed with CBD because she died before she could be tested, was the mother of both a definite case and the probable case who had an abnormal BeLPT but did not show granulomatous disease.

The individuals with CA-CBD identified in this study suffered significant health impacts from the disease, including obstructive, restrictive, and gas exchange pulmonary defects in the majority of cases. All but two had abnormal pulmonary physiology. Those two were evaluated at early stages of disease following their mother's diagnosis. Six of the eight women required treatment with prednisone, a step typically reserved for severe cases due to the adverse side effects of steroid treatment. Despite treatment, three had died of respiratory impairment from CBD as of 2002 (Maier *et al.*, 2008). The authors concluded that “low levels of exposures with significant disease latency can result in significant morbidity and mortality” (*id.*, p. 1017).

OSHA notes that compared with the occupational studies discussed in the previous section, there is comparatively sparse information on exposure levels of Lorain and Reading residents. There remains the possibility that some individuals with CA-CBD may have had higher exposures than were known and reported in these studies, or have had unreported exposure to beryllium dust via contact with beryllium-exposed workers. Nevertheless, the studies conducted in Lorain and Reading demonstrate that long-term exposure to the apparent low levels of airborne beryllium, with sufficient disease latency, can lead to serious or fatal CBD. Genetic susceptibility may play a role in cases of CBD among individuals with very low or infrequent exposures to beryllium. The role of genetic susceptibility in the CBD disease process is discussed in detail in section V.D.3.

### D. Exposure-Response Literature on Beryllium Sensitization and CBD

To further examine the relationship between exposure level and risk of both sensitization and disease, we next review exposure-response studies in the CBD literature. Many publications have reported that exposure levels correlate with risk, including a small number of



exposure-response analyses. Most of these studies examined the association between job-specific beryllium air measurements and prevalence of sensitization and CBD. This section focuses on studies at three facilities that included a more rigorous historical reconstruction of individual worker exposures in their exposure-response analyses.

#### 1. Rocky Flats, CO, Facility

In 2000, Viet *et al.* published a case-control study of participants in the Rocky Flats Beryllium Health Surveillance Program (BHSP), which was established in 1991 to screen workers at the Department of Energy's Rocky Flats, CO, nuclear weapons facility for beryllium sensitization and evaluate sensitized workers for CBD (Viet *et al.*, 2000). The program, which at the time of publication had tested over 5,000 current and former Rocky Flats employees, had identified a total of 127 sensitized individuals as of 1994 when Viet *et al.* initiated their study.

Workers were considered sensitized if two BeLPT results were positive, either from two blood draws or from a single blood draw analyzed by two different laboratories. All sensitized individuals were offered clinical evaluation, and 51 were diagnosed with CBD based on positive lung LPT and evidence of noncaseating granulomas upon lung biopsy. The number of sensitized individuals who declined clinical evaluation was not reported. Two cases, one with CBD and one who was sensitized but not diagnosed with CBD, were excluded from the case-control analysis due to reported or potential prior beryllium exposure at a ceramics plant. Another sensitized individual who had not been diagnosed with CBD was excluded because she could not be matched by the study's criteria to a non-sensitized control within the BHSP database. Viet *et al.* matched a total of 50 CBD cases to 50 controls who were negative on the BeLPT and had the same age ( $\pm 3$  years), gender, race and smoking status, and were otherwise randomly selected from the database. Using the same matching criteria, 74 sensitized workers who were not diagnosed with CBD were age-, gender-, race-, and smoking status-matched to 74 control individuals who tested negative by the BeLPT from the BHSP database.

Viet *et al.* developed exposure estimates for the cases and controls based on daily beryllium air samples collected in one of 36 buildings where beryllium was used at Rocky Flats, the Building 444 Beryllium Machine Shop. Over half of the approximately 500,000

industrial hygiene samples collected at Rocky Flats were taken from this building. Air monitoring in other buildings was reported to be limited and inconsistent and, thus, not utilized in the exposure assessment. The sampling data used to develop worker exposure estimates were exclusively Building 444 fixed airhead (FAH) area samples collected at permanent fixtures placed around beryllium work areas and machinery.

Exposure estimates for jobs in Building 444 were constructed for the years 1960–1988 from this database. Viet *et al.* worked with Rocky Flats industrial hygienists and staff to assign a “building area factor” (BAF) to each of the other buildings, indicating the likely level of exposure in a building relative to exposures in Building 444. Industrial hygienists and staff similarly assigned a job factor (JF) to all jobs, representing the likely level of beryllium exposure relative to the levels experienced by beryllium machinists. A JF of 1 indicated the lowest exposures, and a JF of 10 indicated the highest exposures. For example, administrative work and vehicle operation were assigned a JF of 1, while machining, mill operation, and metallurgical operation were each assigned a JF of 10. Estimated FAH values for each combination of job, building and year in the study subjects' work histories were generated by multiplying together the job and building factors and the mean annual FAH exposure level. Using data collected by questionnaire from each BHSP participant, Viet *et al.* reconstructed work histories for each case and control, including job title and building location in each year of their employment at Rocky Flats. These work histories and the estimated FAH values were used to generate a cumulative exposure estimate (CEE) for each case and control in the study. A long-term mean exposure estimate (MEE) was generated by dividing each CEE by the individual's number of years employed at Rocky Flats.

Viet *et al.*'s statistical analysis of the resulting data set included conditional logistic regression analysis, modeling the relationship between risk of each health outcome and log-transformed CEE and MEE. They found highly statistically significant relationships between log-CEE and risk of CBD (coef = 0.837,  $p = 0.0006$ ) and between log-MEE (coef = 0.855,  $p = 0.0012$ ) and risk of CBD, indicating that risk of CBD increases with exposure level. These coefficients correspond to odds ratios of 6.9 and 7.2 per 10-fold increase in exposure, respectively. Risk of sensitization without CBD did not show

a statistically significant relationship with log-CEE (coef = 0.111,  $p = 0.32$ ), but showed a nearly-significant relationship with log-MEE (coef = 0.230,  $p = 0.097$ ).

#### 2. Cullman, AL, Facility

The Cullman, AL, precision machining facility discussed previously was the subject of a case-control study published by Kelleher *et al.* in 2001. After the diagnosis of an index case of CBD at the plant in 1995, NJMRC researchers worked with the plant to conduct a medical surveillance program using the BeLPT to screen workers biennially for beryllium sensitization and CBD. Of 235 employees screened between 1995 and 1999, 22 (9.4 percent) were found to be sensitized, including 13 diagnosed with CBD (Newman *et al.*, 2001). Concurrently, research was underway by Martyny *et al.* to characterize the particle size distribution of beryllium exposures generated by processes at this plant (Martyny *et al.*, 2000). The exposure research showed that the machining operations during this time period generated respirable particles (10  $\mu\text{m}$  or less) at the worker breathing zone that made up greater than 50 percent of the beryllium mass. Kelleher *et al.* used the dataset of 100 personal lapel samples collected by Martyny *et al.* and other NJMRC researchers in 1996, 1997, and 1999 to characterize exposures for each job in the plant. Following a statistical analysis comparing the samples collected by NJMRC with earlier samples collected at the plant, Kelleher *et al.* concluded that the 1996–1999 data could be used to represent job-specific exposures from earlier periods.

Detailed work history information gathered from plant data and worker interviews was used in combination with job exposure estimates to characterize cumulative and LTW average beryllium exposures for workers in the surveillance program. In addition to cumulative and LTW exposure estimates based the total mass of beryllium reported in their exposure samples, Kelleher *et al.* calculated cumulative and LTW estimates based specifically on exposure to particles < 6  $\mu\text{m}$  and particles < 1  $\mu\text{m}$  in diameter.

To analyze the relationship between exposure level and risk of sensitization and CBD, Kelleher *et al.* performed a case-control analysis using measures of both total beryllium exposure and particle size-fractionated exposure. The analysis included sensitization cases identified in the 1995–1999 surveillance and 206 controls from the group of 215 non-sensitized workers. For nine workers, the researchers could not

reconstruct complete job histories. Logistic regression models using categorical exposure variables showed positive associations between risk of sensitization and the six exposure measures tested: Total CEE, total MEE, and variations of CEE and MEE constructed based on particles < 6 µm and < 1 µm in diameter. None of the associations were statistically significant ( $p < 0.05$ ); however, the authors noted that the dataset was relatively small, with limited power to detect a statistically significant exposure-response relationship.

Although the Viet *et al.* and Kelleher *et al.* exposure-response analyses provide valuable insight into exposure-response for beryllium sensitization and CBD, both studies have limitations that affect their suitability as a basis for quantitative risk assessment. Their limitations primarily involve the exposure data used to estimate workers' exposures. Viet *et al.*'s exposure reconstruction was based on area samples from a single building within a large, multi-building facility. Where possible, OSHA prefers to base risk estimates on exposure data collected in the breathing zone of workers rather than area samples, because data collected in the breathing zone more accurately represent workers' exposures. Kelleher's analysis, on the other hand, was based on personal lapel samples. However, the samples Kelleher *et al.* used were collected between 1996 and 1999, after the facility had initiated new exposure control measures in response to the diagnosis of a case of CBD in 1995. OSHA believes that industrial hygiene samples collected at the Cullman plant prior to 1996 better characterize exposures prior to the new exposure controls. In addition, since the publication of the Kelleher study, the population has continued to be screened for sensitization and CBD. Data collected on workers hired in 2000 and later, after most exposure controls had been completed, can be used to characterize risk at lower levels of exposure than have been examined in many previous studies.

To better characterize the relationship between exposure level and risk of sensitization and CBD, OSHA developed an independent exposure-response analysis based on a dataset maintained by NJMRC on workers at the Cullman, AL, machining plant. The dataset includes exposure samples collected between 1980 and 2005, and has updated work history and screening information for several hundred workers through 2003. OSHA's analysis of the NJMRC data set is presented in the next

section, E. OSHA's Exposure-Response Analysis.

### 3. Elmore, OH, Facility

After OSHA completed its analysis of the NJMRC data set, Schuler *et al.* (2012) published a study examining beryllium sensitization and CBD among 264 short-term workers employed at the previously described Elmore, OH plant in 1999. The analysis used a high-quality exposure reconstruction by Virji *et al.* (2012) and presented a regression analysis of the relationship between beryllium exposure levels and beryllium sensitization and CBD in the short-term worker population. By including only short-term workers, Virji *et al.* were able to construct participants' exposures with more precision than was possible in studies involving workers exposed for longer durations and in time periods with less exposure sampling. In addition, the focus on short-term workers allowed more precise knowledge of when sensitization and CBD occurred than had been the case for previously published cross-sectional studies of long-term workers. Each participant completed a work history questionnaire and was tested for beryllium sensitization, and sensitized workers were offered further evaluation for CBD. The overall prevalence of sensitization was 9.8 percent (26/264). Twenty-two sensitized workers consented to clinical testing for CBD via transbronchial biopsy. Six of those sensitized were diagnosed with CBD (2.3 percent, 6/264).

Schuler *et al.* (2012) used logistic regression to explore the relationship between estimated beryllium exposure and sensitization and CBD, using estimates of total, respirable, and submicron mass concentrations. Exposure estimates were constructed using two exposure surveys conducted in 1999: a survey of total mass exposures (4,022 full-shift personal samples) and a survey of size-separated impactor samples (198 samples). The 1999 exposure surveys and work histories were used to estimate long-term lifetime weighted (LTW) average, cumulative, and highest-job-worked exposure for total, respirable, and submicron beryllium mass concentrations.

For beryllium sensitization, logistic models showed elevated odds ratios for average (OR 1.48) and highest job (OR 1.37) exposure for total mass exposure; the OR for cumulative exposure was smaller (OR 1.23) and borderline statistically significant (95 percent CI barely included unity). Relationships between sensitization and respirable exposure estimates were similarly

elevated for average (OR 1.37) and highest job (OR 1.32). Among the submicron exposure estimates, only highest job (OR 1.24) had a 95 percent CI that just included unity for sensitization. For CBD, elevated odds ratios were observed only for the cumulative exposure estimates and were similar for total mass and respirable exposure (total mass OR 1.66, respirable (OR 1.68). Cumulative submicron exposure showed an elevated, borderline significant odds ratio (OR 1.58). The odds ratios for average exposure and highest-exposed job were not statistically significantly elevated. Schuler *et al.* concluded that both total and respirable mass concentrations of beryllium exposure were relevant predictors of risk for beryllium sensitization and CBD.

### E. OSHA's Exposure-Response Analysis

OSHA evaluated exposure and health outcome data on a population of workers employed at the Cullman machining facility. NJMRC researchers, with consent and information provided by the facility, compiled a dataset containing employee work histories, medical diagnoses, and air sampling results and provided it to OSHA for analysis. OSHA's contractors from Eastern Research Group (ERG) gathered additional information from (1) two surveys of the Cullman plant conducted by OSHA's contractor (ERG, 2003 and ERG, 2004a), (2) published articles of investigations conducted at the plant by researchers from NJMRC (Kelleher *et al.*, 2001; Madl *et al.*, 2007; Martyny *et al.*, 2000; and Newman *et al.*, 2001), (3) a case file from a 1980 OSHA complaint inspection at the plant, (4) comments submitted to the OSHA docket office in 1976 and 1977 by representatives of the metal machining plant regarding their beryllium control program, and (5) personal communications with the plant's current industrial hygienist (ERG, 2009b) and an industrial hygiene researcher at NJMRC (ERG, 2009a).

#### 1. Plant Operations

The Cullman plant is a leading fabricator of precision-machined and processed materials including beryllium and its alloys, titanium, aluminum, quartz, and glass (ERG, 2009b). The plant has approximately 210 machines, primarily mills and lathes, and processes large quantities of beryllium on an annual basis. The plant provides complete fabrication services including ultra-precision machining; ancillary processing (brazing, ion milling, photo etching, precision cleaning, heat treating, stress relief, thermal cycling, mechanical assembly, and chemical

milling/etching); and coatings (plasma spray, anodizing, chromate conversion coating, nickel sulfamate plate, nickel plate, gold plate, black nickel plate, copper plate/strike, passivation, and painting). Most of the plant's beryllium operations involve machining beryllium metal and high beryllium content composite materials (beryllium metal/beryllium oxide metal composites called E-Metal or E-Material), with occasional machining of beryllium oxide/metal matrix (such as AlBeMet, aluminum beryllium matrix) and beryllium-containing alloys. E-Materials such as E-20 and E-60 are currently processed in the E-Cell department.

The 120,000 square-foot plant has two main work areas: a front office area and a large, open production shop. Operations in the production shop include inspection of materials, machining, polishing, and quality assurance. The front office is physically separated from the production shop. Office workers enter through the front of the facility and have access to the production shop through a change room where they must don laboratory coats and shoe covers to enter the production area. Production workers enter the shop area at the rear of the facility where a change/locker room is available to change into company uniforms and work shoes. Support operations are located in separate areas adjacent to the production shop and include management and administration, sales, engineering, shipping and receiving, and maintenance. Management and administrative personnel include two groups: those primarily working in the front offices (front office management) and those primarily working on the shop floor (shop management).

In 1974, the company moved its precision machining operations to the plant's current location in Cullman. Workplace exposure controls reportedly did not change much until the diagnosis of an index case of CBD in 1995. Prior to 1995, exposure controls for machining operations primarily included a low volume/high velocity (LVHV) central exhaust system with operator-adjusted exhaust pickups and wet machining methods. Protective clothing, gloves, and respiratory protection were not required. After the diagnosis, the facility established an in-house target exposure level of  $0.2 \mu\text{g}/\text{m}^3$ , installed change/locker rooms for workers entering the production facility, eliminated pressurized air hoses, discouraged the use of dry sweeping, initiated biennial medical surveillance using the BeLPT, and implemented annual beryllium hazard awareness training.

In 1996, the company instituted requirements for work uniforms and dedicated work shoes for production workers, eliminated dry sweeping in all departments, and purchased high-efficiency particulate air (HEPA) filter vacuum cleaners for workplace cleanup and decontamination. Major engineering changes were also initiated in 1996, including the purchase of a new local exhaust ventilation (LEV) system to exhaust machining operations producing finer aerosols (e.g., dust and fume versus metal chips). The facility also began installing mist eliminators for each machine. Departments affected by these changes included cutter grind (tool and die), E-cell, electrical discharge machining (EDM), flow lines, grind, lapping, and optics. Dry machining operations producing chips were exhausted using the existing LVHV exhaust system (ERG, 2004a). In the course of making the ventilation system changes, old ductwork and baghouses were dismantled and new ductwork and air cleaning devices were installed. The company also installed Plexiglas enclosures on machining operations in 1996–1997, including the lapping, deburring, grinding, EDM, and tool and die operations. In 1998, LEV was installed in EDM and modified in the lap, deburr, and grind departments.

Most exposure controls were reportedly in place by 2000 (ERG, 2009a). In 2004, the plant industrial hygienist reported that all machines had LEV and about 65 percent were also enclosed with either partial or full enclosures to control the escape of machining coolant (ERG, 2004b). Over time, the facility has built enclosures for operations that consistently produce exposures greater than  $0.2 \mu\text{g}/\text{m}^3$ . The company has never required workers to use gloves or other PPE.

## 2. Air Sampling Database and Job Exposure Matrix (JEM)

The NJMRC dataset includes industrial hygiene sampling results collected by the plant (1980–1984 and 1995–2005) and NJMRC researchers (June 1996 to February 1997 and September 1999), including 4,370 breathing zone (personal lapel) samples and 712 area samples (ERG, 2004b). Limited air sampling data is available before 1980 and no exposure data appears to be available for the 10-year time period 1985 through 1994. A review of the NJMRC air sampling database from 1995 through 2005 shows a significant increase in the number of air samples collected beginning in 2000, which the plant industrial hygienist attributes to an increase in the number of air sampling pumps (from 5 to 23)

and the purchase of an automated atomic absorption spectrophotometer.

ERG used the personal breathing zone sampling results contained in the sample database to quantify exposure levels for each year and for several-year periods. Separate exposure statistics were calculated for each job included in the job history database. For each job included in the job history database, ERG estimated the arithmetic mean, geometric mean, median, minimum, maximum, and 95th percentile value for the available exposure samples. Prior to generating these statistics ERG made several adjustments. After consultation with researchers at NJMRC, four particularly high exposures were identified as probably erroneous and excluded from calculations. In addition, a 1996 sample for the HS (Health and Safety) process was removed from the sample calculations after ERG determined it was for a non-employee researcher visiting the facility.

Most samples in the sample database for which sampling times were recorded were long-term samples: 2,503 of the 2,557 (97.9 percent) breathing zone samples with sampling time recorded had times greater than or equal to 400 minutes. No adjustments were made for sampling time, except in the case of four samples for the "maintenance" process for 1995. These results show relatively high values and exceptionally short sampling times consistent with the nature of much maintenance work, marked by short-term exposures and periods of no exposure. The four 1995 maintenance samples were adjusted for an eight-hour sampling time assuming that the maintenance workers received no further beryllium exposure over the rest of their work shift.

OSHA examined the database for trends in exposure by reviewing sample statistics for individual years and grouping years into four time periods that correspond to stages in the plant's approach to beryllium exposure control. These were: 1980–1995, a period of relatively minimal control prior to the 1995 discovery of a case of CBD among the plant's workers; 1996–1997, a period during which some major engineering controls were in the process of being installed on machining equipment; 1998–1999, a period during which most engineering controls on the machining equipment had been installed; and 2000–2003, a period when installation of all exposure controls on machining equipment was complete and exposures very low throughout the plant. Table VI-4 below summarized the available data for each time period. As the four probable sampling errors identified in

the original data set are excluded here, arithmetic mean values are presented.

TABLE VI-4—EXPOSURE VALUES FOR MACHINING JOB TITLES, EXCLUDING PROBABLE SAMPLING ERRORS ( $\mu\text{g}/\text{m}^3$ ) IN NJMRC DATA SET

Job title	1980–1995		1996–1997		1998–1999		2000–2003	
	Samples	Mean	Samples	Mean	Samples	Mean	Samples	Mean
Deburring .....	27	1.17	19	1.29	0	NA	67	0.1
Electrical Discharge Machining .....	2	0.06	2	1.32	16	0.08	63	0.1
Grinding .....	12	3.07	6	0.49	15	0.24	68	0.1
Lapping .....	9	0.15	16	0.24	42	0.21	103	0.1
Lathe .....	18	0.88	8	1.13	40	0.17	200	0.1
Milling .....	43	0.64	15	0.23	95	0.17	434	0.1

Reviewing the revised statistics for individual years for different groupings, OSHA noted that exposures in the 1996–1997 period were for some machining jobs equivalent to, or even higher than, exposure levels recording during the 1980–1995 period. During

1996–1997, major engineering controls were being installed, but exposure levels were not yet consistently reduced.

Table VI-5 below summarizes exposures for the four time periods in jobs other than beryllium machining.

These include jobs such as administrative work, health and safety, inspection, toolmaking ('Tool' and 'Cgrind'), and others. A description of jobs by title is available in the risk assessment background document.

TABLE VI-5—EXPOSURE VALUES FOR NON-MACHINING JOB TITLES ( $\mu\text{g}/\text{m}^3$ ) IN NJMRC DATA SET

Job title	1980–1995		1996–1997		1998–1999		2000–2003	
	Samples	mean	Samples	mean	Samples	mean	Samples	mean
Administration .....	0	NA	0	NA	39	0.052	74	0.061
Assembly .....	0	NA	0	NA	8	0.136	2	0.051
Cathode .....	0	NA	0	NA	0	NA	9	0.156
Cgrind .....	1	0.120	0	NA	14	0.105	76	0.112
Chem .....	0	NA	1	0.529	21	0.277	91	0.152
Ecell .....	0	NA	13	1.873	0	NA	26	0.239
Engineering .....	1	0.065	0	NA	49	0.069	125	0.062
Flow Lines .....	0	NA	0	NA	0	NA	113	0.083
Gas .....	0	NA	0	NA	0	NA	121	0.058
Glass .....	0	NA	0	NA	0	NA	38	0.068
Health and Safety <sup>8</sup> .....	0	NA	0	NA	0	NA	5	0.076
Inspection .....	0	NA	0	NA	32	0.101	150	0.066
Maintenance .....	4	1.257	1	0.160	16	0.200	70	0.126
Msupp .....	0	NA	0	NA	47	0.094	68	0.081
Optics .....	0	NA	0	NA	0	NA	41	0.090
PCIC .....	1	0.040	0	NA	13	0.071	42	0.083
Qroom .....	1	0.280	0	NA	0	NA	2	0.130
Shop .....	0	NA	0	NA	4	0.060	0	NA
Spec .....	3	0.247	0	NA	24	0.083	19	0.087
Tool .....	0	NA	0	NA	0	NA	1	0.070

From Table VI-5, it is evident that exposure samples are not available for many non-machining jobs prior to 2000. Where samples are available before 2000, sample numbers are small, particularly prior to 1998. In jobs for which exposure values are available in 1998–1999 and 2000–2003, exposures appear either to decline from 1998–1999 to 2000–2003 (Assembly, Chem, Inspection, Maintenance) or to be roughly equivalent (Administration,

Cgrind, Engineering, Msupp, PCIC, and Spec). Among the jobs with exposure samples prior to 1998, most had very few (1–5) samples, with the exception of Ecell (13 samples in 1996–1997). Based on this limited information, it appears that exposures declined from the period before the first identification of a CBD case to the period in which exposure controls were introduced.

Because exposure results from 1996–1997 were not found to be consistently reduced in comparison to the 1985–1995 period in primary machining jobs, these two periods were grouped together in the JEM. Exposure monitoring for jobs other than the primary machining operations were represented by a single

mean exposure value for 1980–2003. As respiratory protection was not routinely used at the plant, there was no adjustment for respiratory protection in workers' exposure estimates. The job exposure matrix is presented in full in the background document for the quantitative risk assessment.

### 3. Worker Exposure Reconstruction

The work history database contains job history records for 348 workers, including start years, duration of employment, and percentage of worktime spent in each job. One hundred ninety-eight of the workers had been employed at some point in primary machining jobs, including deburring,

<sup>8</sup> An exceptionally high result (0.845  $\mu\text{g}/\text{m}^3$ , not shown in Table 5) for a 1996 sample for the HS (Health and Safety) process was removed from the sample calculations. OSHA's contractor determined this sample to be associated with a non-employee researcher visiting the facility.

EDM, grinding, lapping, lathing, and milling. The remainder worked only in non-primary machining jobs, such as administration, engineering, quality control, and shop management. The total number of years worked at each job are presented as integers, leaving some uncertainty regarding the worker's exact start and end date at the job.

Based on these records and the JEM described previously, ERG calculated cumulative and average exposure estimates for each worker in the database. Cumulative exposure was calculated as,  $\sum_i e_i t_i$ , where  $e_i$  is the exposure level for job (i), and  $t_i$  is the time spent in job (i). Cumulative exposure was divided by total exposure time to estimate each worker's long-term average exposure. These exposures were computed in a time-dependent manner for the statistical modeling. For workers with beryllium sensitization or CBD, exposure estimates excluded exposures following diagnosis.

Workers who were employed for long time periods in jobs with low-level exposures tend to have low average and cumulative exposures due to the way these measures are constructed, incorporating the worker's entire work history. As discussed in the Health Effects chapter, higher-level exposures or short-term peak exposures such as those encountered in machining jobs may be highly relevant to risk of sensitization. Unfortunately, because it is not possible to continuously monitor individuals' beryllium exposure levels and sensitization status, it is not known exactly when workers became sensitized or what their "true" peak exposures leading up to sensitization were. Only a rough approximation of the upper levels of exposure a worker experienced is possible. ERG constructed a third type of exposure estimate reflecting the exposure level associated with the highest-exposure job (HEJ) and time period experienced by each worker. This exposure estimate (HEJ), the

cumulative exposure estimate, and the average exposure were used in the quartile analysis and statistical analyses.

4. Prevalence of Sensitization and CBD

In the database provided to OSHA, seven workers were reported as sensitized only. Sixteen workers were listed as sensitized and diagnosed with CBD upon initial clinical evaluation. Three workers, first shown to be sensitized only, were later diagnosed with CBD. Tables VI-6, VI-7, and VI-8 below present the prevalence of sensitization and CBD cases across several categories of lifetime-weighted (LTW) average, cumulative, and highest-exposed job (HEJ) exposure. Exposure values were grouped by quartile. Note that all workers with CBD are also sensitized. Thus, the columns "Total Sensitized" and "Total %" refer to all sensitized workers in the dataset, including workers with and without a diagnosis of CBD.

TABLE VI-6—PREVALENCE OF SENSITIZATION AND CBD BY LTW AVERAGE EXPOSURE QUARTILE IN NJMRC DATA SET

Average exposure ( $\mu\text{g}/\text{m}^3$ )	Group size	Sensitized only	CBD	Total sensitized	Total %	CBD %
0.0–0.080	91	1	1	2	2.2	1.0
0.081–0.18	73	2	4	6	8.2	5.5
0.19–0.51	77	0	6	6	7.8	7.8
0.51–2.15	78	4	8	12	15.4	10.3
Total	319	7	19	26	8.2	6.0

TABLE VI-7—PREVALENCE OF SENSITIZATION AND CBD BY CUMULATIVE EXPOSURE QUARTILE IN NJMRC DATA SET

Cumulative exposure ( $\mu\text{g}/\text{m}^3\text{-yrs}$ )	Group size	Sensitized only	CBD	Total sensitized	Total %	CBD %
0.0–0.147	81	2	2	4	4.9	2.5
0.148–1.467	79	0	2	2	2.5	2.5
1.468–7.008	79	3	8	11	13.9	8.0
7.009–61.86	80	2	7	9	11.3	8.8
Total	319	7	19	26	8.2	6.0

TABLE VI-8—PREVALENCE OF SENSITIZATION AND CBD BY HIGHEST-EXPOSED JOB EXPOSURE QUARTILE IN NJMRC DATA SET

HEJ exposure ( $\mu\text{g}/\text{m}^3$ )	Group size	Sensitized only	CBD	Total sensitized	Total %	CBD %
0.0–0.086	86	1	0	1	1.2	0.0
0.091–0.214	81	1	6	7	8.6	7.4
0.387–0.691	76	2	9	11	14.5	11.8
0.954–2.213	76	3	4	7	9.2	5.3
Total	319	7	19	26	8.2	6.0

Table VI-6 shows increasing prevalence of total sensitization and CBD with increasing LTW average exposure, measured both as average and cumulative exposure. The lowest

prevalence of sensitization and CBD was observed among workers with average exposure levels less than or equal to  $0.08 \mu\text{g}/\text{m}^3$ , where two sensitized workers (2.2 percent) including one case

of CBD (1.0 percent) were found. The sensitized worker in this category without CBD had worked at the facility as an inspector since 1972, one of the lowest-exposed jobs at the plant.

Because the job was believed to have very low exposures, it was not sampled prior to 1998. Thus, estimates of exposures in this job are based on data from 1998–2003 only. It is possible that exposures earlier in this worker's employment history were somewhat higher than reflected in his estimated average exposure. The worker diagnosed with CBD in this group had been hired in 1996 in production control, and had an estimated average exposure of 0.08  $\mu\text{g}/\text{m}^3$ . He was diagnosed with CBD in 1997.

The second quartile of LTW average exposure (0.081–0.18  $\mu\text{g}/\text{m}^3$ ) shows a marked rise in overall prevalence of beryllium-related health effects, with six workers sensitized (8.2 percent), of whom four (5.5 percent) were diagnosed with CBD. Among six sensitized workers in the third quartile (0.19–0.50  $\mu\text{g}/\text{m}^3$ ), all were diagnosed with CBD (7.8 percent). Another increase in prevalence is seen from the third to the fourth quartile, with 12 cases of sensitization (15.4 percent), including eight (10.3 percent) diagnosed with CBD.

The quartile analysis of cumulative exposure also shows generally increasing prevalence of sensitization and CBD with increasing exposure. As shown in Table VI–7, the lowest prevalences of CBD and sensitization are in the first two quartiles of cumulative exposure (0.0–0.147  $\mu\text{g}/\text{m}^3\text{-yrs}$ , 0.148–1.467  $\mu\text{g}/\text{m}^3\text{-yrs}$ ). The upper bound on this cumulative exposure range, 1.467  $\mu\text{g}/\text{m}^3\text{-yrs}$ , is the cumulative exposure that a worker would have if exposed to beryllium at a level of 0.03  $\mu\text{g}/\text{m}^3$  for a working lifetime of 45 years; 0.15  $\mu\text{g}/\text{m}^3$  for ten years; or 0.3  $\mu\text{g}/\text{m}^3$  for five years.

A sharp increase in prevalence of sensitization and CBD and total sensitization occurs in the third quartile (1.468–7.008  $\mu\text{g}/\text{m}^3\text{-yrs}$ ), with roughly similar levels of both in the highest group (7.009–61.86  $\mu\text{g}/\text{m}^3\text{-yrs}$ ). Cumulative exposures in the third quartile would be experienced by a worker exposed for 45 years to levels between 0.03 and 0.16  $\mu\text{g}/\text{m}^3$ , for 10 years to levels between 0.15 and 0.7  $\mu\text{g}/\text{m}^3$ , or for five years to levels between 0.3 and 1.4  $\mu\text{g}/\text{m}^3$ .

When workers' exposures from their highest-exposed job are considered, the exposure-response pattern is similar to that for LTW average exposure in the lower quartiles (Table VI–8). The lowest prevalence is observed in the first quartile (0.0–0.86  $\mu\text{g}/\text{m}^3$ ), with sharply rising prevalence from first to second and second to third exposure quartiles. The prevalence of sensitization and CBD in the top quartile (0.954–2.213  $\mu\text{g}/\text{m}^3$ )

decreases relative to the third, with levels similar to the overall prevalence in the dataset. Many workers in the highest exposure quartiles are long-time employees, who were hired during the early years of the shop when exposures were highest. One possible explanation for the drop in prevalence in the highest exposure quartiles is that highly-exposed workers from early periods may have developed CBD and left the plant before sensitization testing began in 1995.

It is of some value to compare the prevalence analysis of the Cullman (NJMRC) data set with the results of the Reading and Tucson studies discussed previously. An exact comparison is not possible, in part because the Reading and Tucson exposure values are associated with jobs and the NJMRC values are estimates of lifetime weighted average, cumulative, and highest-exposed job (HEJ) exposures for individuals in the data set. Nevertheless, OSHA believes it is possible to very roughly compare the results of the Reading and Tucson studies and the results of the NJMRC prevalence analysis presented above. As discussed in detail below, OSHA found a general consistency between the prevalence of sensitization and CBD in the quartiles of average exposure in the NJMRC data set and the prevalence of sensitization and CBD at the Reading and Tucson plants for similar exposure values.

Personal lapel samples collected at the Reading plant between 1995 and 2000 were relatively low overall (median of 0.073  $\mu\text{g}/\text{m}^3$ ), with higher exposures (median of 0.149  $\mu\text{g}/\text{m}^3$ ) concentrated in the wire annealing and pickling process (Schuler *et al.*, 2005). Exposures in the Reading plant in this time period were similar to the second-quartile average (Table VI–6–0.081–0.18  $\mu\text{g}/\text{m}^3$ ). The prevalence of sensitization observed in the NJMRC second quartile was 8.2 percent and appears roughly consistent with the prevalence of sensitization among Reading workers in the mid-1990s (11.5 percent). The reported prevalence of CBD (3.9 percent) among the Reading workforce was also consistent with that observed in the second NJMRC quartile (5.5 percent). After 2000, exposure controls reduced exposures in most Reading jobs to median levels below 0.03  $\mu\text{g}/\text{m}^3$ , with a median value of 0.1  $\mu\text{g}/\text{m}^3$  for the wire annealing and pickling process. The wire annealing and pickling process was enclosed and stringent respirator and skin protection requirements were applied for workers in that area after 2002, essentially eliminating airborne and dermal exposures for those workers.

Thomas *et al.* (2009) reported that one of 45 workers (2.2 percent) hired after the enclosure in 2002 was confirmed as sensitized, a value in line with the sensitization prevalence observed in the lowest quartiles of average exposure (2.2 percent, 0.0–0.08  $\mu\text{g}/\text{m}^3$ ).

As with Reading, the prevalence of sensitization observed at Tucson and in the NJMRC data set are not exactly comparable due to the different natures of the exposure estimates. Nevertheless, in a rough sense the results of the Tucson study and the NJMRC prevalence analysis appear similar. In Tucson, a 1998 BeLPT screening showed that 9.5 percent of workers hired after 1992 were sensitized (Henneberger *et al.*, 2001). Personal full-shift exposure samples collected in production jobs between 1994 and 1999 had a median of 0.2  $\mu\text{g}/\text{m}^3$  (0.1  $\mu\text{g}/\text{m}^3$  for non-production jobs). In the NJMRC data set, a sensitization prevalence of 8.2 percent was seen among workers with average exposures between 0.081 and 0.18  $\mu\text{g}/\text{m}^3$ . At the time of the 1998 screening, workers hired after 1992 had a median one year since first beryllium exposure and, therefore, CBD prevalence was only 1.4 percent. This prevalence is likely an underestimate since CBD often requires more than a year to develop. Longer-term workers at the Tucson plant with a median 14 years since first beryllium exposure had a 9.1 percent prevalence of CBD. There was a 5.5 percent prevalence of CBD among the entire workforce (Henneberger *et al.*, 2001). As with the Reading plant employees, this reported prevalence is reasonably consistent with the 5.5 percent CBD prevalence observed in the second NJMRC quartile.

Beginning in 1999, the Tucson facility instituted strict requirements for respiratory protection and other PPE, essentially eliminating airborne and dermal exposure for most workers. After these requirements were put in place, Cummings *et al.* (2007) reported only one case of sensitization (1 percent; associated with a PPE failure) among 97 workers hired between 2000 and 2004. This appears roughly in line with the sensitization prevalence of 2.2 percent observed in the lowest quartiles of average exposure (0.0–0.08  $\mu\text{g}/\text{m}^3$ ) in the NJMRC data set.

While the literature analysis presented here shows a clear reduction in risk with well-controlled airborne exposures ( $\leq 0.1 \mu\text{g}/\text{m}^3$  on average) and protection from dermal exposure, the level of detail presented in the published studies limits the Agency's ability to characterize risk at all the alternate PELs OSHA is considering. To better understand these risks, OSHA

used the NJMRC dataset to characterize risk of sensitization and CBD among workers exposed to each of the alternate PELs under consideration in the proposed beryllium rule.

*F. OSHA's Statistical Modeling*

OSHA's contractor performed a complementary log-log proportional hazards model using the NJMRC data set. The proportional hazards model is a generalization of logistic regression that allows for time-dependent exposures and differential time at risk. The proportional hazards model accounts for the fact that individuals in the dataset are followed for different amounts of time, and that their exposures change over time. The proportional hazards model provides hazards ratios, which estimate the relative risk of disease at a specified time for someone with exposure level 1 compared to exposure level 2. To perform this analysis, OSHA's

contractor constructed exposure files with time-dependent cumulative and average exposures for each worker in the data set in each year that a case of sensitization or CBD was identified. Workers were included in only those years after they started working at the plant and continued to be followed. Sensitized cases were not included in analysis of sensitization after the year in which they were identified as being sensitized, and CBD cases were not included in analyses of CBD after the year in which they were diagnosed with CBD. Follow-up is censored after 2002 because work histories were deemed to be less reliable after that date.

The results of the discrete proportional hazards analyses are summarized in Tables VI-9-12 below. All coefficients used in the models are displayed, including the exposure coefficient, the model constant for diagnosis in 1995, and additional exposure-independent coefficients for

each succeeding year (1996-1999 for sensitization and 1996-2002 for CBD) of diagnosis that are fit in the discrete time proportional hazards modeling procedure. Model equations and variables are explained more fully in the companion risk assessment background document.

Relative risk of sensitization increased with cumulative exposure (p = 0.05). A positive, but not statistically significant, association was observed with LTW average exposure (p = 0.09). The association was much weaker for exposure duration (p = 0.31), consistent with the expected biological action of an immune hypersensitivity response where onset is believed to be more dependent on the concentration of the sensitizing agent at the target site rather than the number of years of occupational exposure. The association was also much weaker for highest-exposed job (HEJ) exposure (p = 0.3).

TABLE VI-9—PROPORTIONAL HAZARDS MODEL—CUMULATIVE EXPOSURE AND SENSITIZATION

Variable	Coefficient	95% Confidence interval	P-value
Cumulative Exposure (µg/m <sup>3</sup> -yrs) .....	0.031	0.00 to 0.063 .....	0.05
constant .....	-3.48	-4.27 to -2.69 .....	<0.001
1996 .....	-1.49	-3.04 to 0.06 .....	0.06
1997 .....	-0.29	-1.31 to 0.72 .....	0.57
1998 .....	-1.56	-3.11 to -0.01 .....	0.05
1999 .....	-1.57	-3.12 to -0.02 .....	0.05

TABLE VI-10—PROPORTIONAL HAZARDS MODEL—LTW AVERAGE EXPOSURE AND SENSITIZATION

Variable	Coefficient	95% Confidence interval	P-value
Average Exposure (µg/m <sup>3</sup> ) .....	0.54	-0.09 to 1.17 .....	0.09
constant .....	-3.55	-4.42 to -2.69 .....	<0.001
1996 .....	-1.48	-3.03 to 0.07 .....	0.06
1997 .....	-0.29	-1.31 to 0.72 .....	0.57
1998 .....	-1.54	-3.09 to 0.01 .....	0.05
1999 .....	-1.53	-3.08 to 0.03 .....	0.05

TABLE VI-11—PROPORTIONAL HAZARDS MODEL—EXPOSURE DURATION AND SENSITIZATION

Variable	Coefficient	95% Confidence interval	P-value
Exposure Duration (years) .....	0.03	-0.03 to 0.08 .....	0.31
constant .....	-3.55	-4.57 to -2.53 .....	<0.001
1996 .....	-1.48	-3.03 to 0.70 .....	0.06
1997 .....	-0.30	-1.31 to 0.72 .....	0.57
1998 .....	-1.59	-3.14 to -0.04 .....	0.05
1999 .....	-1.62	-3.17 to -0.72 .....	0.04

TABLE VI-12—PROPORTIONAL HAZARDS MODEL—HEJ EXPOSURE AND SENSITIZATION

Variable	Coefficient	95% Confidence interval	P-value
HEJ Exposure (µg/m <sup>3</sup> ) .....	0.31	-0.27 to 0.88 .....	0.30
constant .....	-3.42	-4.27 to -2.56 .....	<0.001
1996 .....	-1.49	-3.04 to 0.06 .....	0.06
1997 .....	-0.31	-1.33 to 0.70 .....	0.55
1998 .....	-1.59	-3.14 to -0.04 .....	0.05
1999 .....	-1.60	-3.15 to -0.05 .....	0.04

The proportional hazards models for the CBD endpoint (Tables VI-13 through 16 below) showed positive relationships with cumulative exposure (p = 0.09) and duration of exposure (p = 0.10). However, the association with the cumulative exposure metric was not as strong as that for sensitization, probably due to the smaller number of CBD cases. LTW average exposure and HEJ exposure were not closely related to relative risk of CBD (p-values > 0.5).

TABLE VI-13—PROPORTIONAL HAZARDS MODEL—CUMULATIVE EXPOSURE AND CBD

Variable	Coefficient	95% Confidence interval	P-value
Cumulative Exposure (µg/m <sup>3</sup> -yrs)	0.03	.00 to 0.07	0.09
constant	-3.77	-4.67 to -2.86	<0.001
1997	-0.59	-1.86 to 0.68	0.36
1998	-2.01	-4.13 to 0.11	0.06
1999	-0.63	-1.90 to 0.64	0.33
2002	-2.13	-4.25 to -0.01	0.05

TABLE VI-14—PROPORTIONAL HAZARDS MODEL—LTW AVERAGE EXPOSURE AND CBD

Variable	Coefficient	95% Confidence interval	P-value
Average Exposure (µg/m <sup>3</sup> )	0.24	-0.59 to 1.06	0.58
constant	-3.62	-4.60 to -2.64	<0.001
1997	-0.61	-1.87 to 0.66	0.35
1998	-2.02	-4.14 to 0.10	0.06
1999	-0.64	-1.92 to 0.63	0.32
2002	-2.15	-4.28 to -0.02	0.05

TABLE VI-15—PROPORTIONAL HAZARDS MODEL—EXPOSURE DURATION AND CBD

Variable	Coefficient	95% Confidence interval	P-value
Exposure Duration (yrs)	0.05	-0.01 to 0.11	0.10
constant	-4.18	-5.40 to -2.96	<0.001
1997	-0.53	1.84 to 0.69	0.38
1998	-2.01	-4.13 to 0.11	0.06
1999	-0.67	-1.94 to 0.60	0.30
2002	-2.22	-4.34 to -0.10	0.04

TABLE VI-16—PROPORTIONAL HAZARDS MODEL—HEJ EXPOSURE AND CBD

Variable	Coefficient	95% Confidence interval	P-value
HEJ Exposure (µg/m <sup>3</sup> )	0.03	-0.70 to 0.77	0.93
constant	-3.49	-4.45 to -2.53	<0.001
1997	-0.62	-1.88 to 0.65	0.34
1998	-2.05	-4.16 to 0.07	0.06
1999	-0.68	-1.94 to 0.59	0.30
2002	-2.21	-4.33 to -0.09	0.04

In addition to the models reported above, comparable models were fit to the upper 95 percent confidence interval of the HEJ exposure; log-transformed cumulative exposure; log-transformed LTW average exposure; and log-transformed HEJ exposure. Each of these measures was positively but not significantly associated with sensitization.

OSHA used the proportional hazards models based on cumulative exposure, shown in Tables VI-9 and VI-13, to derive quantitative risk estimates. Of the metrics related to exposure level, the cumulative exposure metric showed the most consistent association with

sensitization and CBD in these models. Table VI-17 summarizes these risk estimates for sensitization and the corresponding 95 percent confidence intervals separately for 1995 and 1999, the years with the highest and lowest baseline rates, respectively. The estimated risks for CBD are presented in VI-18. The expected number of cases is based on the estimated conditional probability of being a case in the given year. The models provide time-specific point estimates of risk for a worker with any given exposure level, and the corresponding interval is based on the uncertainty in the exposure coefficient

(i.e., the predicted values based on the 95 percent confidence limits for the exposure coefficient).

Each estimate represents the number of sensitized workers the model predicts in a group of 1000 workers at risk during the given year with an exposure history at the specified level and duration. For example, in the exposure scenario where 1000 workers are occupationally exposed to 2 µg/m<sup>3</sup> for 10 years in 1995, the model predicts that about 56 (55.7) workers would be sensitized that year. The model for CBD predicts that about 42 (41.9) workers would be diagnosed with CBD that year.



TABLE VI-17a—PREDICTED CASES OF SENSITIZATION PER 1000 WORKERS EXPOSED AT CURRENT AND ALTERNATE PELS BASED ON PROPORTIONAL HAZARDS MODEL, CUMULATIVE EXPOSURE METRIC, WITH CORRESPONDING INTERVAL BASED ON THE UNCERTAINTY IN THE EXPOSURE COEFFICIENT

[1995 Baseline]

1995 Exposure level (µg/m³)	Exposure duration							
	5 years		10 years		20 years		45 years	
	Cumulative (µg/m³-yrs)	cases/1000	µg/m³-yrs	cases/1000	µg/m³-yrs	cases/1000	µg/m³-yrs	cases/1000
2.0	10.0	41.1 30.3–56.2	20.0	55.7 30.3–102.9	40.0	101.0 30.3–318.1	90.0	394.4 30.3–999.9
1.0	5.0	35.3 30.3–41.3	10.0	41.1 30.3–56.2	20.0	55.7 30.3–102.9	45.0	116.9 30.3–408.2
0.5	2.5	32.7 30.3–35.4	5.0	35.3 30.3–41.3	10.0	41.1 30.3–56.2	22.5	60.0 30.3–119.4
0.2	1.0	31.3 30.3–32.3	2.0	32.2 30.3–34.3	4.0	34.3 30.3–38.9	9.0	39.9 30.3–52.9
0.1	0.5	30.8 30.3–31.3	1.0	31.3 30.3–32.3	2.0	32.2 30.3–34.3	4.5	34.8 30.3–40.1

TABLE VI-17b—PREDICTED CASES OF SENSITIZATION PER 1000 WORKERS EXPOSED AT CURRENT AND ALTERNATE PELS BASED ON PROPORTIONAL HAZARDS MODEL, CUMULATIVE EXPOSURE METRIC, WITH CORRESPONDING INTERVAL BASED ON THE UNCERTAINTY IN THE EXPOSURE COEFFICIENT

[1999 Baseline]

1999 Exposure level (µg/m³)	Exposure duration							
	5 years		10 years		20 years		45 years	
	Cumulative (µg/m³-yrs)	cases/1000	µg/m³-yrs	cases/1000	µg/m³-yrs	cases/1000	µg/m³-yrs	cases/1000
2.0	10.0	8.4 6.2–11.6	20.0	11.5 6.2–21.7	40.0	21.3 6.2–74.4	90.0	96.3 6.2–835.4
1.0	5.0	7.2 6.2–8.5	10.0	8.4 6.2–11.6	20.0	11.5 6.2–21.7	45.0	24.8 6.2–100.5
0.5	2.5	6.7 6.2–7.3	5.0	7.2 6.2–8.5	10.0	8.4 6.2–11.6	22.5	12.4 6.2–25.3
0.2	1.0	6.4 6.2–6.6	2.0	6.6 6.2–7.0	4.0	7.0 6.2–8.0	9.0	8.2 6.2–10.9
0.1	0.5	6.3 6.2–6.4	1.0	6.4 6.2–6.6	2.0	6.6 6.2–7.0	4.5	7.1 6.2–8.2

TABLE VI-18a—PREDICTED NUMBER OF CASES OF CBD PER 1000 WORKERS EXPOSED AT CURRENT AND ALTERNATIVE PELS BASED ON PROPORTIONAL HAZARDS MODEL, CUMULATIVE EXPOSURE METRIC, WITH CORRESPONDING INTERVAL BASED ON THE UNCERTAINTY IN THE EXPOSURE COEFFICIENT

[1995 baseline]

1995 Exposure level (µg/m³)	Exposure duration							
	5 years		10 years		20 years		45 years	
	Cumulative (µg/m³-yrs)	Estimated cases/1000 95% c.i.	µg/m³-yrs	Estimated cases/1000 95% c.i.	µg/m³-yrs	Estimated cases/1000 95% c.i.	µg/m³-yrs	Estimated cases/1000 95% c.i.
2.0	10.0	30.9 22.8–44.0	20.0	41.9 22.8–84.3	40.0	76.6 22.8–285.5	90.0	312.9 22.8–999.9
1.0	5.0	26.6 22.8–31.7	10.0	30.9 22.8–44.0	20.0	41.9 22.8–84.3	45.0	88.8 22.8–375.0
0.5	2.5	24.6 22.8–26.9	5.0	26.6 22.8–31.7	10.0	30.9 22.8–44.0	22.5	45.2 22.8–98.9
0.2	1.0	23.5 22.8–24.3	2.0	24.2 22.8–26.0	4.0	25.8 22.8–29.7	9.0	30.0 22.8–41.3
0.1	0.5	23.1 22.8–23.6	1.0	23.5 22.8–24.3	2.0	24.2 22.8–26.0	4.5	26.2 22.8–30.7

TABLE VI-18b—PREDICTED NUMBER OF CASES OF CBD PER 1000 WORKERS EXPOSED AT CURRENT AND ALTERNATIVE PELS BASED ON PROPORTIONAL HAZARDS MODEL, CUMULATIVE EXPOSURE METRIC, WITH CORRESPONDING INTERVAL BASED ON THE UNCERTAINTY IN THE EXPOSURE COEFFICIENT

[2002 baseline]

2002 Exposure level ( $\mu\text{g}/\text{m}^3$ )	Exposure duration							
	5 years		10 years		20 years		45 years	
	Cumulative ( $\mu\text{g}/\text{m}^3\text{-yrs}$ )	Estimated cases/1000 95% c.i.	$\mu\text{g}/\text{m}^3\text{-yrs}$	Estimated cases/1000 95% c.i.	$\mu\text{g}/\text{m}^3\text{-yrs}$	Estimated cases/1000 95% c.i.	$\mu\text{g}/\text{m}^3\text{-yrs}$	Estimated cases/1000 95% c.i.
2.0 .....	10.0	3.7 2.7–5.3	20.0	5.1 2.7–10.4	40.0	9.4 2.7–39.2	90.0	43.6 2.7–679.8
1.0 .....	5.0	3.2 2.7–3.8	10.0	3.7 2.7–5.3	20.0	5.1 2.7–10.4	45.0	11.0 2.7–54.3
0.5 .....	2.5	3.0 2.7–3.2	5.0	3.2 2.7–3.8	10.0	3.7 2.7–5.3	22.5	5.5 2.7–12.3
0.2 .....	1.0	2.8 2.7–2.9	2.0	2.9 2.7–3.1	4.0	3.1 2.7–3.6	9.0	3.6 2.7–5.0
0.1 .....	0.5	2.8 2.7–2.8	1.0	2.8 2.7–2.9	2.0	2.9 2.7–3.1	4.5	3.1 2.7–3.7

The statistical modeling analysis predicts high risk of both sensitization (96–394 cases per 1000, or 9.6–39.4 percent) and CBD (44–313 cases per 1000, or 4.4–31.3 percent) at the current PEL of  $2 \mu\text{g}/\text{m}^3$  for an exposure duration of 45 years ( $90 \mu\text{g}/\text{m}^3\text{-yr}$ ). The predicted risks of < 8.2–39.9 per 1000 (0.8–3.9 percent) cases of sensitization or 3.6 to 30.0 per 1000 (0.4–3 percent) cases of CBD are substantially less for a 45-year exposure at the proposed PEL,  $0.2 \mu\text{g}/\text{m}^3$  ( $9 \mu\text{g}/\text{m}^3\text{-yr}$ ).

The model estimates are not directly comparable to prevalence values discussed in previous sections. They assume a group without turnover and are based on a comparison of unexposed and hypothetically exposed workers at specific points in time, whereas the prevalence analysis simply reports the percentage of workers at the Cullman plant with sensitization or CBD in each exposure category. Despite the difficulty of direct comparison, the level of risk seen in the prevalence analysis and predicted in the modeling analysis appear roughly similar at low exposures. In the second quartile of cumulative exposure ( $0.148\text{--}1.467 \mu\text{g}/\text{m}^3\text{-yr}$ ), prevalence of sensitization and CBD was 2.5 percent. This is roughly congruent with the model predictions for workers with cumulative exposures between  $0.5$  and  $1 \mu\text{g}/\text{m}^3\text{-yr}$ : 6.3–31.3 cases of sensitization per 1000 workers (0.6–3.1 percent) and 2.8 to 23.5 cases of CBD per 1000 workers (0.28–2.4 percent). As discussed in the background document for this analysis, most workers in the data set had low cumulative exposures (roughly half below  $1.5 \mu\text{g}/\text{m}^3\text{-years}$ ). It is difficult to make any statement about the results at higher levels, because there were few

workers with high exposure levels and the higher quartiles of cumulative exposure include an extremely wide range of exposures. For example, the highest quartile of cumulative exposure was  $7.009\text{--}61.86 \mu\text{g}/\text{m}^3\text{-yr}$ . This quartile, which showed an 11.3 percent prevalence of sensitization and 8.8 percent prevalence of CBD, includes the cumulative exposure that a worker exposed for 45 years at the proposed PEL would experience ( $9 \mu\text{g}/\text{m}^3\text{-yr}$ ) near its lower bound. Its upper bound approaches the cumulative exposure that a worker exposed for 45 years at the current PEL would experience ( $90 \mu\text{g}/\text{m}^3\text{-yr}$ ).

Due to limitations including the size of the dataset, relatively limited exposure data from the plant's early years, study size-related constraints on the statistical analysis of the dataset, and limited follow-up time on many workers, OSHA must interpret the model-based risk estimates presented in Tables VI-17 and VI-18 with caution. The Cullman study population is a relatively small group and can support only limited statistical analysis. For example, its size precludes inclusion of multiple covariates in the exposure-response models or a two-stage exposure-response analysis to model both sensitization and the subsequent development of CBD within the subpopulation of sensitized workers. The limited size of the Cullman dataset is characteristic of studies on beryllium-exposed workers in modern, low-exposure environments, which are typically small-scale processing plants (up to several hundred workers, up to 20–30 cases). However, these recent studies also have important strengths: They include workers hired after the

institution of stringent exposure controls, and have extensive exposure sampling using full-shift personal lapel samples. In contrast, older studies of larger populations tend to have higher exposures, less exposure data, and exposure data collected in short-term samples or outside of workers' breathing zones.

Another limitation of the Cullman dataset, which is common to recent low-exposure studies, is the short follow-up time available for many of the workers. While in some cases CBD has been known to develop in short periods (< 2 years), it more typically develops over a longer time period. Sensitization occurs in a typically shorter time frame, but new cases of sensitization have been observed in workers exposed to beryllium for many years. Because the data set is limited to individuals then working at the plant, the Cullman data set cannot capture CBD occurring among workers who retire or leave the plant. OSHA expects that the dataset does not fully represent the risk of sensitization, and is likely to particularly under-represent CBD among workers exposed to beryllium at this facility. The Agency believes the short follow-up time to be a significant source of uncertainty in the statistical analysis, a factor likely to lead to underestimation of risk in this population.

A common source of uncertainty in quantitative risk assessment is the series of choices made in the course of statistical analysis, such as model type, inclusion or exclusion of additional explanatory variables, and the assumption of linearity in exposure-response. Sensitivity analyses and statistical checks were conducted to test the validity of the choices and

assumptions in the exposure-response analysis and the impact of alternative choices on the end results. These analyses did not yield substantially different results, adding to OSHA's confidence in the conclusions of its preliminary risk assessment.

OSHA's contractor examined whether smoking and age were confounders in the exposure-response analysis by adding them as variables in the discrete proportional hazards model. Neither smoking status nor age was a statistically significant predictor of sensitization or CBD. The model coefficients, 95 percent confidence intervals, and p values can be found in the background document. A sensitivity analysis was done using the standard Cox model that treats survival time as continuous rather than discrete. The model coefficients with the standard Cox using cumulative exposure were 0.025 and very similar to the 0.03 reported in Tables VI-9 and VI-13 above. The interaction between exposure and follow-up time was not significant in these models, suggesting that the proportional hazard assumption should not be rejected. The proportional hazards model assumes a linear relationship between exposure level and relative risk. The linearity assumption was assessed using a fractional polynomial approach. For both sensitization and CBD, the best-fitting fractional polynomial model did not fit significantly better than the linear model. This result supports OSHA's use of the linear model to estimate risk. The details of these statistical analyses can be found in the background document.

The possibility that the number of times a worker has been tested for sensitization might influence the probability of a positive test was examined (surveillance bias). Surveillance bias could occur if workers were tested because they showed some sign of disease, and not tested otherwise. It is also possible that the original analysis included erroneous assumptions about the dates of testing for sensitization and CBD. OSHA's contractor performed a sensitivity analysis, modifying the original analysis to gauge the effect of different assumptions about testing dates. In the sensitivity analysis, the exposure coefficients increased for all four indices of exposure when the sensitization analysis was restricted to times when cohort members were assumed to be tested. The exposure coefficient was statistically significant for duration of exposure but not for cumulative, LTW average, or HEJ exposure. The increase in exposure coefficients suggests that the original

models may have underestimated the exposure-response relationship for sensitization and CBD.

Errors in exposure measurement are a common source of uncertainty in quantitative risk assessments. Because errors in high exposures can heavily influence modeling results, OSHA's contractor performed sensitivity analyses excluding the highest 5 percent of cumulative exposures (those above 25.265  $\mu\text{g}/\text{m}^3\text{-yrs}$ ) and the highest 10 percent of cumulative exposures (those above 18.723  $\mu\text{g}/\text{m}^3\text{-yrs}$ ). As discussed in more detail in the background document, exposure coefficients were not statistically significant when these exposures were dropped. This is not surprising, given that the exclusion of high exposure values reduced the size of the data set. Prior to excluding high exposure values, the data set was already relatively small and many of the exposure coefficients were non-significant or weakly significant in the original analyses. As a result, the sensitivity analyses did not provide much information about uncertainty due to exposure measurement error and its effects on the modeling analysis.

Particle size, particle surface area, and beryllium compound solubility are believed to be important factors influencing the risk of sensitization and CBD among beryllium-exposed workers. The workers at the Cullman machining plant were primarily handling insoluble beryllium compounds, such as beryllium metal and beryllium metal/beryllium oxide composites. Particle size distributions from a limited number of airborne beryllium samples collected just after the 1996 installation of engineering controls indicate worker exposure to a substantial proportion of respirable particulates. There was no available particle size data for the 1980 to 1995 period prior to installation of engineering controls when total beryllium mass exposure levels were greatest. Particle size data was also lacking from 1998 to 2003 when additional control measures were in place and total beryllium mass exposures were lowest. For these reasons, OSHA was not able to quantitatively account for the influence of particle size and solubility in developing the risk estimates based on the Cullman data set. However, it is not unreasonable to expect the CBD experienced by this cohort to generally reflect the risk from exposure to beryllium that is relatively insoluble and enriched with respirable particles. As explained previously, the role of particle size and surface area on risk of sensitization is more difficult to predict.

Additional uncertainty is introduced when extrapolating the quantitative estimates presented above to operations that process beryllium compounds that have different solubility and particle characteristics than those encountered at the Cullman machining plant. OSHA does not have sufficient information to quantitatively assess the degree to which risks of beryllium sensitization and CBD based on the NJMRC data may be impacted in workplaces where such beryllium forms and processes are used. However, OSHA does not expect this uncertainty to alter its qualitative conclusions with regard to the risk at the current PEL and at alternate PELs as low as 0.1  $\mu\text{g}/\text{m}^3$ . The existing studies provide clear evidence of sensitization and CBD risk among workers exposed to a number of beryllium forms as a result of different processes such as beryllium machining, beryllium-copper alloy production, and beryllium ceramics production. The Agency believes all of these forms of beryllium exposure contribute to the overall risk of sensitization and CBD among beryllium-exposed workers.

#### *G. Lung Cancer*

OSHA considers lung cancer to be an important health endpoint for beryllium-exposed workers. The International Agency for Research on Cancer (IARC), National Toxicology Program (NTP), and American Conference of Governmental Industrial Hygienists (ACGIH) have all classified beryllium as a known human carcinogen. The National Academy of Sciences (NAS), Environmental Protection Agency, the Agency for Toxic Substances and Disease Registry (ATSDR), the National Institute of Occupational Safety and Health (NIOSH), and other reputable scientific organizations have reviewed the scientific evidence demonstrating that beryllium is associated with an increased incidence of cancer. OSHA also has performed an extensive review of the scientific literature regarding beryllium and cancer. This includes an evaluation of human epidemiological, animal cancer, and mechanistic studies described in the Health Effects section of this preamble. Based on the weight of evidence, the Agency has preliminarily determined beryllium to be an occupational carcinogen.

Although epidemiological and animal evidence supports a conclusion of beryllium carcinogenicity, there is considerable uncertainty surrounding the mechanism of carcinogenesis for beryllium. The evidence for direct genotoxicity of beryllium and its compounds has been limited and

inconsistent (NAS, 2008; IARC, 1993; EPA, 1998; NTP, 2002; ATSDR, 2002). One plausible pathway for beryllium carcinogenicity described in the Health Effects section of this preamble includes a chronic, sustained neutrophilic inflammatory response that induces epigenetic alterations leading to the neoplastic changes necessary for carcinogenesis. The National Cancer Institute estimates that nearly one-third of all cancers are caused by chronic inflammation (NCI, 2009). This mechanism of action has also been hypothesized for crystalline silica and other agents that are known to be human carcinogens but have limited evidence of genotoxicity.

OSHA's review of epidemiological studies of lung cancer mortality among beryllium workers found that most did not characterize exposure levels sufficiently for exposure-response analysis. However, one NIOSH study evaluated the association between beryllium exposure and lung cancer mortality based on data from a beryllium processing plant in Reading, PA (Sanderson *et al.*, 2001a). As discussed in the Health Effects section of this preamble, this case-control study evaluated lung cancer incidence in a cohort of workers employed at the plant from 1940 to 1969 and followed through 1992. For each lung cancer victim, 5 age- and race-matched controls were selected by incidence density sampling, for a total of 142 lung cancer cases and 710 controls.

Between 1971 and 1992, the plant collected close to 7,000 high volume filter samples consisting of both general area and short-term, task-based breathing zone measurements for production jobs and exclusively area measurements for office, lunch, and laboratory areas (Sanderson *et al.*, 2001b). In addition, a few (< 200) impinger and high-volume filter samples were collected by other organizations between 1947 and 1961, and about 200 6-to-8-hour personal samples were collected in 1972 and 1975. Daily-weighted-average (DWA) exposure calculations based on the impinger and high-volume samples collected prior to the 1960s showed that exposures in this period were extremely high. For example, about half of production jobs had estimated DWAs ranging between 49 and 131  $\mu\text{g}/\text{m}^3$  in the period 1935–1960, and many of the “lower-exposed” jobs had DWAs of approximately 20–30  $\mu\text{g}/\text{m}^3$  (Table II, Sanderson *et al.*, 2001b). Exposures were reported to have decreased between 1959 and 1962 with the installation of ventilation controls and improved housekeeping and following

the passage of the OSH Act in 1970. While no exposure measurements were available from the period 1961–1970, measurements from the period 1971–1980 showed a dramatic reduction in exposures plant-wide. Estimated DWAs for all jobs in this period ranged from 0.1  $\mu\text{g}/\text{m}^3$  to 1.9  $\mu\text{g}/\text{m}^3$ . Calendar-time-specific beryllium exposure estimates were made for every job based on the DWA calculations and were used to estimate workers' cumulative, average, and maximum exposures. Exposure estimates were lagged by 10 and 20 years in order to account for exposures that did not contribute to lung cancer because they occurred after the induction of cancer.

Results of a conditional logistic regression analysis showed an increased risk of lung cancer in workers with higher exposures when dose estimates were lagged by 10 and 20 years (Sanderson *et al.*, 2001a). The authors noted that there was considerable uncertainty in the estimation of exposure in the 1940s and 1950s and the shape of the dose-response curve for lung cancer. NIOSH later reanalyzed the data, adjusting for potential confounders of hire age and birth year (Schubauer-Berigan *et al.*, 2008). The study reported a significant increasing trend ( $p < 0.05$ ) in the odds ratio when increasing quartiles of average (log transformed) exposure were lagged by 10 years. However, it did not find a significant trend when quartiles of cumulative (log transformed) exposure were lagged by 0, 10, or 20 years.

OSHA is interested in lung cancer risk estimates from a 45-year (*i.e.*, working lifetime) exposure to beryllium levels between 0.1  $\mu\text{g}/\text{m}^3$  and 2  $\mu\text{g}/\text{m}^3$ . The majority of case and control workers in the Sanderson *et al.* case-control analysis were first hired during the 1940s when exposures were extremely high (estimated DWAs > 20  $\mu\text{g}/\text{m}^3$  for most jobs). The cumulative, average, and maximum beryllium exposure concentration estimates for the 142 known lung cancer cases were:  $46.06 \pm 9.3 \mu\text{g}/\text{m}^3\text{-days}$ ,  $22.8 \pm 3.4 \mu\text{g}/\text{m}^3$ , and  $32.4 \pm 13.8 \mu\text{g}/\text{m}^3$ , respectively. About two-thirds of cases and half of controls worked at the plant for less than a year. Thus, a risk assessment based on this exposure-response analysis would need to extrapolate from very high to very low exposures, based on a working population with extremely short tenure. While OSHA risk assessments must often make extrapolations to estimate risk within the range of exposures of interest, the Agency acknowledges that these issues of short tenure and extremely high exposures would create substantial uncertainty in a risk

assessment based on this study population.

In addition, the relatively high exposures of even the least-exposed workers in the NIOSH study may create methodological issues for the lung cancer case-control study design. Mortality risk is expressed as an odds ratio that compares higher exposure quartiles to the lowest quartile. It is preferable that excess risks attributable to occupational beryllium be determined relative to an unexposed or minimally exposed reference population. However, in the NIOSH study workers in the lowest quartile were exposed well above the OSHA PEL (average exposure < 11.2  $\mu\text{g}/\text{m}^3$ ) and may have had a significant lung cancer risk. This issue would introduce further uncertainty in lung cancer risks estimated from this epidemiological study.

In 2010, researchers at NIOSH published a quantitative risk assessment based on an update of the Reading cohort analyzed by Sanderson *et al.*, as well as workers from two smaller plants (Schubauer-Berigan *et al.*, 2010b). This new risk assessment addresses several of OSHA's concerns regarding the Sanderson *et al.* analysis. The new cohort was exposed, on average, to lower levels of beryllium and had fewer short-term workers. Finally, the updated cohorts followed the populations through 2005, increasing the length of follow-up time overall by an additional 17 years of observation. For these reasons, OSHA considers the Schubauer-Berigan risk analysis more appropriate than the Sanderson *et al.* analysis for its preliminary risk assessment.

The cohort studied by Schubauer-Berigan *et al.* included 5,436 male workers who had worked for at least two days at the Reading facility and beryllium processing plants at Hazleton PA and Elmore OH prior to 1970. The authors developed job-exposure matrices (JEMs) for the three plants based on extensive historical exposure data, primarily short-term general area and personal breathing zone samples, collected on a quarterly basis from a wide variety of operations. These samples were used to create daily weighted average (DWA) estimates of workers' full-shift exposures, using records of the nature and duration of tasks performed by workers during a shift. Details on the JEM and DWA construction can be found in Sanderson *et al.* (2001a), Chen *et al.* (2001), and Couch *et al.* (2010).

Workers' cumulative exposures ( $\mu\text{g}/\text{m}^3\text{-days}$ ) were estimated by summing daily average exposures (assuming five

workdays per week). To estimate mean exposure ( $\mu\text{g}/\text{m}^3$ ), cumulative exposure was divided by exposure time (in days). Maximum exposure ( $\mu\text{g}/\text{m}^3$ ) was estimated as the highest annual DWA on record for a worker prior to the study cutoff date of December 31, 2005 and accounting where appropriate for lag time. Exposure estimates were lagged by 5, 10, 15, and 20 years in order to account for exposures that may not have

contributed to lung cancer because of the long latency required for manifestation of the disease. The authors also fit models with no lag time. As shown in Table VI–19 below, estimated exposure levels for workers from the Hazleton and Elmore plants were on average far lower than those for workers from the Reading plant. The median worker from Hazleton had a mean exposure across his tenure of less

than  $2 \mu\text{g}/\text{m}^3$ , while the median worker from Elmore had a mean exposure of less than  $1 \mu\text{g}/\text{m}^3$ . The Elmore and Hazleton worker populations also had fewer short-term workers than the Reading population. This was particularly evident at Hazleton where the median value for cumulative exposure among cases was higher than at Reading despite the much lower mean and maximum exposure levels.

TABLE VI–19—COHORT DESCRIPTION AND DISTRIBUTION OF CASES BY EXPOSURE LEVEL

		All plants	Reading plant	Hazleton plant	Elmore plant
Number of cases .....		293	218	30	45
Number of non-cases .....		5143	3337	583	1223
Median value for mean exposure .....	<i>No lag</i> .....	15.42	25	1.443	0.885
( $\mu\text{g}/\text{m}^3$ ) among cases .....	<i>10-year lag</i> .....	15.15	25	1.443	0.972
Median value for cumulative exposure.	<i>No lag</i> .....	2843	2895	3968	1654
( $\mu\text{g}/\text{m}^3$ -days) among cases .....	<i>10-year lag</i> .....	2583	2832	3648	1449
Median value for maximum exposure .....	<i>No lag</i> .....	25	25.1	3.15	2.17
( $\mu\text{g}/\text{m}^3$ ) among cases .....	<i>10-year lag</i> .....	25	25	3.15	2.17
Number of cases with potential asbestos exposure.		100 (34%)	68 (31%)	16 (53%)	16 (36%)
Number of cases who were professional workers.		26 (9%)	21 (10%)	3 (10%)	2 (4%)

Table adapted from Schubauer-Berigan *et al.* 2011, Table 1.

Schubauer-Berigan *et al.* analyzed the data set using a variety of exposure-response modeling approaches, including categorical analyses and continuous-variable piecewise log-linear and power models, described in Schubauer-Berigan *et al.* (2011). All models adjusted for birth cohort and plant. As exposure values were log-transformed for the power model analyses, the authors added small values to exposures of 0 in lagged analyses ( $0.05 \mu\text{g}/\text{m}^3$  for mean and maximum exposure,  $0.05 \mu\text{g}/\text{m}^3$ -days for cumulative exposure). The authors used restricted cubic spline models to assess the shape of the exposure-response curve and suggest appropriate parametric model forms. The Akaike Information Criterion (AIC) value was used to evaluate the fit of different model forms and lag times.

Because smoking information was available for only about 25 percent of the cohort, smoking could not be controlled for directly in the models. The authors reported that within the subset with smoking information, there

was little difference in smoking by cumulative or maximum exposure category (p. 6), suggesting that smoking was unlikely to act as a confounder in the cohort. In addition to models based on the full cohort, Schubauer-Berigan *et al.* also prepared risk estimates based on models excluding professional workers and workers believed to have asbestos exposure. These models were intended to mitigate the potential impact of smoking and asbestos as confounders. If professional workers had both lower beryllium exposures and lower smoking rates than production workers, smoking could be a confounder in the cohort comprising both production and professional workers. However, the authors reasoned that smoking was unlikely to be correlated with beryllium exposure among production workers, and would therefore probably not act as a confounder in a cohort excluding professional workers.

The authors found that lung cancer risk was strongly and significantly related to mean, cumulative, and maximum measures of workers'

exposure (all models reported in Schubauer-Berigan *et al.*, 2011). They selected the best-fitting categorical, power, and monotonic piecewise log-linear (PWL) models with a 10-year lag to generate hazard ratios for male workers with a mean exposure of  $0.5 \mu\text{g}/\text{m}^3$  (the current NIOSH Recommended Exposure Limit for beryllium).<sup>9</sup> To estimate excess lifetime risk of cancer, they multiplied this hazard ratio by the 2004–2006 background lifetime lung cancer rate among U.S. males who had survived, cancer-free, to age 30. In addition, they estimated the mean exposure that would be associated with an excess lifetime risk of one in 1000, a value often used as a benchmark for significant risk in OSHA regulations. At OSHA's request, they also estimated excess lifetime risks for workers with mean exposures at the current PEL of  $2 \mu\text{g}/\text{m}^3$  each of the other alternate PELs under consideration:  $1 \mu\text{g}/\text{m}^3$ ,  $0.2 \mu\text{g}/\text{m}^3$ , and  $0.1 \mu\text{g}/\text{m}^3$  (Schubauer-Berigan, 4/22/11). The resulting risk estimates are presented in Table VI–20 below.

<sup>9</sup> Here, "monotonic PWL model" means a model producing a monotonic exposure-response curve in the 0–2  $\mu\text{g}/\text{m}^3$  region.

TABLE VI-20—EXCESS LIFETIME RISK PER 1000 [95% CONFIDENCE INTERVAL] FOR MALE WORKERS AT ALTERNATE PELS  
[NIOSH models]

Exposure-response model	Mean exposure				
	0.1 µg/m <sup>3</sup>	0.2 µg/m <sup>3</sup>	0.5 µg/m <sup>3</sup>	1 µg/m <sup>3</sup>	2 µg/m <sup>3</sup>
Best monotonic PWL—all workers .....	7.3[2.0–13]	15[3.3–29]	45[9–98]	120[20–340]	200[29–370]
Best monotonic PWL—excluding professional and asbestos workers .....	3.1[<0–11]	6.4[<0–23]	17[<0–74]	39[39–230]	61[<0–280]
Best categorical—all workers .....	4.4[1.3–8]	9[2.7–17]	25[6–48]	59[13–130]	170[29–530]
Best categorical—excluding professional and asbestos workers .....	1.4[<0–6.0]	2.7[<0–12]	7.1[<0–35]	15[<0–87]	33[<0–290]
Power model—all workers .....	12[6–19]	19[9.3–29]	30[15–48]	40[19–66]	52[23–88]
Power model—excluding professional and asbestos workers .....	19[8.6–31]	30[13–50]	49[21–87]	68[27–130]	90[34–180]

Schubauer-Berigan *et al.* discuss several strengths, weaknesses, and uncertainties of their analysis. Strengths include long (> 30 years) follow-up time for members of the cohort and the extensive exposure and work history data available for the development of exposure estimates for workers in the cohort. Among the weaknesses and uncertainties of the study are the limited information available on workers' smoking habits: smoking information was available only for workers employed in 1968, about 25 percent of the cohort. In addition, the JEMs used did not account for possible respirator use among workers in the cohort. The authors note that workers' exposures may therefore have been overestimated, and that overestimation may have been especially severe for workers with high estimated exposures. They suggest that overestimation of exposures for workers in highly exposed positions may have caused attenuation of the exposure-response curve in some models at higher exposures.

The NIOSH publication did not discuss the reasons for basing risk estimates on mean exposure rather than cumulative exposure that is more commonly used for lung cancer risk analysis. OSHA believes the decision may involve the nonmonotonic relationship NIOSH observed between cancer risk and cumulative exposure level. As discussed previously, workers from the Reading plant frequently had very short tenures and high exposures yielding lower cumulative exposures compared to cohort workers from other plants with longer employment. Despite the low estimated cumulative exposures among the short-term Reading workers, they may be at high risk of lung cancer due to the tendency of beryllium to persist in the lung for long periods. This exposure misclassification could lead to the appearance of a nonmonotonic relationship between cumulative

exposure and lung cancer risk. It is possible that a dose-rate effect may exist for beryllium, such that the risk from a cumulative exposure gained by long-term, low-level exposure is not equivalent to the risk from a cumulative exposure gained by very short-term, high-level exposure. In this case, mean exposure level may better correlate with the risk of lung cancer than cumulative exposure level. For these reasons OSHA considers the NIOSH choice of mean exposure metric to be appropriate and scientifically defensible for this particular dataset.

#### H. Preliminary Conclusions

As described above, OSHA's risk assessment for beryllium sensitization and CBD relied on two approaches: (1) review of the literature and (2) analysis of a dataset provided by NJRMC. First, the Agency reviewed the scientific literature to ascertain whether there is substantial risk to workers exposed at and below the current PEL and to characterize the expected impact of more stringent controls on workers' risk of sensitization and CBD. This review focused on facilities where exposures were primarily below the current PEL, and where several rounds of BeLPT and CBD screening had been conducted to evaluate the effectiveness of various exposure control measures. Second, OSHA investigated the exposure-response relationship for beryllium sensitization and CBD by analyzing a dataset that NJMRC provided on workers at a prominent, long-established beryllium machining facility. Although exposure-response studies have been published on sensitization and CBD, OSHA believes the nature and quality of their exposure data significantly limits their value for the Agency's risk assessment. Therefore, OSHA developed an independent exposure-response analysis using the NJMRC dataset, which was recently

updated, includes workers exposed at low levels, and includes extensive exposure data collected in workers' breathing zones, as is preferred by OSHA.

OSHA's review of the scientific literature found substantial risk of both sensitization and CBD in workplaces in compliance with OSHA's current PEL (*e.g.*, Kreiss *et al.*, 1992; Schuler *et al.*, 2000; Madl *et al.*, 2007). At these plants, including a copper-beryllium processing facility, a beryllia ceramics facility, and a beryllium machining facility, exposure reduction programs that primarily used engineering controls to reduce airborne exposures to median levels at or around 0.2 µg/m<sup>3</sup> had only limited impact on workers' risk. Cases of sensitization continued to occur frequently among newly hired workers, and some of these workers developed CBD within the short follow-up time.

In contrast, industrial hygiene programs that minimized both airborne and dermal exposure substantially lowered workers' risk of sensitization in the first years of employment. Programs that drastically reduced respiratory exposure via a combination of engineering controls and respiratory protection, minimized the potential for skin exposure via dermal PPE, and employed stringent housekeeping methods to keep work areas clean and prevent transfer of beryllium between areas sharply curtailed new cases of sensitization among newly-hired workers. For example, studies conducted at copper-beryllium processing, beryllium production, and beryllia ceramics facilities show that reduction of exposures to below 0.1 µg/m<sup>3</sup> and protection from dermal exposure, in combination, achieved a substantial reduction in sensitization risk among newly-hired workers. However, even these stringent measures did not protect all workers from sensitization.

The most recent epidemiological literature on programs that have been successful in reducing workers' risk of sensitization have had very short follow-up time; therefore, they cannot address the question of how frequently workers sensitized in very low-exposure environments develop CBD. Clinical evaluation for CBD was not reported for workers at the copper-beryllium processing, beryllium production, and ceramics facilities. However, cases of CBD among workers exposed at low levels at a machining plant and cases of CA-CBD demonstrate that individuals exposed to low levels of airborne beryllium can develop CBD, and over time, can progress to severe disease. This conclusion is also supported by case reports within the literature of workers with CBD who may have been minimally exposed to beryllium, such as a worker employed only in administration at a beryllium ceramics facility (Kreiss *et al.*, 1996).

The Agency's analysis of the Cullman dataset provided by NJMRC showed strong exposure-response trends using multiple analytical approaches, including examination of sensitization and disease prevalence by exposure categories and a proportional hazards modeling approach. In the prevalence analysis, cases of sensitization and disease were evident at all levels of exposure. The lowest prevalence of sensitization (2.0 percent) and CBD (1.0 percent) was observed among workers with LTW average exposure levels below 0.1  $\mu\text{g}/\text{m}^3$ , while those with LTW average exposure between 0.1–0.2  $\mu\text{g}/\text{m}^3$  showed a marked increase in overall prevalence of sensitization (9.8 percent) and CBD (7.3 percent). Prevalence of sensitization and CBD also increased with cumulative exposure.

OSHA's proportional hazards analysis of the Cullman dataset found increasing risk of sensitization with both cumulative exposure and average exposure. OSHA also found a positive relationship between risk of CBD and cumulative exposure, but not between CBD and average exposure. The Agency used the cumulative exposure model results to estimate hazards ratios and risk of sensitization and CBD at the current PEL of 2  $\mu\text{g}/\text{m}^3$  and each of the alternate PELs under consideration: 1  $\mu\text{g}/\text{m}^3$ , 0.5  $\mu\text{g}/\text{m}^3$ , 0.2  $\mu\text{g}/\text{m}^3$ , and 0.1  $\mu\text{g}/\text{m}^3$ . To estimate risk of CBD from a working lifetime of exposure, the Agency calculated the cumulative exposure associated with 45 years of exposure at each level, for total cumulative exposures of 90, 45, 22.5, 9, and 4.5  $\mu\text{g}/\text{m}^3$ -years. The risk estimates for sensitization and CBD ranged from 100–403 and 40–290 cases, respectively,

per 1000 workers exposed at the current PEL of 2  $\mu\text{g}/\text{m}^3$ . The risks are projected to be substantially lower for both sensitization and CBD at 0.1  $\mu\text{g}/\text{m}^3$  and range from 7.2–35 cases per 1000 and 3.1–26 cases per 1000, respectively. In these ways, the modeling results are similar to results observed from published studies of the Reading, Tucson, and Cullman plants and the OSHA analysis of sensitization and CBD prevalence within the Cullman plant.

OSHA has a high level of confidence in the finding of substantial risk of sensitization and CBD at the current PEL, and the Agency believes that a standard requiring a combination of more stringent controls on beryllium exposure will reduce workers' risk of both sensitization and CBD. Programs that have reduced median levels to below 0.1  $\mu\text{g}/\text{m}^3$ , tightly controlled both respiratory and dermal exposure, and incorporated stringent housekeeping measures have substantially reduced risk of sensitization within the first years of exposure. These conclusions are supported by the results of several studies conducted in state-of-the-art facilities dealing with a variety of production activities and physical forms of beryllium. In addition, these conclusions are supported by OSHA's statistical analysis of a dataset with highly detailed exposure and work history information on several hundred beryllium workers. While there is uncertainty regarding the precision of model-derived risk estimates, they provide further evidence that there is substantial risk of sensitization and CBD associated with exposure at the current PEL, and that this risk can be substantially lessened by stringent measures to reduce workers' beryllium exposure levels.

Furthermore, OSHA believes that beryllium-exposed workers' risk of lung cancer will be reduced by more stringent control of airborne beryllium exposures. The risk estimates from NIOSH's recent lung cancer study, described above, range from 33 to 140 excess lung cancers per 1000 workers exposed at the current PEL of 2  $\mu\text{g}/\text{m}^3$ . The NIOSH risk assessment's six best-fitting models each predict substantial reductions in risk with reduced exposure, ranging from 3 to 19 excess lung cancers per 1000 workers exposed at the proposed PEL of 0.1  $\mu\text{g}/\text{m}^3$ . The evidence of lung cancer risk from NIOSH's risk assessment provides additional support for OSHA's preliminary conclusions regarding the significance of risk to workers exposed to beryllium levels at and below the current PEL. However, the lung cancer risks require a sizable low dose

extrapolation below beryllium exposure levels experienced by workers in the NIOSH study. As a result, there is a greater uncertainty in the lung cancer risk estimates and lesser confidence in their significance of risk below the current PEL than with beryllium sensitization and CBD. The preliminary conclusions with regard to significance of risk are presented and further discussed in section VIII of the preamble.

## VII. Expert Peer Review of Health Effects and Preliminary Risk Assessment

In 2010, Eastern Research Group, Inc. (ERG), under contract to the Occupational Safety and Health Administration (OSHA),<sup>10</sup> conducted an independent, scientific peer review of (1) a draft Preliminary Beryllium Health Effects Evaluation (OSHA, 2010a), (2) a draft Preliminary Beryllium Risk Assessment (OSHA, 2010b), and (3) two NIOSH study manuscripts (Schubauer-Berigan *et al.*, 2011 and 2011a). This section of the preamble describes the review process and summarizes peer reviewers' comments and OSHA's responses.

ERG conducted a search for nationally recognized experts in the areas of occupational epidemiology, occupational medicine, toxicology, immunology, industrial hygiene/exposure assessment, and risk assessment/biostatistics as requested by OSHA. ERG sought experts familiar with beryllium health effects research and who had no conflict of interest (COI) or apparent bias in performing the review. Interested candidates submitted evidence of their qualifications and responded to detailed COI questions. ERG also searched the Internet to determine whether qualified candidates had made public statements or declared a particular bias regarding beryllium regulation.

From the pool of qualified candidates, ERG selected five experts to conduct the review, based on:

- Their qualifications, including their degrees, years of relevant experience, number of related peer-reviewed publications, experience serving as a peer reviewer for OSHA or other government organizations, and committee and association memberships related to the review topic;
- Lack of any actual, potential, or perceived conflict of interest; and
- The need to ensure that the panel collectively was sufficiently broad and

<sup>10</sup> Task Order No. DOLQ59622303, Contract No. GS10F0125P, with a period of performance from May, 2010 through December, 2010.

diverse to fairly represent the relevant scientific and technical perspectives and fields of knowledge appropriate to the review.

OSHA reviewed the qualifications of the candidates proposed by ERG to verify that they collectively represented the technical areas of interest. ERG then contracted the following experts to perform the review.

(1) *John Balmes, MD, Professor of Medicine, University of California-San Francisco*

*Expertise:* pulmonary and occupational medicine, CBD, occupational lung disease, epidemiology, occupational exposures, medical surveillance.

(2) *Patrick Breyse, Ph.D., Professor, Johns Hopkins University Bloomberg School of Public Health*

*Expertise:* industrial hygiene, occupational/environmental health engineering, exposure monitoring/analysis, biomarkers, beryllium exposure assessment

(3) *Terry Gordon, Ph.D., Professor, New York University School of Medicine.*

*Expertise:* inhalation toxicology, pulmonary disease, beryllium toxicity and carcinogenicity, CBD genetic susceptibility, mode of action, animal models.

(4) *Milton Rossman, MD, Professor of Medicine, Hospital of the University of Pennsylvania School of Medicine.*

*Expertise:* pulmonary and clinical medicine, immunology, beryllium sensitization, BeLPT, clinical diagnosis for CBD.

(5) *Kyle Steenland, Ph.D., Professor, Emory University, Rollins School of Public Health.*

*Expertise:* occupational epidemiology, biostatistics, risk and exposure assessment, lung cancer, CBD, exposure-response models.

Reviewers were provided with the Technical Charge and Instructions (see ERG, 2010), a Request for Peer Review of NIOSH Manuscripts (see ERG, 2010), the draft Preliminary OSHA Health Effects Evaluation (OSHA, 2010a), the draft Preliminary Beryllium Risk Assessment (OSHA, 2010b), and access to relevant references. Each reviewer independently provided comments on the Health Effects, Risk Assessment, and NIOSH documents. A briefing call was held early in the review to ensure that reviewers understood the peer review process. ERG organized the call and OSHA representatives were available to respond to technical questions of clarification. Reviewers were invited to submit any subsequent questions of clarification.

The written comments from each reviewer were received and organized by ERG by charge questions. The unedited individual and reorganized comments were submitted to OSHA and the reviewers in preparation for a follow-up conference call. The conference call, organized and facilitated by ERG, provided an

opportunity for OSHA to clarify individual reviewer's comments. After the call, reviewers were given the opportunity to revise their written comments to include the clarifications or additional information provided on the call. ERG submitted the revised comments to OSHA organized by both individual reviewer and by charge question. A final peer review report is available in the docket (ERG, 2010). Section VII.A of this preamble summarizes the comments received on the draft health effects document and OSHA's responses to those comments. Section VII.B summarizes comments received on the draft Preliminary Risk Assessment and the OSHA response.

#### *A. Peer Review of Draft Health Effects Evaluation*

The Technical Charge to peer reviewers posed general questions on the draft health effects document as well as specific questions pertaining to particle/chemical properties, kinetics and metabolism, acute beryllium disease, development of beryllium sensitization and CBD, genetic susceptibility, epidemiological studies of sensitization and CBD, animal models of chronic beryllium disease, genotoxicity, lung cancer epidemiological studies, animal cancer studies, other health effects, and preliminary conclusions drawn by OSHA.

OSHA asked the peer reviewers to generally comment on whether the draft health effects evaluation included the important studies, appropriately addressed their strengths and limitations, accurately described the results, and drew scientifically sound conclusions. Overall, the reviewers felt that the studies were described in sufficient detail, the interpretations accurate, and the conclusions reasonable. They agreed that the OSHA document covered the significant health endpoints related to occupational beryllium exposure. However, several reviewers requested that additional studies and other specific information be included in various sections of the document and these are discussed further below.

The reviewers had similar suggestions to improve the section V.A of this preamble on physical/chemical properties and section V.B on kinetics/metabolism. Dr. Balmes requested that physical and chemical characteristics of beryllium more clearly relate to development of sensitization and progression to CBD. Dr. Gordon requested greater consistency in the terminology used to describe particle characteristics, sampling methodologies,

and the particle deposition in the respiratory tract. Dr. Breyse agreed and requested that the respiratory deposition discussion be better related to the onset of sensitization and CBD. Dr. Rossman suggested that the discussion of particle/chemical characteristics might be better placed after section V.D on the immunobiology of sensitization and CBD.

OSHA made a number of revisions to sections V.A and V.B to address the peer review comments above. Terminology used to describe particle characteristics in various studies was modified to be more consistent and better reflect the authors' intent in the published research articles. Section V.B.1 on respiratory kinetics of inhaled beryllium was modified to more clearly describe particle deposition in the different regions of the respiratory tract and their influence on CBD. At the recommendation of Dr. Gordon, a confusing figure was removed since it did not portray particle deposition in a clear manner. Rather than relocate the entire discussion of particle/chemical characteristics, a new section V.B.5 was added to specifically address the influence of beryllium particle characteristics and chemical form on the development of sensitization and CBD. Other section areas were shortened to remove information that was not necessarily relevant to the overall disease process. Statements were added on the effect of pre-existing diseases and smoking on beryllium clearance from the lung. It was made clear that the precise role of dermal exposure in beryllium sensitization is not completely understood. These smaller changes were made at the request of individual reviewers.

There were a couple of comments from reviewers pertaining to acute beryllium disease (ABD). Dr. Rossman commented that ABD did not make the development of CBD more likely. He requested that the document include a reference to the Van Ordstrand et al. (1943) article that first reported ABD in the U.S. Dr. Balmes pointed out that pathologists, rather than clinicians, interpret ABD pathology from lung tissue biopsy. Dr. Gordon commented that ABD is of lesser importance than CBD to the risk assessment and suggested that discussion of ABD be moved later in the document.

The Van Ordstrand reference was included in section V.C on acute beryllium diseases and statements were modified to address the peer review comments above. While OSHA agrees that ABD does not have a great impact on the Agency risk findings, the Agency believes the current organization does



not create confusion on this point and decided not to move the ABD section later in the document. A statement that ABD is only relevant at exposures higher than the current PEL has been added to section V.C. Other reviewers did not feel the ABD discussion needed to be moved to a later section.

Most reviewers found the description of the development and pathogenesis of CBD in section V.D to be accurate and understandable. Dr. Breyse felt the section could better delineate the steps in disease development (*e.g.*, development of beryllium sensitization, CBD progression) and recommended the 2008 National Academy of Sciences report as a model. He and Dr. Gordon felt the section overemphasized the role of apoptosis in CBD development. Dr. Breyse and Dr. Balmes recommended avoiding the phrase 'subclinical' to describe sensitization and asymptomatic CBD, preferring the term 'early stage' as a more appropriate description. Dr. Balmes requested clarification regarding accumulation of inflammatory cells in the bronchoalveolar lavage (BAL) fluid during CBD development. Dr. Rossman suggested some additional description of beryllium binding with the HLA-class II receptor and subsequent interaction with the naïve CD4<sup>+</sup> T cells in the development of sensitization.

OSHA extensively reorganized section V.D to clearly delineate the disease process in a more linear fashion starting with the formation of beryllium antigen complex, its interaction with naïve T-cells to trigger CD4<sup>+</sup> T-cell proliferation, and development of beryllium sensitization. This is presented in section V.D.1. A figure has been added that schematically presents this process in its entirety and the steps at which dermal exposure and genetic factors are believed to influence disease development (Figure 2 in section V.D). Section V.D.2 describes how subsequent inhalation and the persistent residual presence of beryllium in the lung leads to CD4<sup>+</sup> T cell differentiation, cytokine production, accumulation of inflammatory cells in the alveolar region, granuloma formation, and progression of CBD. The section was modified to present apoptosis as only one of the plausible mechanisms for development/progression of CBD. The 'early stage' terminology was adopted and the role of inflammatory cells in BAL was clarified.

While peer reviewers felt genetic susceptibility was adequately characterized, Dr. Rossman, Dr. Gordon, and Dr. Breyse suggested that additional study data be discussed to provide more depth on the subject, particularly the role genetic

polymorphisms in providing a negatively charged HLA protein binding site for the positively charged beryllium ion. Section V.D.3 on genetic susceptibility now includes more information on the importance of gene-environment interaction in the development of CBD in low-exposed workers. The section expands on HLA-DPB1 alleles that influence beryllium-hapten binding and its impact on CBD risk.

All reviewers found the definition of CBD to be clear and understandable. However, several reviewers commented on the document discussion of the BeLPT which operationally defines beryllium sensitization. Drs. Balmes and Rossman requested a more clear statement that two abnormal blood BeLPT results were generally necessary to confirm sensitization. Dr. Balmes and Dr. Breyse requested more discussion of historical changes in the BeLPT method that have led to improvement in test performance and reductions in interlaboratory variability. These comments were addressed in an expanded document section V.D.5.b on criteria for sensitization and CBD case definition following development of the BeLPT.

Reviewers made suggestions to improve presentation of the many epidemiological studies of sensitization and CBD in the draft health effects document. Dr. Breyse and Dr. Gordon recommended that common weaknesses that apply to multiple studies be more rigorously discussed. Dr. Gordon requested that the discussion of the Beryllium Case Registry be modified to clarify the case inclusion criteria. Most reviewers called for the addition of tables to assist in summarizing the epidemiological study information.

A paragraph has been added near the beginning of section V.D.5 that identifies the common challenges to interpreting the epidemiological evidence that supports the occurrence of sensitization and CBD at occupational beryllium exposures below the current PEL. These include studies with small numbers of subjects and CBD cases, potential exposure misclassification resulting from lack of personal and short-term exposure data prior to the late 1990s, and uncertain dermal contribution among other issues. Table A.1 summarizing the key sensitization and CBD epidemiological studies was added to this preamble in appendix A of section V. Subsection V.D.5.a on studies conducted prior to the BeLPT has been reorganized to more clearly present the need for the Registry prior to listing the inclusion criteria.

Several reviewers requested that the draft health effects document discuss additional occupational studies on sensitization and CBD. Dr. Balmes suggested including Bailey *et al.* (2010) on reduction in sensitization at a beryllium production plant and Arjomandi *et al.* (2010) on CBD among workers in a nuclear weapons facility. Dr. Breyse recommended adding a brief discussion of Taiwo *et al.* (2008) on sensitization in aluminum smelter workers. Dr. Gordon and Dr. Rossman suggested mention of Curtis, (1951) on cutaneous hypersensitivity to beryllium as important for the role of dermal exposure. Dr. Rossman also provided a reference to a number of other sensitization and CBD articles of historical significance.

The above studies have been incorporated in several subsections of V.D.5 on human epidemiological evidence. The 1951 Curtis study is mentioned in the introduction to section V.D.5 as evidence of sensitization from dermal exposure. The Bailey *et al.* (2010) study is discussed in subsection V.D.5.d on beryllium metal processing and alloy production. The Arjomandi *et al.* (2010) study is discussed subsection V.D.5.h on nuclear weapons facilities and cleanup of former facilities. The Taiwo *et al.* (2008) study is discussed in subsection V.D.5.i on aluminum smelting. The other historical studies of historical significance are referenced in subsection V.D.5.a on studies conducted prior to the BeLPT.

Dr. Gordon suggested that the draft health effects document make clear that limitations in study design and lack of an appropriate model limited extrapolation of animal findings to the human immune-based respiratory disease. Dr. Rossman also remarked on the lack of a good animal model that consistently demonstrates a specific cell-mediated immune response to beryllium. Section V.D.6 was modified to include a statement that lack of a dependable animal model combined with studies that used single doses, few animals or abbreviated observation periods have limited the utility of the data. Table A.2 was added that summarizes important information on key animal studies of beryllium-induced immune response and lung inflammation.

In general, peer reviewers considered the preliminary conclusions with regard to sensitization and CBD to be reasonable and well presented in the draft health effects evaluation. All reviewers agreed that the scientific evidence supports sensitization as a necessary condition and an early endpoint in the development of CBD.

The peer reviewers did not consider the presented evidence to convincingly show lung burden to be an important dose metric. Dr. Gordon explained that some animal studies in dogs have indicated that lung dose does influence granuloma formation but the importance of dose relative to genetic susceptibility, and physical/chemical form is unclear. He suggested the document indicate that many factors, including lung burden, affect the pulmonary tissue response to beryllium particles in the workplace.

There were other suggested improvements to the preliminary conclusion section of the draft document. Dr. Breyse felt that presenting the range of observed prevalence from occupational studies would help support the Agency findings. He also recommended that the preliminary conclusions make clear that CBD is a very complex disease and certain steps involved in the onset and progression are not yet clearly understood. Dr. Rossman pointed out that a report from Mroz *et al.* (2009) updated information on the rate at which beryllium sensitized individuals progress to CBD.

A statement has been added to section V.D.7 on the preliminary sensitization and CBD conclusions to indicate that all facets of development and progression of sensitization and CBD are not fully understood. Study references and prevalence ranges were provided to support the conclusion that epidemiological evidence demonstrates that sensitization and CBD occur from present-day exposures below OSHA's PEL. Statements were modified to indicate animal studies provide important insights into the roles of chemical form, genetic susceptibility, and residual lung burden in the development of beryllium lung disease. Updated information on rate of progression from sensitization to CBD was also included.

Reviewers made suggestions to improve presentation of the epidemiological studies of lung cancer that were similar to their comments on the CBD studies. Dr. Steenland requested that a table summarizing the lung cancer studies be added. He also recommended that more emphasis be placed on the SMR results from the Ward *et al.* (1992) study. Dr. Balmes felt that more detail was presented on the animal cancer studies than necessary to convey the relevant message. All reviewers thought that the Schubauer-Berigan *et al.* (2010) cohort mortality study that addressed some of the shortcomings of earlier lung cancer mortality studies should be discussed in the health effects document.

The recent Schubauer-Berigan *et al.* (2010) study conducted by the NIOSH Division of Surveillance, Hazard Evaluations, and Field Studies is now described and discussed in section V.E.2 on human epidemiology studies. Table A.3 summarizing the range of exposure measurements, study strengths and limitations, and other key lung cancer epidemiological study information was added to the health effects preamble. Section V.E.3 on the animal cancer studies already contained several tables that present study data so OSHA decided a summary table was not needed in this section.

Reviewers were asked two questions regarding the OSHA preliminary conclusions on beryllium-induced lung cancer: was the inflammation mechanism presented in the lung cancer section reasonable; and were there other mechanisms or modes of action to be considered? All reviewers agreed that inflammation was a reasonable mechanistic presentation as outlined in the document. Dr. Gordon requested OSHA clarify that inflammation may not be the sole mechanism for carcinogenicity. OSHA inserted statements in section V.E.5 on the preliminary lung cancer conclusions clarifying that tumorigenesis secondary to inflammation is a reasonable mechanism of action but other plausible mechanisms independent of inflammation may also contribute to the lung cancer associated with beryllium exposure.

There were a few comments from reviewers on health effects other than sensitization/CBD and lung cancer in the draft document. Dr. Balmes requested that the term "beryllium poisoning" not be used when referring to the hepatic effects of beryllium. He also offered language to clarify that the cardiovascular mortality among beryllium production workers in the Ward study cohort was probably due to ischemic heart disease and not the result of impaired lung function. Dr. Gordon requested removal of references to hepatic studies from in vitro and intravenous administration done at very high dose levels of little relevance to the occupational exposures of interest to OSHA. These changes were made to section V.F on other health effects.

#### *B. Peer Review of the Draft Preliminary Risk Assessment*

The Technical Charge to peer reviewers for review of the draft preliminary risk assessment was to ensure OSHA selected appropriate study data, assessed the data in a scientifically credible manner, and clearly explained its analysis. Specific

charge questions were posed regarding choice of data sets, risk models, and exposure metrics; the role of dermal exposure and dermal protection; construction of the job exposure matrix; characterization of the risk estimates and their uncertainties; and whether a quantitative assessment of lung cancer risk, in addition to sensitization and CBD, was warranted.

Overall, the peer reviewers were highly supportive of the Agency's approach and major conclusions. They offered valuable suggestions for revisions and additional analysis to improve the clarity and certain technical aspects of the risk assessment. These suggestions and the steps taken by OSHA to address them are summarized here. A final peer review report (ERG, 2010c) and a risk assessment background document (OSHA, 2014a) are available in the docket.

OSHA asked peer reviewers a series of questions regarding its selection of surveys from a beryllium ceramics facility, a beryllium machining facility, and a beryllium alloy processing facility as the critical studies that form the basis of the preliminary risk assessment. Research showed that these workplaces had well characterized and relatively low beryllium exposures and underwent plant-wide screenings for sensitization and CBD before and after implementation of exposure controls. The reviewers were requested to comment on whether the study discussions were clearly presented, whether the role of dermal exposure and dermal protection were adequately addressed, and whether the preliminary conclusions regarding the observed exposure-related prevalence and reduction in risk were reasonable and scientifically credible. They were also asked to identify other studies that should be reviewed as part of the sensitization/CBD risk assessment.

Every peer reviewer felt the key studies were appropriate and their selection clearly explained in the document. Every peer reviewer regarded the preliminary conclusions from the OSHA review of these studies to be reasonable and scientifically sound. This conclusion stated that substantial risk of sensitization and CBD were observed in facilities where the highest exposed processes had median full-shift beryllium exposures around 0.2  $\mu\text{g}/\text{m}^3$  or higher and that the greatest reduction in risk was achieved when exposures for all processes were lowered to 0.1  $\mu\text{g}/\text{m}^3$  or below.

The reviewers suggested that three additional studies be added to the risk assessment review of the

epidemiological literature. Dr. Balmes felt the document would be strengthened by including the Bailey *et al.* (2010) investigation of sensitization in a population of workers at the beryllium metal, alloy, and oxide production plant in Elmore, OH and the Arjomandi *et al.* (2010) publication on a group of 50 sensitized workers from a nuclear plant. Dr. Breyse suggested the study by Taiwo *et al.* (2008) on sensitization among workers in four aluminum smelters be considered.

A new subsection VI.A.3 was added to the preliminary risk assessment that describes the changes in beryllium exposure measurements, prevalence of sensitization and CBD, and implementation of exposure controls between 1992 and 2006 at the Elmore plant. This subsection includes a discussion of the Bailey *et al.* study. A summary of the Taiwo *et al.* (2008) study was added as subsection VI.A.5. A discussion of the Arjomandi *et al.* (2010) study was added in subsection VI.B as evidence that sensitized workers with primarily low beryllium exposure go on to develop CBD. However, the low rates of CBD among this group of sensitized workers also suggest that low beryllium exposure may reduce CBD risk when compared to worker populations with higher exposure levels.

While the majority of reviewers stated that OSHA adequately addressed the role of dermal exposure in sensitization and the importance of dermal protection for workers, a few had additional suggestions for OSHA's discussion. Dr. Breyse and Dr. Gordon pointed out that because the beryllium exposure control programs featured steps to reduce both skin contact and inhalation, it was difficult to distinguish between the effects of reducing airborne and dermal exposure. A statement was added to subsection VI.B that concurrent implementation of respirator use, dermal protection and engineering changes made it difficult to attribute reduced risk to any single control measure. Since the Cullman plant did not require glove use, OSHA believes it to be the best data set available for evaluating the effects of airborne exposure control on risk of sensitization.

Dr. Breyse requested additional discussion of the role of respiratory protection in achieving reduction in risk. Dr. Gordon suggested some additional clarification regarding mean and median exposure measures. Additional information on respiratory programs and exposure measures (*e.g.*, median, arithmetic and geometric means), where available, were presented

for each of the studies discussed in subsection VI.A.

The peer reviewers generally agreed that it was reasonable to conclude that community-acquired CBD (CA-CBD) resulted from low beryllium exposures. Drs. Breyse, Balmes and others noted that higher short-term excursions could not be ruled out. Dr. Gordon suggested that genetic susceptibility may have a role in cases of CA-CBD. Dr. Rossman raised the possibility that some CA-CBD cases could occur from contact with beryllium workers. All these points were added to subsection VI.C.

OSHA asked the peer reviewers to evaluate the choice of the National Jewish Medical and Research Center (NJMRC) data set on the Cullman, AL machinist population as a basis for exposure-response analysis and the reliance on cumulative exposure as the basis for the exposure-response analysis of sensitization and CBD. All peer reviewers indicated that the choice of the NJMRC data set for exposure-response analysis was clearly explained and reasonable and that they knew of no better data set for the analysis. Dr. Rossman commented that the NJMRC data set was an excellent source of exposures to different levels of beryllium and testing and evaluation of the workers. Dr. Steenland and Dr. Gordon suggested that the results from the OSHA analysis of the NJMRC data be compared with the available data from the studies of other beryllium facilities discussed in the epidemiological literature analysis. While a rigorous quantitative comparison (*e.g.*, meta analysis) is difficult due to differences in the study designs and data types available for each study, subsection VI.E.4 compares the results of OSHA's prevalence analysis from the Cullman data with results from studies of the Tucson and Reading facilities.

OSHA asked the peer reviewers to evaluate methods used to construct the job exposure matrix (JEM) and to estimate beryllium exposure for each worker in the NJMRC data set. The JEM procedure was briefly summarized in the review document and described in detail as part of a risk assessment technical background document made available to the reviewers (OSHA, 2014a). Dr. Balmes felt that a more thorough discussion of the JEM would strengthen the preamble document. Dr. Gordon requested information about values assigned exposures below the limit of detection. Dr. Steenland requested that both the preamble and technical background document contain additional information on aspects of the JEM construction such as the job

categories, job-specific exposure values, how jobs were grouped, and how non-machining jobs were handled in the JEM. He suggested the entire JEM be included in the technical background document. OSHA greatly expanded subsection VI.E.2 on air sampling and JEM to include more detailed discussion of the JEM construction. Exposure values for machining and non-machining job titles were provided in Tables VI-4 and VI-5. The procedures and rationale for grouping job-specific measurements into four time periods was explained. Jobs were not grouped in the JEM; rather, individual exposure estimates were created for each job in the work history data set. The technical background document further clarifies the JEM construction and the full JEM is included as an appendix to the revised background document (OSHA, 2014a). Subsection VI.E.3 on worker exposure reconstruction contains further detail about the work histories.

Peer reviewers fully supported OSHA's choice of the cumulative exposure metric to estimate risk of CBD from the NJMRC data set. As explained by Dr. Steenland, "cumulative exposure is often the choice for many chronic diseases as opposed to average or highest exposure." He pointed out that the cumulative exposure metric also fit the CBD data better than other metrics. The reviewers generally felt that short-term peak exposure was probably the measure of airborne exposure most relevant to risk of beryllium sensitization. However, peer reviewers agreed that data required to capture workers' short-term peak exposures and to relate the peak exposure levels to sensitization were not available. Dr. Breyse explained that "short-term (hrs to minutes) peak exposures may be important to sensitization risk, while long term averages are more important for CBD risk. Unfortunately data for short-term peak exposures may not exist." Dr. Steenland explained that of the available metrics "cumulative exposure fits the sensitization data better than the two alternatives, and hence is the best metric." Statements were added to subsection VI.E.3 to indicate that while short-term exposures may be highly relevant to risk of sensitization, the individual peak exposures leading up to onset of sensitization was not able to be determined in the NJMRC Cullman study.

Peer reviewers found the methods used in the statistical exposure-response analysis to be clearly described. With the exception of Dr. Steenland, reviewers believed that a detailed critique of the statistical approach was

beyond their level of expertise. Dr. Steenland supported OSHA's overall approach to the risk modeling and recommended additional analyses to explore the sensitivity of OSHA's results to alternate choices and to test the validity of aspects of the analysis. Dr. Steenland recommended that the logistic regression used by OSHA as a preliminary first analysis be dropped as an inappropriate model for a situation where it is important to account for changing exposures and case onset over time. Instead, he suggested a sensitivity analysis in which exposure-response coefficients generated using a traditional Cox proportionate hazards model be compared to the discrete time Cox model analog (*i.e.*, complementary log-log Cox model) used by OSHA. The sensitivity analysis would facilitate examination of the proportional hazard assumption implied by the use of these models. Dr. Steenland advocated that OSHA include a table that displayed the mean number of BeLPT tests for the study population in order to address whether the number of sensitization tests introduced a potential bias. He inquired about the possibility of determining a sensitization incidence rate using cumulative or average exposure. Dr. Steenland suggested that the model control for additional potential confounders, such as age, smoking status, race and gender. He wanted a more complete explanation of the model constant for the year of diagnosis in Tables VI-9 through VI-12 to be included in the preamble as it was in the technical background document. Dr. Steenland recommended a sensitivity analysis that excludes the highest 5 to 10 percent of cumulative exposures which might address potential model uncertainty at the high end exposures. He requested that the results of statistical tests for non-linearity be included and confidence intervals for the risk estimates in Tables VI-17 and VI-18 be determined.

Many of Dr. Steenland's comments were addressed in subsection VI.F on the statistical modeling. The logistic regression analysis was removed from the section. A sensitivity analysis using the standard Cox model that treats survival time as continuous rather than discrete was added to the risk assessment background document and results were described in subsection VI.F. The interaction between exposure and follow-up time was not significant in the models suggesting that the proportional hazard assumption should not be rejected. The model coefficients using the standard Cox model were similar to model coefficients for the

discrete model. Given this, OSHA did not feel it necessary to further estimate risks using the continuous Cox model at specific exposure levels.

A table of the mean number of BeLPT tests across the study population was added to the risk assessment background document. Subsection VI.F describes the table results and its impact on the statistical modeling. Smoking status and age were included in the discrete Cox proportional hazards model and not found to be significant predictors of beryllium sensitization. However, the available study population composition did not allow a confounder analysis of race and gender. OSHA chose not to include a detailed explanation of the model constant for the year of diagnosis in the preamble section. OSHA agrees with Dr. Steenland that the risk assessment background document adequately describes the model terms. For that reason, OSHA prefers that the risk assessment preamble focus on the results and major points of the analysis and refer the reader to the more technical background document for an explanation of model parameters. The linearity assumption was assessed using a fractional polynomial approach. The best fitting polynomials did not fit significantly better than the linear model. The details of the analysis were included in the risk assessment background document. Tables VI-17 and VI-18 now include the upper 95 percent confidence limits on the model-predicted cases of sensitization and CBD for the current and alternative PELs.

Most peer reviewers felt the major uncertainties of the risk assessment were clearly and adequately discussed in the documents they reviewed. Dr. Breyse requested that the risk assessment cover potential underestimation of risk from exposure misclassification bias. He requested further discussion of the degree to which the risk estimates from the Cullman machining plant could be extrapolated to workplaces that use other physical (*e.g.*, particle size) and chemical forms of beryllium. He went on to question the strength of evidence that insoluble forms of beryllium cause CBD. Dr. Breyse also suggested that the assumptions used in the risk modeling be consolidated and more clearly presented. Dr. Steenland felt that there was potential underestimation of CBD risk resulting from exclusion of former workers and case status of current workers after employment.

Discussion of these uncertainties was added in the final paragraphs of section VI.F. The section was modified to more clearly identify assumptions with regard

to the risk modeling such as an assumed linearity in exposure-response and cumulative dose equivalency when extrapolating risks over a 45-year working lifetime. Section VI.F recognizes the uncertainties in risk that can result from reconstructing individual exposures with very limited sampling data prior to 1994. The potential exposure misclassification can limit the strength of exposure-response relationships and result in the underestimation of risk. A more technical discussion of modeling assumptions and exposure measurement error are provided in the risk assessment background document. Section VI.F points out that the NJMRC data set does not capture CBD that occurred among workers who retired or left the Cullman plant. This and the short follow-up time is a source of uncertainty that likely leads to underestimation of risk. The section indicates that it is not unreasonable to expect the risk estimates to generally reflect onset of sensitization and CBD from exposure to beryllium forms that are relatively insoluble and enriched with respirable particles as encountered at the Cullman machining plant. Additional uncertainty is introduced when extrapolating the risk estimates to beryllium compounds of vastly different solubility and particle characteristics. OSHA does not agree with the comment suggesting that the association between CBD and insoluble forms of beryllium is weak. The principle sources of beryllium encountered at the Cullman machining plant, the Reading copper beryllium processing plant and the Tucson ceramics plant where excessive CBD was observed are insoluble forms of beryllium, such as beryllium metal, beryllium alloy, and beryllium oxide.

Finally, OSHA asked the peer reviewers to evaluate its treatment of lung cancer in the earlier draft preliminary risk assessment (OSHA, 2010b). When that document was prepared, OSHA had elected not to conduct a lung cancer risk assessment. The Agency believed that the exposure-response data available to conduct a lung cancer risk assessment from a Sanderson *et al.* study of a Reading, PA beryllium plant by was highly problematic. The Sanderson study primarily involved workers with extremely high and short-term exposures above airborne exposure levels of interest to OSHA ( $2 \mu\text{g}/\text{m}^3$  and below).

Just prior to arranging the peer review, a NIOSH study was published by Schubauer-Berigan *et al.* updating the Reading, PA cohort studied by Sanderson *et al.* and adding cohorts

from two additional plants in Elmore, OH and Hazleton, PA (Schubauer-Berigan, 2011). At OSHA's request, the peer reviewers reviewed this study to determine whether it could provide a better basis for lung cancer risk analysis than the Sanderson *et al.* study. The reviewers found that the NIOSH update addressed the major concerns OSHA had expressed about the Sanderson study. In particular, they pointed out that workers in the Elmore and Hazleton cohorts had longer tenure at the plants and experienced lower exposures than those at the Reading, PA plant. Dr. Steenland recommended that "OSHA consider the new NIOSH data and develop risk estimates for lung cancer as well as sensitization and CBD." Dr. Breyse believed that the NIOSH data "suggest that a risk assessment for lung cancer should be conducted by OSHA and the results be compared to the CBD/sensitization risk assessment before recommending an appropriate exposure concentration." While acknowledging the improvements in the quality of the data, other reviewers were more restrained in their support for quantitative estimates of lung cancer risk. Dr. Gordon stated that despite improvements, there was "still uncertainty associated with the paucity of data below the current PEL of 2  $\mu\text{g}/\text{m}^3$ ." Dr. Rossman noted that the NIOSH study "did not address the problem of the uncertainty of the mechanism of beryllium carcinogenicity." He felt that the updated NIOSH lung cancer mortality data "should not change the Agency's rationale for choosing to establish its risk findings for the proposed rule on its analysis for beryllium sensitization and CBD." Dr. Balmes agreed that "the agency will be on firmer ground by focusing on sensitization and CBD."

The preliminary risk assessment preamble subsection VI.G on lung cancer includes a discussion of the quantitative lung cancer risk assessment published by NIOSH researchers in 2010 (Schubauer-Berigan, 2011). The discussion describes the lower exposure levels, longer tenure, fewer short-term workers and additional years of observation that make the data more suitable for risk assessment. NIOSH relied on several modeling approaches to show that lung cancer risk was significantly related to both mean and cumulative beryllium exposure. Subsection VI.G provides the excess lifetime lung cancer risks predicted from several best-fitting NIOSH models at beryllium exposures of interest to OSHA (Table VI-20). Using the piecewise log-linear proportional

hazards model favored by NIOSH, there is a projected drop in excess lifetime lung cancer risks from approximately 61 cases per 1000 exposed workers at the current PEL of 2.0  $\mu\text{g}/\text{m}^3$  to approximately 6 cases per 1000 at the proposed PEL of 0.2  $\mu\text{g}/\text{m}^3$ . Subsection VI.H on preliminary conclusions indicates that these projections support a reduced risk of lung cancer from more stringent control of beryllium exposures but that the lung cancer risk estimates are more uncertain than those for sensitization and CBD.

### VIII. Significance of Risk

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." 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.

The Agency's burden to establish significant risk is based on the requirements of the OSH Act (29 U.S.C. 651 *et seq.*). 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 the *Benzene* decision, 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" (*Industrial Union Department, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607, 642 (1980) (plurality opinion)). Examining section 3(8) more closely, the Court described OSHA's obligation to demonstrate significant risk:

"[S]afe" is not the equivalent of "risk-free." A workplace can hardly be considered "unsafe" unless it threatens the workers with a significant risk of harm. Therefore, before the Secretary can promulgate any permanent health or safety standard, he must make a threshold finding that the place of employment is unsafe in the sense that significant risks are present and can be eliminated or lessened by a change in practices (*Id.*).

As the Court made clear, the Agency 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 a significant risk determination. The Court stated that "it is the Agency's responsibility to

determine in the first instance what it considers to be a 'significant' risk," (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" (448 U.S. at 659). The Court also stated that, 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" (448 U.S. at 656). Furthermore:

A reviewing court [is] to give OSHA some leeway where its findings must be made on the frontiers of scientific knowledge . . . . [T]he Agency is free to use conservative assumptions in interpreting the data with respect to carcinogens, risking error on the side of overprotection rather than underprotection [so long as such assumptions are based on] a body of reputable scientific thought (448 U.S. at 656).

Thus, to make the significance of risk determination for a new or proposed standard, OSHA uses the best available scientific evidence to identify material health impairments associated with potentially hazardous occupational exposures and to evaluate exposed workers' risk of these impairments.

The OSH Act also requires that the Agency make a finding that the toxic material or harmful physical agent at issue causes material impairment to worker health. In that regard, the Act directs the Secretary of Labor to set standards based on the available evidence where no employee, over his/her working life time, will suffer from material impairment of health or functional capacity, even if such employee has regular exposure to the hazard, to the extent feasible (29 U.S.C. 655(b)(5)).

As with significant risk, what constitutes material impairment in any given case is a policy determination for 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—and that OSHA may act with a "pronounced bias towards worker safety" (*Id.; Bldg & Constr. Trades Dep't v. Brock*, 838 F.2d 1258, 1266 (D.C. Cir. 1988)). OSHA's long-standing policy is to consider 45 years as a "working life,"

over which it must evaluate material impairment and risk.

In formulating this proposed beryllium standard, OSHA has reviewed the best available evidence pertaining to the adverse health effects of occupational beryllium exposure, including lung cancer and chronic beryllium disease (CBD), and has evaluated the risk of these effects from exposures allowed under the current standard as well as the expected impact of the proposed standard on risk. Based on its review of extensive epidemiological and experimental research, OSHA has preliminarily determined that long-term exposure at the current Permissible Exposure Limit (PEL) would pose a significant risk of material impairment to workers' health, and that adoption of the new PEL and other provisions of the proposed rule will substantially reduce this risk.

#### A. Material Impairment of Health

In this preamble at section V, Health Effects, OSHA reviewed the scientific evidence linking occupational beryllium exposure to a variety of adverse health effects, including CBD and lung cancer. Based on this review, OSHA preliminarily concludes that beryllium exposure causes these effects. The Agency's preliminary conclusion was strongly supported by a panel of independent peer reviewers, as discussed in section VII.

Here, OSHA discusses its preliminary conclusion that CBD and lung cancer constitute material impairments of health, and briefly reviews other adverse health effects that can result from beryllium exposure. Based on this preliminary conclusion and on the scientific evidence linking beryllium exposure to both CBD and lung cancer, OSHA concludes that occupational exposure to beryllium causes "material impairment of health or functional capacity" within the meaning of the OSH Act.

##### 1. Chronic Beryllium Disease

CBD is a respiratory disease in which the body's immune system reacts to the presence of beryllium in the lung, causing a progression of pathological changes including chronic inflammation and tissue scarring. CBD can also impair other organs such as the liver, skin, spleen, and kidneys and cause adverse health effects such as granulomas of the skin and lymph nodes and cor pulmonale (*i.e.*, enlargement of the heart) (Conradi *et al.*, 1971; ACCP, 1965; Kriebel *et al.*, 1988a and b). In early, asymptomatic stages of CBD, small granulomatous lesions and mild inflammation occur in the lungs. Early

stage CBD among some workers has been observed to progress to more serious disease even after the worker is removed from exposure (Mroz, 2009), probably because common forms of beryllium have slow clearance rates and can remain in the lung for years after exposure. Sood *et al.* has reported that cessation of exposure can sometimes have beneficial effects on lung function (Sood *et al.*, 2004). However, this was based on a small study of six patients with CBD, and more research is needed to better determine the relationship between exposure duration and disease progression. In general, progression of CBD from early to late stages is understood to vary widely, responding differently to exposure cessation and treatment for different individuals (Sood, 2009; Mroz, 2009).

Over time, the granulomas can spread and lead to lung fibrosis (scarring) and moderate to severe loss of pulmonary function, with symptoms including a persistent dry cough and shortness of breath (Saber and Dweik, 2000). Fatigue, night sweats, chest and joint pain, clubbing of fingers (due to impaired oxygen exchange), loss of appetite, and unexplained weight loss may occur as the disease progresses. Corticosteroid therapy, in workers whose beryllium exposure has ceased, has been shown to control inflammation, ease symptoms (*e.g.*, difficulty breathing, fever, cough, and weight loss) and in some cases prevent the development of fibrosis (Marchand-Adam *et al.*, 2008). Thus early treatment can lead to CBD regression in some patients, although there is no cure (Sood, 2004). Other patients have shown short-term improvements from corticosteroid treatment, but then developed serious fibrotic lesions (Marchand-Adam *et al.*, 2008). Once fibrosis has developed in the lungs, corticosteroid treatment cannot reverse the damage (Sood, 2009). Persons with late-stage CBD experience severe respiratory insufficiency and may require supplemental oxygen (Rossman, 1991). Historically, late-stage CBD often ended in death (NAS, 2008).

While the use of steroid therapy has mitigated CBD mortality, treatment with corticosteroids has side effects that need to be measured against the possibility of progression of disease (Trikudanathan and McMahon, 2008; Lipworth, 1999; Gibson *et al.*, 1996; Zaki *et al.*, 1987). Adverse effects associated with long-term corticosteroid use include, but are not limited to, increased risk of opportunistic infections (Lionakis and Kontoyiannis, 2003; Trikudanathan and McMahon, 2008); accelerated bone loss or osteoporosis leading to increased risk of fractures or breaks (Hamida *et al.*,

2011; Lehouck *et al.*, 2011; Silva *et al.*, 2011; Sweiss *et al.*, 2011; Langhammer *et al.*, 2009); psychiatric effects including depression, sleep disturbances, and psychosis (Warrington and Bostwick, 2006; Brown, 2009); adrenal suppression (Lipworth, 1999; Frauman, 1996); ocular effects including cataracts, ocular hypertension, and glaucoma (Ballonzolli and Bouchier, 2010; Trikudanathan and McMahon, 2008; Lipworth, 1999); an increase in glucose intolerance (Trikudanathan and McMahon, 2008); excessive weight gain (McDonough *et al.*, 2008; Torres and Nowson, 2007; Dallman *et al.*, 2007; Wolf, 2002; Cheskin *et al.*, 1999); increased risk of atherosclerosis and other cardiovascular syndromes (Franchimont *et al.*, 2002); skin fragility (Lipworth, 1999); and poor wound healing (de Silva and Fellows, 2010). Studies relating the long-term effect of corticosteroid use for the treatment of CBD need to be undertaken to evaluate the treatment's overall effectiveness against the risk of adverse side effects from continued usage.

OSHA considers late-stage CBD to be a material impairment of health, as it involves permanent damage to the pulmonary system, causes additional serious adverse health effects, can have adverse occupational and social consequences, requires treatment associated with severe and lasting side effects, and may in some cases be life-threatening. Furthermore, OSHA believes that material impairment begins prior to the development of symptoms of the disease.

Although there are no symptoms associated with early-stage CBD, during which small lesions and inflammation appear in the lungs, the Agency has preliminarily concluded that the earliest stage of CBD is material impairment of health. OSHA bases this conclusion on evidence showing that early-stage CBD is a measurable change in the state of health which, with and sometimes without continued exposure, can progress to symptomatic disease. Thus, prevention of the earliest stages of CBD will prevent development of more serious disease. The OSHA Lead Standard established the Agency's position that a 'subclinical' health effect may be regarded as a material impairment of health. In the preamble to that standard, the Agency said:

OSHA believes that while incapacitating illness and death represent one extreme of a spectrum of responses, other biological effects such as metabolic or physiological changes are precursors or sentinels of disease which should be prevented . . . Rather than revealing beginnings of illness the standard must be selected to prevent an earlier point

of measurable change in the state of health which is the first significant indicator of possibly more severe ill health in the future. The basis for this decision is twofold—first, pathophysiologic changes are early stages in the disease process which would grow worse with continued exposure and which may include early effects which even at early stages are irreversible, and therefore represent material impairment themselves. Secondly, prevention of pathophysiologic changes will prevent the onset of the more serious, irreversible and debilitating manifestations of disease.<sup>11</sup> (43 FR 52952, 52954, November 14, 1978)

Since the Lead rulemaking, OSHA has also found other non-symptomatic health conditions to be material impairments of health. In the Bloodborne Pathogens (BP) rulemaking, OSHA maintained that material impairment includes not only workers with clinically “active” hepatitis from the hepatitis B virus (HBV) but also includes asymptomatic HBV “carriers” who remain infectious and are able to put others at risk of serious disease through contact with body fluids (*e.g.*, blood, sexual contact) (56 FR 64004, December 6, 1991). OSHA stated: “Becoming a carrier [of Hepatitis B] is a material impairment of health even though the carrier may have no symptoms. This is because the carrier will remain infectious, probably for the rest of his or her life, and any person who is not immune to HBV who comes in contact with the carrier’s blood or certain other body fluids will be at risk of becoming infected” (56 FR 64004, 64036).

OSHA preliminarily finds that early-stage CBD is the type of asymptomatic health effect the Agency determined to be a material impairment of health in the lead standard. Early stage CBD involves lung tissue inflammation without symptomatology that can worsen with—or without—continued exposure. The lung pathology progresses over time from a chronic inflammatory response to tissue scarring and fibrosis accompanied by moderate to severe loss in pulmonary function. Early stage CBD is clearly a precursor of advanced clinical disease, prevention of which will prevent symptomatic

<sup>11</sup> Even if asymptomatic CBD were not itself a material impairment of health, the D.C. Circuit upheld OSHA’s authority to regulate to prevent subclinical health effects as precursors to disease in *United Steelworkers of America, AFL-CIO v. Marshall*, 647 F.2d 1189, 1252 (D.C. Cir. 1980), which reviewed the Lead standard. Without deciding whether the early symptoms of disease were themselves a material impairment, the court concluded that OSHA may regulate subclinical effects if it can demonstrate on the basis of substantial evidence that preventing subclinical effects would help prevent the clinical phase of disease (*Id.*).

disease. OSHA argued in the Lead standard that such precursor effects should be considered material health impairments in their own right, and that the Agency should act to prevent them when it is feasible to do so. Therefore, OSHA preliminarily finds all stages of CBD to be material impairments of health.

## 2. Lung Cancer

OSHA considers lung cancer, a frequently fatal disease, to be a material impairment of health. OSHA’s finding that inhaled beryllium causes lung cancer is based on the best available epidemiological data, reflects evidence from animal and mechanistic research, and is consistent with the conclusions of other government and public health organizations (see this preamble at section V, Health Effects). For example, the International Agency for Research on Cancer (IARC), National Toxicology Program (NTP), and American Conference of Governmental Industrial Hygienists (ACGIH) have all classified beryllium as a known human carcinogen (IARC, 2009).

The Agency’s epidemiological evidence comes from multiple studies of U.S. beryllium workers (Sanderson *et al.*, 2001a; Ward *et al.*, 1992; Wagoner *et al.*, 1980; Mancuso *et al.*, 1979). Most recently, a NIOSH cohort study found significantly increased lung cancer mortality among workers at seven beryllium processing facilities (Schubauer-Berigan *et al.*, 2011). The cohort was exposed, on average, to lower levels of beryllium than those in most previous studies, had fewer short-term workers, and had sufficient follow-up time to observe lung cancer in the population. OSHA considers the Schubauer-Berigan study to be the best available epidemiological evidence regarding the risk of lung cancer from beryllium at exposure levels near the PEL.<sup>12</sup>

Supporting evidence of beryllium carcinogenicity comes from various animal studies as well as in vitro genotoxicity and other studies (EPA, 1998; ATSDR, 2002; Gordon and Bowser, 2003; NAS, 2008; Nickell-Brady *et al.*, 1994; NTP, 1999 and 2005; IARC, 1993 and 2009). Multiple mechanisms may be involved in the carcinogenicity of beryllium, and factors such as epigenetics, mitogenicity, reactive oxygen-mediated indirect genotoxicity, and chronic inflammation may contribute to the lung cancer associated

<sup>12</sup> The scientific peer review panel for OSHA’s Preliminary Risk Assessment agreed with the Agency that the Schubauer-Berigan analysis improves upon the previously available data for lung cancer risk assessment.

with beryllium exposure, although the results of studies testing the direct genotoxicity of beryllium are mixed (EPA summary, 1998). While there is uncertainty regarding the exact mechanism of carcinogenesis for beryllium, the overall weight of evidence for the carcinogenicity of beryllium is strong. Therefore, the Agency has preliminarily determined beryllium to be an occupational carcinogen.

## 3. Other Impairments

While OSHA has relied primarily on the relationship between occupational beryllium exposure and CBD and lung cancer to demonstrate the necessity of the standard, the Agency has also determined that several other adverse health effects can result from exposure to beryllium. Inhalation of high airborne concentrations of beryllium (well above the 2 µg/m<sup>3</sup> OSHA PEL) can cause acute beryllium disease, a severe (sometimes fatal), rapid-onset inflammation of the lungs. Hepatic necrosis, damage to the heart and circulatory system, chronic renal disease, mucosal irritation and ulceration, and urinary tract cancer have also reportedly been associated with occupational exposures well above the current PEL (see this preamble at section V, Health Effects, subsection E, Epidemiological Studies, and subsection F, Other Health Effects). These adverse systemic effects and acute beryllium disease mostly occurred prior to the introduction of occupational and environmental standards set in 1970–1972 (OSHA, 1971; ACGIH, 1971; ANSI, 1970) and 1974 (EPA, 1974) and therefore are less relevant today than in the past. Because they occur only rarely in current-day occupational environments, they are not addressed in OSHA’s risk analysis or significance of risk determination.

The Agency has also determined that beryllium sensitization, a precursor which occurs before early stage CBD and is an essential step for worker development of the disease, can result from exposure to beryllium. The Agency takes no position at this time on whether sensitization constitutes a material impairment of health, because it was unnecessary to do so as part of this rulemaking. As discussed in Section V, Health Effects, only sensitized individuals can develop CBD (NAS, 2008). OSHA’s risk assessment for sensitization informs the Agency’s understanding of what exposure control measures have been successful in preventing sensitization, which in turn prevents development of CBD. Therefore sensitization is considered in the next section on significance of risk.

In *AFL-CIO v. Marshall*, 617 F.2d 636, 654 n.83 (D.C. Cir. 1979) (*Cotton Dust*), the D.C. Circuit upheld OSHA's authority to regulate to prevent precursors to a material impairment of health without deciding whether the precursors themselves constituted material impairment of health.

### B. Significance of Risk and Risk Reduction

To evaluate the significance of the health risks that result from exposure to hazardous chemical agents, OSHA relies on the best available epidemiological, toxicological, and experimental evidence. The Agency uses both qualitative and quantitative methods to characterize the risk of disease resulting from workers' exposure to a given hazard over a working lifetime at levels of exposure reflecting compliance with current standards and compliance with the new standards being proposed.

As discussed above, the Agency's characterization of risk is guided in part by the *Benzene* decision. In *Benzene*, the Court broadly describes the range of risks OSHA might determine to be significant:

It is the Agency's responsibility to determine in the first instance what it considers to be a "significant" risk. Some risks are plainly acceptable and others are plainly unacceptable. If, for example, 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 percent benzene will be fatal, a reasonable person might well consider the risk significant and take the appropriate steps to decrease or eliminate it (*Benzene*, 448 U.S. at 655).

The Court further stated, "The requirement that a 'significant' risk be identified is not a mathematical straitjacket. . . . Although the Agency has no duty to calculate the exact probability of harm, it does have an obligation to find that a significant risk is present before it can characterize a place of employment as 'unsafe', "and proceed to promulgate a regulation (*Id.*).

In this preamble at section VI, Preliminary Risk Assessment, OSHA finds that the available epidemiological data are sufficient to evaluate risk for beryllium sensitization, CBD, and lung cancer among beryllium-exposed workers. The preliminary findings from this assessment are summarized below.

#### 1. Risk of Beryllium Sensitization and CBD

OSHA's preliminary risk assessment for CBD and beryllium sensitization

relies on studies conducted at a Tucson, AZ beryllium ceramics plant (Kreiss *et al.*, 1996; Henneberger *et al.*, 2001; Cummings *et al.*, 2006); a Reading, PA alloy processing plant (Schuler *et al.*, 2005; Thomas *et al.*, 2009); a Cullman, AL beryllium machining plant (Kelleher *et al.*, 2001; Madl *et al.*, 2007); and an Elmore, OH metal, alloy, and oxide production plant (Kreiss *et al.*, 1997; Bailey *et al.*, 2010; Schuler *et al.*, 2012). The Agency uses these studies to demonstrate the significance of risk at the current PEL and the significant reduction in risk expected with reduction of the PEL. In addition to the effects OSHA anticipates from reduction of airborne beryllium exposure, the Agency expects that dermal protection provisions in the proposed rule will further reduce risk. Studies conducted in the 1950s by Curtis *et al.* showed that soluble beryllium particles could penetrate the skin and cause beryllium sensitization (Curtis 1951, NAS 2008). Tinkle *et al.* established that 0.5- and 1.0- $\mu\text{m}$  particles can penetrate intact human skin surface and reach the epidermis, where beryllium particles would encounter antigen-presenting cells and initiate sensitization (Tinkle *et al.*, 2003). Tinkle *et al.* further demonstrated that beryllium oxide and beryllium sulfate, applied to the skin of mice, generate a beryllium-specific, cell-mediated immune response similar to human beryllium sensitization (Tinkle *et al.*, 2003). In the epidemiological studies discussed below, the exposure control programs that most effectively reduced the risk of beryllium sensitization and CBD incorporated both respiratory and dermal protection. OSHA has preliminarily determined that an effective exposure control program should incorporate both airborne exposure reduction and dermal protection provisions.

In the Tucson ceramics plant, 4,133 short-term breathing zone measurements collected between 1981 and 1992 had a median of 0.3  $\mu\text{g}/\text{m}^3$ . Kreiss *et al.* reported that eight (5.9 percent) of 136 workers tested for beryllium sensitization in 1992 were sensitized, six (4.4 percent) of whom were diagnosed with CBD. Exposure control programs were initiated in 1992 to reduce workers' airborne beryllium exposure, but the programs did not address dermal exposure. Full-shift personal samples collected between 1994 and 1999 showed a median beryllium exposure of 0.2  $\mu\text{g}/\text{m}^3$  in production jobs and 0.1  $\mu\text{g}/\text{m}^3$  in production support (Cummings *et al.*, 2007). In 1998, a second screening found that 6, (9 percent) of 69 tested

workers hired after the 1992 screening, were sensitized, of whom 1 was diagnosed with CBD. All of the sensitized workers had been employed at the plant for less than 2 years (Henneberger *et al.*, 2001), too short a time period for most people to develop CBD following sensitization. Of the 77 Tucson workers hired prior to 1992 who were tested in 1998, 8 (10.4 percent) were sensitized and all but 1 of these (9.7 percent) were diagnosed with CBD (Henneberger *et al.*, 2001).

Kreiss *et al.*, studied workers at a beryllium metal, alloy, and oxide production plant in Elmore, OH. Workers participated in a BeLPT survey in 1992 (Kreiss *et al.*, 1997). Personal lapel samples collected during 1990–1992 had a median value of 1.0  $\mu\text{g}/\text{m}^3$ . Kreiss *et al.* reported that 43 (6.9 percent) of 627 workers tested in 1992 were sensitized, 6 of whom were diagnosed with CBD (4.4 percent).

Newman *et al.* conducted a series of BeLPT screenings of workers at a Cullman, AL precision machining facility between 1995 and 1999 (Newman *et al.*, 2001). Personal lapel samples collected at this plant in the early 1980s and in 1995 from all machining processes combined had a median of 0.33  $\mu\text{g}/\text{m}^3$  (Madl *et al.*, 2007). After a sentinel case of CBD was diagnosed at the plant in 1995, the company implemented engineering and administrative controls and PPE designed to reduce workers' beryllium exposures in machining operations. Personal lapel samples collected extensively between 1996 and 1999 in machining jobs have an overall median of 0.16  $\mu\text{g}/\text{m}^3$ , showing that the new controls reduced machinists' exposures during this period. However, the results of BeLPT screenings conducted in 1995–1999 showed that the exposure control program initiated in 1995 did not sufficiently protect workers from beryllium sensitization and CBD. In a group of 60 workers who had been employed at the plant for less than a year, and thus would not have been working there prior to 1995, 4 (6.7 percent) were found to be sensitized. Two of these workers (3.35 percent) were diagnosed with CBD. (Newman *et al.*, 2001).

Sensitization and CBD were studied in a population of workers at a Reading, PA copper beryllium plant, where alloys containing a low level of beryllium were processed (Schuler *et al.*, 2005). Personal lapel samples were collected in production and production support jobs between 1995 and May 2000. These samples showed primarily very low airborne beryllium levels, with a median of 0.073  $\mu\text{g}/\text{m}^3$ . The wire



annealing and pickling process had the highest personal lapel sample values, with a median of 0.149  $\mu\text{g}/\text{m}^3$ . Despite these low exposure levels, a BeLPT screening conducted in 2000 showed that 5, (11.5 percent) workers of 43 hired after 1992 were sensitized (evaluation for CBD not reported). Two of the sensitized workers had been hired less than a year before the screening (Thomas *et al.*, 2009).

In summary, the epidemiological literature on beryllium sensitization and CBD that OSHA's risk assessment relied on show sensitization prevalences ranging from 6.5 percent to 11.5 percent and CBD prevalences ranging from 1.3 percent to 9.7 percent among workers who had full-shift exposures well below the current PEL and median full-shift exposures at or below the proposed PEL, and whose follow-up time was less than 45 years. As referenced earlier, OSHA is interested in the risk associated with a 45-year (*i.e.*, working lifetime) exposure. Because CBD often develops over the course of years following sensitization, the risk of CBD that would result from 45 years' occupational exposure to airborne beryllium is likely to be higher than the prevalence of CBD observed among these workers.<sup>13</sup> In either case, based on these studies, the risks to workers appear to be significant.

The available epidemiological evidence shows that reducing workers' levels of airborne beryllium exposure can substantially reduce risk of beryllium sensitization and CBD. The best available evidence on effective exposure control programs comes partly from studies of programs introduced around 2000 at Reading, Tucson, and Elmore that used a combination of engineering controls, dermal and respiratory PPE, and stringent housekeeping measures to reduce workers' dermal exposures and airborne exposures to levels well below the proposed PEL of 0.2  $\mu\text{g}/\text{m}^3$ . These programs have substantially lowered the risk of sensitization among new workers. As discussed earlier, prevention of beryllium sensitization prevents subsequent development of CBD.

In the Reading, PA copper beryllium plant, full-shift airborne exposures in all jobs were reduced to a median of 0.1  $\mu\text{g}/\text{m}^3$  or below and dermal protection was required for production-area workers beginning in 2000–2001 (Thomas *et al.*, 2009). After these adjustments were made, 2 (5.4 percent) of 37 newly hired workers became sensitized. Thereafter,

in 2002, the process with the highest exposures (median 0.1  $\mu\text{g}/\text{m}^3$ ) was enclosed and workers involved in that process were required to use respiratory protection. As a result, the remaining jobs had very low exposures (medians ~ 0.03  $\mu\text{g}/\text{m}^3$ ). Among 45 workers hired after the enclosure was built and respiratory protection instituted, 1 was found to be sensitized (2.2 percent). This is a sharp reduction in sensitization from the 11.5 percent of 43 workers, discussed above, who were hired after 1992 and had been sensitized by the time of testing in 2000.

In the Tucson beryllium ceramics plant, respiratory and skin protection was instituted for all workers in production areas in 2000. BeLPT testing done in 2000–2004 showed that only 1 (1 percent) worker had been sensitized out of 97 workers hired during that time period (Cummings *et al.*, 2007; testing for CBD not reported). This contrasts with the prevalence of sensitization in the 1998 Tucson BeLPT screening, which found that 6 (9 percent) of 69 workers hired after 1992 were sensitized (Cummings *et al.*, 2007).

The modern Elmore facility provides further evidence that combined reductions in respiratory exposure (via respirator use) and dermal exposure are effective in reducing risk of beryllium sensitization. In Elmore, historical beryllium exposures were higher than in Tucson, Reading, and Cullman. Personal lapel samples collected at Elmore in 1990–1992 had a median of 1.0  $\mu\text{g}/\text{m}^3$ . In 1996–1999, the company took steps to reduce workers' beryllium exposures, including engineering and process controls (Bailey *et al.*, 2010; exposure levels not reported). Skin protection was not included in the program until after 1999. Beginning in 1999 all new employees were required to wear loose-fitting powered air-purifying respirators (PAPR) in manufacturing buildings (Bailey *et al.*, 2010). Skin protection became part of the protection program for new employees in 2000, and glove use was required in production areas and for handling work boots beginning in 2001. Bailey *et al.*, (2010) compared the occurrence of beryllium sensitization and CBD in 2 groups of workers: 1) 258 employees who began work at the Elmore plant between January 15, 1993 and August 9, 1999 (the “pre-program group”) and were tested in 1997 and 1999, and 2) 290 employees who were hired between February 21, 2000 and December 18, 2006 and underwent BeLPT testing in at least one of frequent rounds of testing conducted after 2000 (the “program group”). They found that, as of 1999, 23 (8.9 percent) of the pre-program group

were sensitized to beryllium. The prevalence of sensitization among the “program group” workers, who were hired after the respiratory protection and PPE measures were put in place, was around 2–3 percent. Respiratory protection and skin protection substantially reduced, but did not eliminate, risk of sensitization. Evaluation of sensitized workers for CBD was not reported.

OSHA's preliminary risk assessment also includes analysis of a data set provided to OSHA by the National Jewish Research and Medical Center (NJMRC). The data set describes a population of 319 beryllium-exposed workers at a Cullman, AL machining facility. It includes exposure samples collected between 1980 and 2005, and has updated work history and screening information for over three hundred workers through 2003. Seven (2.2 percent) workers in the data set were reported as sensitized only. Sixteen (5.0 percent) workers were listed as sensitized and diagnosed with CBD upon initial clinical evaluation. Three (1.0 percent) workers, first shown to be sensitized only, were later diagnosed with CBD. The data set includes workers exposed at airborne beryllium levels near the proposed PEL, and extensive exposure data collected in workers' breathing zones, as is preferred by OSHA. Unlike the Tucson, Reading, and Elmore facilities, respirator use was not generally required for workers at the Cullman facility. Thus, analysis of this data set shows the risk associated with varying levels of airborne exposure, rather than the virtual elimination of airborne exposure via respiratory PPE. Also unlike the Tucson, Elmore, and Reading facilities, glove use was not reported to be mandatory in the Cullman facility. Thus, OSHA believes reductions in risk at the Cullman facility to be the result of airborne exposure control, rather than the combination of airborne and dermal exposure controls at the Tucson, Elmore, and Reading facilities.

OSHA analyzed the prevalence of beryllium sensitization and CBD among workers at the Cullman facility who were exposed to airborne beryllium levels at and below the current PEL of 2  $\mu\text{g}/\text{m}^3$ . In addition, a statistical modeling analysis of the NJMRC Cullman data set was conducted under contract with Dr. Roslyn Stone of the University of Pittsburgh Graduate School of Public Health, Department of Biostatistics. OSHA summarizes these analyses briefly below, and in more detail in this preamble at section VI, Preliminary Risk Assessment.

<sup>13</sup> This point was emphasized by members of the scientific peer review panel for OSHA's Preliminary Risk Assessment (see this preamble at section VII).

Tables 1 and 2 below present the prevalence of sensitization and CBD cases across several categories of lifetime-weighted (LTW) average and highest-exposed job (HEJ) exposure at

the Cullman facility. The HEJ exposure is the exposure level associated with the highest-exposure job and time period experienced by each worker. The columns "Total" and "Total percent"

refer to all sensitized workers in the dataset, including workers with and without a diagnosis of CBD.

TABLE 1—PREVALENCE OF SENSITIZATION AND CBD BY LIFETIME WEIGHTED AVERAGE EXPOSURE QUARTILE, CULLMAN, AL MACHINING FACILITY

LTW Average exposure ( $\mu\text{g}/\text{m}^3$ )	Group size	Sensitized only	CBD	Total	Total %	CBD %
0.0–0.080 .....	91	1	1	2	2.2	1.0
0.081–0.18 .....	73	2	4	6	8.2	5.5
0.19–0.51 .....	77	0	6	6	7.8	7.8
0.51–2.15 .....	78	4	8	12	15.4	10.3
Total .....	319	7	19	26	8.2	6.0

Source: Section VI, Preliminary Risk Assessment.

TABLE 2—PREVALENCE OF SENSITIZATION AND CBD BY HIGHEST-EXPOSED JOB EXPOSURE QUARTILE, CULLMAN, AL MACHINING FACILITY

HEJ Exposure ( $\mu\text{g}/\text{m}^3$ )	Group size	Sensitized only	CBD	Total	Total %	CBD %
0.0–0.086 .....	86	1	0	1	1.2	0.0
0.091–0.214 .....	81	1	6	7	8.6	7.4
0.387–0.691 .....	76	2	9	11	14.5	11.8
0.954–2.213 .....	76	3	4	7	9.2	5.3
Total .....	319	7	19	26	8.2	6.0

Source: Section VI, Preliminary Risk Assessment.

The current PEL of  $2 \mu\text{g}/\text{m}^3$  is close to the upper bound of the highest quartile of LTW average (0.51–2.15  $\mu\text{g}/\text{m}^3$ ) and HEJ (0.954–2.213) exposure levels. In the highest quartile of LTW average exposure, there were 12 cases of sensitization (15.4 percent), including 8 (10.3 percent) diagnosed with CBD. Notably, the Cullman workers had been exposed to beryllium dust for considerably less than 45 years at the time of testing. A high prevalence of sensitization (9.2 percent) and CBD (5.3 percent) is seen in the top quartile of HEJ exposure as well, with even higher prevalences in the third quartile (0.387–0.691  $\mu\text{g}/\text{m}^3$ ).<sup>14</sup>

The proposed PEL of  $0.2 \mu\text{g}/\text{m}^3$  is close to the upper bound of the second quartile of LTW average (0.81–0.18  $\mu\text{g}/\text{m}^3$ ) and HEJ (0.091–0.214  $\mu\text{g}/\text{m}^3$ ) exposure levels and to the lower bound of the third quartile of LTW average (0.19–0.50  $\mu\text{g}/\text{m}^3$ ) exposures. The second quartile of LTW average exposure shows a high prevalence of beryllium-related health effects, with six

workers sensitized (8.2 percent), of whom four (5.5 percent) were diagnosed with CBD. The second quartile of HEJ exposure also shows a high prevalence of beryllium-related health effects, with seven workers sensitized (8.6 percent), of whom 6 (7.4 percent) were diagnosed with CBD. Among six sensitized workers in the third quartile of LTW average exposures, all were diagnosed with CBD (7.8 percent). The prevalence of CBD among workers in these quartiles was approximately 5–8 percent, and overall sensitization (including workers with and without CBD) was about 8 percent. OSHA considers these rates as evidence that the risk of developing CBD is significant among workers exposed at and below the current PEL, even down to the proposed PEL. Much lower prevalences of sensitization and CBD were found among workers with exposure levels less than or equal to about  $0.08 \mu\text{g}/\text{m}^3$ . Two sensitized workers (2.2 percent), including 1 case of CBD (1.0 percent), were found among

workers with LTW average exposure levels and HEJ exposure levels less than or equal to  $0.08 \mu\text{g}/\text{m}^3$  and  $0.086 \mu\text{g}/\text{m}^3$ , respectively. Strict control of airborne exposure to levels below  $0.1 \mu\text{g}/\text{m}^3$  can, therefore, significantly reduce risk of sensitization and CBD. Although OSHA recognizes that maintaining exposure levels below  $0.1 \mu\text{g}/\text{m}^3$  may not be feasible in some operations (see this preamble at section IX, Summary of the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis), the Agency believes that workers in facilities that meet the proposed action level of  $0.1 \mu\text{g}/\text{m}^3$  will be at less risk of sensitization and CBD than workers in facilities that cannot meet the action level.

Table 3 below presents the prevalence of sensitization and CBD cases across cumulative exposure quartiles, based on the same Cullman data used to derive Tables 1 and 2. Cumulative exposure is the sum of a worker's exposure across the duration of his employment.

<sup>14</sup> This exposure-response pattern is sometimes attributed to a "healthy worker effect" or to

exposure misclassification, as discussed in this

preamble at section VI, Preliminary Risk Assessment.

TABLE 3—PREVALENCE OF SENSITIZATION AND CBD BY CUMULATIVE EXPOSURE QUARTILE CULLMAN, AL MACHINING FACILITY

Cumulative exposure (µg/m³ yrs)	Group size	Sensitized only	CBD	Total	Total %	CBD %
0.0–0.147 .....	81	2	2	4	4.9	2.5
0.148–1.467 .....	79	0	2	2	2.5	2.5
1.468–7.008 .....	79	3	8	11	13.9	8.0
7.009–61.86 .....	80	2	7	9	11.3	8.8
Total .....	319	7	19	26	8.2	6.0

Source: Section VI, Preliminary Risk Assessment.

A 45-year working lifetime of occupational exposure at the current PEL would result in 90 µg/m³-years, a value far higher than the cumulative exposures of workers in this data set, who worked for periods of time less than 45 years and whose exposure levels were mostly well below the PEL. Workers with 45 years of exposure to the proposed PEL would have a cumulative exposure (9 µg/m³-years) in the highest quartile for this worker population. As with the average and HEJ exposures, the greatest risk of sensitization and CBD appears at high exposure levels (≤ 1.468 µg/m³-years). The third cumulative quartile, at which a sharp increase in sensitization and CBD appears, is bounded by 1.468 and 7.008 µg/m³-years. This is equivalent to 0.73–3.50 years of exposure at the current PEL of 2 µg/m³, or 7.34–35.04 years of exposure at the proposed PEL of 0.2 µg/m³. Prevalence of both sensitization and CBD is substantially lower in the second cumulative quartile (0.148–1.467 µg/m³-years). This is equivalent to approximately 0.7 to 7 years at the proposed PEL of 0.2 µg/m³, or 1.5 to 15 years at the proposed action level of 0.1 µg/m³. This supports that maintaining exposure levels below the proposed PEL, where feasible, will help to protect long-term workers against risk of beryllium sensitization and early stage CBD.

As discussed in the Health Effects section (V.D), CBD often worsens with increased time and level of exposure. In a longitudinal study, workers initially identified as beryllium sensitized through workplace surveillance developed early stage CBD defined by granulomatous inflammation but no apparent physiological abnormalities (Newman *et al.*, 2005). A study of workers with this early stage CBD showed significant declines in breathing capacity and gas exchange over the 30 years from first exposure (Mroz *et al.*, 2009). Many of the workers went on to develop more severe disease that required immunosuppressive therapy despite being removed from exposure.

While precise beryllium exposure levels were not available on the individuals in these studies, most started work in the 1980s and 1990s and were likely exposed to average levels below the current 2 µg/m³ PEL. The evidence for time-dependent disease progression indicates that the CBD risk estimates for a 45-year lifetime exposure at the current PEL will include a higher proportion of individuals with advanced clinical CBD than found among the workers in the NJMRC data set.

Studies of community-acquired (CA) CBD support the occurrence of advanced clinical CBD from long-term exposure to airborne beryllium (Eisenbud, 1998; Maier *et al.*, 2008). A discussion of the study findings can be found in this preamble at section VI.C, Preliminary Risk Assessment. For example, one study evaluated 16 potential cases of CA-CBD in individuals that resided near a beryllium production facility in the years between 1943 and 2001 (Maier *et al.*, 2008). Five cases of definite CBD and three cases of probable CBD were found. Two of the subjects with probable cases died before they could be confirmed with the BeLPT; the third had an abnormal BeLPT and radiography consistent with CBD, but granulomatous disease was not pathologically proven. The individuals with CA-CBD identified in this study suffered significant health impacts from the disease, including obstructive, restrictive, and gas exchange pulmonary defects. Six of the eight cases required treatment with prednisone, a step typically reserved for severe cases due to the adverse side effects of steroid treatment. Despite treatment, three had died of respiratory impairment as of 2002. There was insufficient information to estimate exposure to the individuals, but the limited amount of ambient air sampling in the 1950s suggested that average beryllium levels in the area where the cases resided were below 2 µg/m³. The authors concluded that “low levels of exposures with

significant disease latency can result in significant morbidity and mortality” (Maier *et al.*, 2008, p. 1017).

OSHA believes that the literature review, prevalence analysis, and the evidence for time-dependent progression of CBD described above provide sufficient information to draw preliminary conclusions about significance of risk, and that further quantitative analysis of the NJMRC data set is not necessary to support the proposed rule. The studies OSHA used to support its preliminary conclusions regarding risk of beryllium sensitization and CBD were conducted at modern industrial facilities with exposure levels in the range of interest for this rulemaking, so a model is not needed to extrapolate risk estimates from high to low exposures, as has often been the case in previous rules. Nevertheless, the Agency felt further quantitative analysis might provide additional insight into the exposure-response relationship for sensitization and CBD.

Using the NJMRC data set, Dr. Stone ran a complementary log-log proportional hazards model, an extension of logistic regression that allows for time-dependent exposures and differential time at risk. Relative risk of sensitization increased with cumulative exposure (p = 0.05). A positive, but not statistically significant association was observed with LTW average exposure (p = 0.09). There was little association with highest-exposed job (HEJ) exposure (p = 0.3). Similarly, the proportional hazards models for the CBD endpoint showed positive relationships with cumulative exposure (p = 0.09), but LTW average exposure and HEJ exposure were not closely related to relative risk of CBD (p-values > 0.5). Dr. Stone used the cumulative exposure models to generate risk estimates for sensitization and CBD.

Tables 4 and 5 below present risk estimates from these models, assuming 5, 10, 20, and 45 years of beryllium exposure. The tables present sensitization and CBD risk estimates based on year-specific intercepts, as

explained in the section on Risk Assessment and the accompanying background document. Each estimate represents the number of sensitized workers the model predicts in a group of 1000 workers at risk during the given year with an exposure history at the specified level and duration. For example, in the exposure scenario for

1995, if 1000 workers were occupationally exposed to 2 µg/m<sup>3</sup> for 10 years, the model predicts that about 56 (55.7) workers would be identified as sensitized. The model for CBD predicts that about 42 (41.9) workers would be diagnosed with CBD that year. The year 1995 shows the highest risk estimates generated by the model for both

sensitization and CBD, while 1999 and 2002 show the lowest risk estimates generated by the model for sensitization and CBD, respectively. The corresponding 95 percent confidence intervals are based on the uncertainty in the exposure coefficient.

TABLE 4a—PREDICTED CASES OF SENSITIZATION PER 1000 WORKERS EXPOSED AT CURRENT AND ALTERNATE PELS BASED ON PROPORTIONAL HAZARDS MODEL, CUMULATIVE EXPOSURE METRIC, WITH CORRESPONDING INTERVAL BASED ON THE UNCERTAINTY IN THE EXPOSURE COEFFICIENT. 1995 BASELINE.

1995	Exposure duration							
	5 years		10 years		20 years		45 years	
	Cumulative (µg/m <sup>3</sup> -yrs)	cases/1000	µg/m <sup>3</sup> -yrs	cases/1000	µg/m <sup>3</sup> -yrs	cases/1000	µg/m <sup>3</sup> -yrs	cases/1000
2.0	10.0	41.1 30.3–56.2	20.0	55.7 30.3–102.9	40.0	101.0 30.3–318.1	90.0	394.4 30.3–999.9
1.0	5.0	35.3 30.3–41.3	10.0	41.1 30.3–56.2	20.0	55.7 30.3–102.9	45.0	116.9 30.3–408.2
0.5	2.5	32.7 30.3–35.4	5.0	35.3 30.3–41.3	10.0	41.1 30.3–56.2	22.5	60.0 30.3–119.4
0.2	1.0	31.3 30.3–32.3	2.0	32.2 30.3–34.3	4.0	34.3 30.3–38.9	9.0	39.9 30.3–52.9
0.1	0.5	30.8 30.3–31.3	1.0	31.3 30.3–32.3	2.0	32.2 30.3–34.3	4.5	34.8 30.3–40.1

Source: Section VI, Preliminary Risk Assessment.

TABLE 4b—PREDICTED CASES OF SENSITIZATION PER 1000 WORKERS EXPOSED AT CURRENT AND ALTERNATE PELS BASED ON PROPORTIONAL HAZARDS MODEL, CUMULATIVE EXPOSURE METRIC, WITH CORRESPONDING INTERVAL BASED ON THE UNCERTAINTY IN THE EXPOSURE COEFFICIENT. 1999 BASELINE.

1999	Exposure duration							
	5 years		10 years		20 years		45 years	
	Cumulative (µg/m <sup>3</sup> -yrs)	cases/1000	µg/m <sup>3</sup> -yrs	cases/1000	µg/m <sup>3</sup> -yrs	cases/1000	µg/m <sup>3</sup> -yrs	cases/1000
2.0	10.0	8.4 6.2–11.6	20.0	11.5 6.2–21.7	40.0	21.3 6.2–74.4	90.0	96.3 6.2–835.4
1.0	5.0	7.2 6.2–8.5	10.0	8.4 6.2–11.6	20.0	11.5 6.2–21.7	45.0	24.8 6.2–100.5
0.5	2.5	6.7 6.2–7.3	5.0	7.2 6.2–8.5	10.0	8.4 6.2–11.6	22.5	12.4 6.2–25.3
0.2	1.0	6.4 6.2–6.6	2.0	6.6 6.2–7.0	4.0	7.0 6.2–8.0	9.0	8.2 6.2–10.9
0.1	0.5	6.3 6.2–6.4	1.0	6.4 6.2–6.6	2.0	6.6 6.2–7.0	4.5	7.1 6.2–8.2

Source: Section VI, Preliminary Risk Assessment.

TABLE 5a—PREDICTED NUMBER OF CASES OF CBD PER 1000 WORKERS EXPOSED AT CURRENT AND ALTERNATIVE PELS BASED ON PROPORTIONAL HAZARDS MODEL, CUMULATIVE EXPOSURE METRIC, WITH CORRESPONDING INTERVAL BASED ON THE UNCERTAINTY IN THE EXPOSURE COEFFICIENT. 1995 BASELINE.

1995	Exposure duration							
	5 years		10 years		20 years		45 years	
	Cumulative (µg/m <sup>3</sup> -yrs)	Estimated cases/1000 (95% c.i.)	µg/m <sup>3</sup> -yrs	Estimated cases/1000 (95% c.i.)	µg/m <sup>3</sup> -yrs	Estimated cases/1000 (95% c.i.)	µg/m <sup>3</sup> -yrs	Estimated cases/1000 (95% c.i.)
2.0	10.0	30.9 22.8–44.0	20.0	41.9 22.8–84.3	40.0	76.6 22.8–285.5	90.0	312.9 22.8–999.9
1.0	5.0	26.6 22.8–31.7	10.0	30.9 22.8–44.0	20.0	41.9 22.8–84.3	45.0	88.8 22.8–375.0

TABLE 5a—PREDICTED NUMBER OF CASES OF CBD PER 1000 WORKERS EXPOSED AT CURRENT AND ALTERNATIVE PELS BASED ON PROPORTIONAL HAZARDS MODEL, CUMULATIVE EXPOSURE METRIC, WITH CORRESPONDING INTERVAL BASED ON THE UNCERTAINTY IN THE EXPOSURE COEFFICIENT. 1995 BASELINE.—Continued

1995	Exposure duration							
	5 years		10 years		20 years		45 years	
	Cumulative (µg/m³-yrs)	Estimated cases/1000 (95% c.i.)	µg/m³-yrs	Estimated cases/1000 (95% c.i.)	µg/m³-yrs	Estimated cases/1000 (95% c.i.)	µg/m³-yrs	Estimated cases/1000 (95% c.i.)
0.5	2.5	24.6 22.8–26.9	5.0	26.6 22.8–31.7	10.0	30.9 22.8–44.0	22.5	45.2 22.8–98.9
0.2	1.0	23.5 22.8–24.3	2.0	24.2 22.8–26.0	4.0	25.8 22.8–29.7	9.0	30.0 22.8–41.3
0.1	0.5	23.1 22.8–23.6	1.0	23.5 22.8–24.3	2.0	24.2 22.8–26.0	4.5	26.2 22.8–30.7

Source: Section VI, Preliminary Risk Assessment.

TABLE 5b—PREDICTED NUMBER OF CASES OF CBD PER 1000 WORKERS EXPOSED AT CURRENT AND ALTERNATIVE PELS BASED ON PROPORTIONAL HAZARDS MODEL, CUMULATIVE EXPOSURE METRIC, WITH CORRESPONDING INTERVAL BASED ON THE UNCERTAINTY IN THE EXPOSURE COEFFICIENT. 2002 BASELINE.

2002	Exposure duration							
	5 years		10 years		20 years		45 years	
	Cumulative (µg/m³-yrs)	Estimated cases/1000 (95% c.i.)	µg/m³-yrs	Estimated cases/1000 (95% c.i.)	µg/m³-yrs	Estimated cases/1000 (95% c.i.)	µg/m³-yrs	Estimated cases/1000 (95% c.i.)
2.0	10.0	3.7 2.7–5.3	20.0	5.1 2.7–10.4	40.0	9.4 2.7–39.2	90.0	43.6 2.7–679.8
1.0	5.0	3.2 2.7–3.8	10.0	3.7 2.7–5.3	20.0	5.1 2.7–10.4	45.0	11.0 2.7–54.3
0.5	2.5	3.0 2.7–3.2	5.0	3.2 2.7–3.8	10.0	3.7 2.7–5.3	22.5	5.5 2.7–12.3
0.2	1.0	2.8 2.7–2.9	2.0	2.9 2.7–3.1	4.0	3.1 2.7–3.6	9.0	3.6 2.7–5.0
0.1	0.5	2.8 2.7–2.8	1.0	2.8 2.7–2.9	2.0	2.9 2.7–3.1	4.5	3.1 2.7–3.7

Source: Section VI, Preliminary Risk Assessment.

As shown in Tables 4 and 5, the exposure-response models Dr. Stone developed based on the Cullman data set predict a high risk of both sensitization (about 96–394 cases per 1000 exposed workers) and CBD (about 44–313 cases per 1000) at the current PEL of 2 µg/m³ for an exposure duration of 45 years (90 µg/m³-yr). For a 45-year exposure at the proposed PEL of 0.2 µg/m³, risk estimates for sensitization (about 8–40 cases per 1000 exposed workers) and CBD (about 4–30 per 1000 exposed workers) are substantially reduced. Thus, the model predicts that the risk of sensitization and CBD at a PEL of 0.2 µg/m³ will be about 10 percent of the risk at the current PEL of 2 µg/m³.

OSHA does not believe the risk estimates generated by these exposure-response models to be highly accurate. Limitations of the analysis include the size of the dataset, relatively sparse exposure data from the plant’s early years, study size-related constraints on

the statistical analysis of the dataset, and limited follow-up time on many workers. The Cullman study population is a relatively small group and can support only limited statistical analysis. For example, its size precludes inclusion of multiple covariates in the exposure-response models or a two-stage exposure-response analysis to model both sensitization and the subsequent development of CBD within the subpopulation of sensitized workers. The limited size of the Cullman dataset is characteristic of studies on beryllium-exposed workers in modern, low-exposure environments, which are typically small-scale processing plants (up to several hundred workers, up to 20–30 cases).

Despite these issues with the statistical analysis, OSHA believes its main policy determinations are well supported by the best available evidence, including the literature review and careful examination of the prevalence of sensitization and CBD

among workers with exposure levels comparable to the current and proposed PELs in the NJMRC data set. The previously described literature analysis and prevalence analysis demonstrate that workers with occupational exposure to airborne beryllium at the current PEL face a risk of becoming sensitized to beryllium and progressing to both early and advanced stages of CBD that far exceeds the value of 1 in 1000 used by OSHA as a benchmark of clearly significant risk. Furthermore, OSHA’s preliminary risk assessment indicates that risk of beryllium sensitization and CBD can be significantly reduced by reduction of airborne exposure levels, along with respiratory and dermal protection measures, as demonstrated in facilities such as the Tucson ceramics plant, the Elmore beryllium production facility, and the Reading copper beryllium facility described in the literature review.

OSHA's preliminary risk assessment also indicates that despite the reduction in risk expected with the proposed PEL, the risk to workers with average exposure levels of 0.2 µg/m<sup>3</sup> is still clearly significant (see this preamble at section VI). In the prevalence analysis, workers with LTW average or HEJ exposures close to 0.2 µg/m<sup>3</sup> experienced high levels of sensitization and CBD. This finding is corroborated by the literature analysis, which showed that workers exposed to mean plant-wide airborne exposures between 0.1 and 0.5 µg/m<sup>3</sup> had a similarly high prevalence of sensitization and CBD. Given the significant risk at these levels of exposure, the Agency believes that the proposed action level of 0.1 µg/m<sup>3</sup>, dermal protection requirements, and other ancillary provisions of the proposed rule are key to reducing the risk of beryllium sensitization and CBD among exposed workers. OSHA preliminarily concludes that the proposed standard, including the PEL of 0.2 µg/m<sup>3</sup>, the action level of 0.1 µg/m<sup>3</sup>, and provisions to limit dermal exposure to beryllium, together will significantly reduce workers' risk of beryllium sensitization and CBD from occupational beryllium exposure.

2. Risk of Lung Cancer

OSHA's review of epidemiological studies of lung cancer mortality among beryllium workers found that most did

not characterize exposure levels sufficiently to characterize risk of lung cancer at the current and proposed PELs. However, as discussed in this preamble at section V, Health Effects and section VI, Preliminary Risk Assessment, NIOSH recently published a quantitative risk assessment based on beryllium exposure and lung cancer mortality among 5436 male workers employed at beryllium processing plants in Reading, PA; Elmore, OH; and Hazleton, PA, prior to 1970 (Schubauer-Berigan *et al.*, 2010b). This new risk assessment addresses important sources of uncertainty for previous lung cancer analyses, including the sole prior exposure-response analysis for beryllium and lung cancer, conducted by Sanderson *et al.* (2001) on workers from the Reading plant alone. Workers from the Elmore and Hazleton plants who were added to the analysis by Schubauer-Berigan *et al.* were, in general, exposed to lower levels of beryllium than those at the Reading plant. The median worker from Hazleton had a mean exposure across his tenure of less than 2 µg/m<sup>3</sup>, while the median worker from Elmore had a mean exposure of less than 1 µg/m<sup>3</sup>. The Elmore and Hazleton worker populations also had fewer short-term workers than the Reading population. Finally, the updated cohorts followed the worker populations through 2005, increasing the length of follow-up time

compared to the previous exposure-response analysis. For these reasons, OSHA based its preliminary risk assessment for lung cancer on the Schubauer-Berigan risk analysis.

Schubauer-Berigan *et al.* (2011) analyzed the data set using a variety of exposure-response modeling approaches, described in this preamble at section VI, Preliminary Risk Assessment. The authors found that lung cancer mortality risk was strongly and significantly related to mean, cumulative, and maximum measures of workers' exposure to beryllium (all models reported in Schubauer-Berigan *et al.*, 2011). They selected the best-fitting models to generate risk estimates for male workers with a mean exposure of 0.5 µg/m<sup>3</sup> (the current NIOSH Recommended Exposure Limit for beryllium). In addition, they estimated the mean exposure that would be associated with an excess lung cancer mortality risk of one in one thousand. At OSHA's request, the authors also estimated excess risks for workers with mean exposures at each of the other alternate PELs under consideration: 1 µg/m<sup>3</sup>, 0.2 µg/m<sup>3</sup>, and 0.1 µg/m<sup>3</sup>. Table 6 presents the estimated excess risk of lung cancer mortality associated with various levels of beryllium exposure allowed under the current rule, based on the final models presented in Schubauer-Berigan *et al.*'s risk assessment.

TABLE 6—EXCESS RISK OF LUNG CANCER MORTALITY PER 1000 MALE WORKERS AT ALTERNATE PELS (NIOSH MODELS)

Exposure-response model	Mean exposure				
	0.1 µg/m <sup>3</sup>	0.2 µg/m <sup>3</sup>	0.5 µg/m <sup>3</sup>	1 µg/m <sup>3</sup>	2 µg/m <sup>3</sup>
Best monotonic PWL—all workers .....	7.3	15	45	120	200
Best monotonic PWL—excluding professional and asbestos workers .....	3.1	6.4	17	39	61
Best categorical—all workers .....	4.4	9	25	59	170
Best categorical—excluding professional and asbestos workers .....	1.4	2.7	7.1	15	33
Power model—all workers .....	12	19	30	40	52
Power model—excluding professional and asbestos workers .....	19	30	49	68	90

Source: Section VI, Preliminary Risk Assessment.

The lowest estimate of excess lung cancer deaths from the six final models presented by Schubauer-Berigan *et al.* is 33 per 1000 workers exposed at a mean level of 2 µg/m<sup>3</sup>, the current PEL. Risk estimates as high as 200 lung cancer deaths per 1000 result from the other five models presented. Regardless of the model chosen, the excess risk of about 33 to 200 per 1000 workers is clearly significant, falling well above the level of risk the Supreme Court indicated a

reasonable person might consider acceptable (See *Benzene*, 448 U.S. at 655). The proposed PEL of 0.2 µg/m<sup>3</sup> is expected to reduce these risks significantly, to somewhere between 2.7–30 excess lung cancer deaths per 1000 workers. These risk estimates still fall above the threshold of 1 in 1000 that OSHA considers clearly significant. However, the Agency believes the lung cancer risks should be regarded with a greater degree of uncertainty than the

risk estimates for CBD discussed previously. While the risk estimates for CBD at the proposed PEL were determined from exposure levels observed in occupational studies, the lung cancer risks are extrapolated from much higher exposure levels.

C. Conclusions

As discussed above, OSHA used the best available scientific evidence to identify adverse health effects of

occupational beryllium exposure, and to evaluate exposed workers' risk of these impairments. The Agency reviewed extensive epidemiological and experimental research pertaining to adverse health effects of occupational beryllium exposure, including lung cancer, immunological sensitization to beryllium, and CBD, and has evaluated the risk of these effects from exposures allowed under the current and proposed standards. The Agency has, additionally, reviewed previous policy determinations and case law regarding material impairment of health, and has preliminarily determined that CBD, in all stages, and lung cancer constitute material health impairments. Furthermore, OSHA has preliminarily determined that long-term exposure to beryllium at the current PEL would pose a risk of CBD and lung cancer greater than the risk of 1 per 1000 exposed workers the Agency considers clearly significant. OSHA's risk assessment for beryllium indicates that adoption of the new PEL, action level, and dermal protection provisions of the proposed rule will significantly reduce this risk. OSHA therefore believes it has met the statutory requirements pertaining to significance of risk, consistent with the OSH Act, Supreme Court precedent, and the Agency's previous policy decisions.

## IX. Summary of the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis

### A. Introduction and Summary

OSHA's Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis (PEA) addresses issues related to the costs, benefits, technological and economic feasibility, and the economic impacts (including impacts on small entities) of this proposed respirable beryllium rule and evaluates regulatory alternatives to the proposed 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), unless a statute requires another regulatory approach. Executive Order 13563 emphasized the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. The full PEA has been placed in OSHA rulemaking docket OSHA-H005C-2006-0870. 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 PEA is to:

- Identify the establishments and industries potentially affected by the proposed rule;
- Estimate current exposures and the technologically feasible methods of controlling these exposures;
- Estimate the benefits resulting from employers coming into compliance with the proposed rule in terms of reductions in cases of lung cancer and chronic beryllium disease;
- Evaluate the costs and economic impacts that establishments in the regulated community will incur to achieve compliance with the proposed rule;
- Assess the economic feasibility of the proposed rule for affected industries; and
- Assess the impact of the proposed rule on small entities through an Initial Regulatory Flexibility Analysis (IRFA), to include an evaluation of significant regulatory alternatives to the proposed rule that OSHA has considered.

The PEA contains the following chapters:

Chapter I. Introduction  
 Chapter II. Assessing 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. Initial Regulatory Flexibility Analysis

The PEA includes all of the economic analyses OSHA is required to perform, including the findings of technological and economic feasibility and their supporting materials required by the OSH Act as interpreted by the courts (in Chapters III, IV, V, and VI); those required by EO 12866 and EO 13563 (primarily in Chapters III, V, and VII, though these depend on material in other chapters); and those required by the Regulatory Flexibility Act (in Chapters VI, VIII, and IX, though these depend, in part, on materials presented in other chapters).

Key findings of these chapters are summarized below and in sections IX.B through IX.I of this PEA summary.

### Profile of Affected Industries

This proposed rule would affect employers and employees in many different industries across the economy. As described in Section IX.C and reported in Table IX-2 of this preamble, OSHA estimates that a total of 35,051

employees in 4,088 establishments are potentially at risk from exposure to beryllium.

### Technological Feasibility

As described in more detail in Section IX.D of this preamble and in Chapter IV of the PEA, OSHA assessed, for all affected sectors, the current exposures and the technological feasibility of the proposed PEL of 0.2  $\mu\text{g}/\text{m}^3$ .

Tables IX-5 in section IX.D of this preamble summarizes all nine application groups (industry sectors and production processes) studied in the technological feasibility analysis. The technological feasibility analysis includes information on current exposures, descriptions of engineering controls and other measures to reduce exposures, and a preliminary assessment of the technological feasibility of compliance with the proposed PELs.

The preliminary technological feasibility analysis shows that for the majority of the job groups evaluated, exposures are either already at or below the proposed PEL, or can be adequately controlled with additional engineering and work practice controls. Therefore, OSHA preliminarily concludes that the proposed PEL of 0.2  $\mu\text{g}/\text{m}^3$  is technologically feasible for most operations most of the time.

Based on the currently available evidence, it is more difficult to determine whether an alternative PEL of 0.1  $\mu\text{g}/\text{m}^3$  would also be feasible in most operations. For some application groups, a PEL of 0.1  $\mu\text{g}/\text{m}^3$  would almost certainly be feasible. In other application groups, a PEL of 0.1  $\mu\text{g}/\text{m}^3$  appears feasible, except for establishments working with high beryllium content alloys. For application groups with the highest exposure, the exposure monitoring data necessary to more fully evaluate the effectiveness of exposure controls adopted after 2000 are not currently available to OSHA, which makes it difficult to determine the feasibility of achieving exposure levels at or below 0.1  $\mu\text{g}/\text{m}^3$ .

OSHA also evaluated the feasibility of a STEL of 2.0  $\mu\text{g}/\text{m}^3$ . The majority of the available short-term measurements are below 2.0  $\mu\text{g}/\text{m}^3$ ; therefore OSHA preliminarily concludes that the proposed STEL of 2.0  $\mu\text{g}/\text{m}^3$  can be achieved for most operations most of the time. OSHA recognizes that for a small number of tasks, short-term exposures may exceed the proposed STEL, even after feasible control measures to reduce TWA exposure to below the proposed PEL have been implemented, and therefore assumes that the use of

respiratory protection will continue to be required for some short-term tasks. It is more difficult based on the currently available evidence to determine whether the alternative STEL of 1.0 µg/m<sup>3</sup> would also be feasible in most operations based on lack of detail in the activities of the workers presented in the data. OSHA expects additional use of respiratory protection would be required for tasks in which peak exposures can be reduced to less than 2.0 µg/m<sup>3</sup> but not less than 1.0 µg/m<sup>3</sup>. Due to limitations in the available sampling data and the higher detection limits for short term measurements, OSHA could not determine the percentage of the STEL measurements that are less than or equal to 0.5 µg/m<sup>3</sup>.

**Costs of Compliance**

As described in more detail in Section IX.E and reported, by application group and NAICS code, in Table IX-7 of this preamble, the total annualized cost of compliance with the proposed standard is estimated to be about \$37.6 million. The major cost elements associated with the revisions to the standard are housekeeping (\$12.6 million), engineering controls (\$9.5 million), training (\$5.8 million), and medical surveillance (\$2.9 million).

The compliance costs are expressed as annualized costs in order to evaluate economic impacts against annual revenue and annual profits, to be able to compare the economic impact of the rulemaking with other OSHA regulatory actions, and to be able to add and track Federal regulatory compliance costs and economic impacts in a consistent manner. Annualized costs also represent a better measure for assessing the longer-term potential impacts of the rulemaking. The annualized costs were calculated by annualizing the one-time costs over a period of 10 years and applying a discount rate of 3 percent (and an alternative discount rate of 7 percent).

The estimated costs for the proposed beryllium standard represent the additional costs necessary for employers to achieve full compliance. They do not include costs associated with current compliance that has already been achieved with regard to the new requirements or costs necessary to achieve compliance with existing beryllium requirements, to the extent that some employers may currently not

be fully complying with applicable regulatory requirements.

**Economic Impacts**

To assess the nature and magnitude of the economic impacts associated with compliance with the proposed rule, OSHA developed quantitative estimates of the potential economic impact of the new requirements on entities in each of the affected industry sectors. The estimated compliance costs were compared with industry revenues and profits to provide an assessment of the economic feasibility of complying with the revised standard and an evaluation of the potential economic impacts.

As described in greater detail in Section IX.F of this preamble and in Chapter VI of the PEA, the costs of compliance with the proposed rulemaking are not large in relation to the corresponding annual financial flows associated with each of the affected industry sectors. The estimated annualized costs of compliance represent about 0.11 percent of annual revenues and about 1.52 percent of annual profits, on average, across all affected firms. Compliance costs do not represent more than 1 percent of revenues or more than 16.25 percent of profits in any affected industry.

Based on its analysis of the relative inelasticity of demand for beryllium-containing inputs and products and of possible international trade effects, OSHA concluded that most or all costs arising from this proposed beryllium rule would be passed on in higher prices rather than absorbed in lost profits and that any price increases would result in minimal loss of business to foreign competition.

Given the minimal potential impact on prices or profits in the affected industries, OSHA has preliminarily concluded that compliance with the requirements of the proposed rulemaking would be economically feasible in every affected industry sector.

**Benefits, Net Benefits, and Cost-Effectiveness**

As described in more detail in Section VIII.G of this preamble, OSHA estimated the benefits, net benefits, and incremental benefits of the proposed beryllium rule. That section also contains a sensitivity analysis to show how robust the estimates of net benefits are to changes in various cost and

benefit parameters. A full explanation of the derivation of the estimates presented there is provided in Chapter VII of the PEA for the proposed rule.

OSHA estimated the benefits associated with the proposed beryllium PEL of 0.2 µg/m<sup>3</sup> and, for analytical purposes to comply with OMB Circular A-4, with alternative beryllium PELs of .1 µg/m<sup>3</sup> and .5 µg/m<sup>3</sup> by applying the dose-response relationship developed in the Agency’s preliminary risk assessment—summarized in Section VI of this preamble—to current exposure levels. OSHA determined current exposure levels by first developing an exposure profile for industries with workers exposed to beryllium, 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 summarized in Table IX-3 in Section IX.C of this preamble.

By applying the dose-response relationship to estimates of current exposure levels across industries, it is possible to project the number of cases of the following diseases expected to occur in the worker population given current exposure levels (the “baseline”):

- fatal cases of lung cancer,
- fatal cases of chronic beryllium disease (CBD), and
- morbidity related to chronic beryllium disease.

Table IX-1 provides a summary of OSHA’s best estimate of the costs and benefits of the proposed rule. As shown, the proposed rule, once it is fully effective, is estimated to prevent 96 fatalities and 50 non-fatal beryllium-related illnesses annually, and the monetized annualized benefits of the proposed rule are estimated to be \$575.8 million using a 3-percent discount rate and \$255.3 million using a 7-percent discount rate. Also as shown in Table IX-1, the estimated annualized cost of the rule is \$37.6 million using a 3-percent discount rate and \$39.1 million using a 7-percent discount rate. The proposed rule is estimated to generate net benefits of \$538.2 million annually using a 3-percent discount rate and \$216.2 million annually using a 7-percent discount rate. The estimated costs and benefits of the proposed rule, disaggregated by industry sector, were previously presented in Table I-1 in this preamble.

**TABLE IX-1—ANNUALIZED COSTS, BENEFITS AND NET BENEFITS OF OSHA’S PROPOSED BERYLLIUM STANDARD OF 0.2 µg/m<sup>3</sup>**

Discount Rate .....		3%	7%
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TABLE IX-1—ANNUALIZED COSTS, BENEFITS AND NET BENEFITS OF OSHA’S PROPOSED BERYLLIUM STANDARD OF 0.2 µg/m<sup>3</sup>—Continued

Annualized Costs			
Engineering Controls .....		\$9,540,189	\$10,334,036
Respirators .....		249,684	252,281
Exposure Assessment .....		2,208,950	2,411,851
Regulated Areas and Beryllium Work Areas .....		629,031	652,823
Medical Surveillance .....		2,882,076	2,959,448
Medical Removal .....		148,826	166,054
Exposure Control Plan .....		1,769,506	1,828,766
Protective Clothing and Equipment .....		1,407,365	1,407,365
Hygiene Areas and Practices .....		389,241	389,891
Housekeeping .....		12,574,921	12,917,944
Training .....		5,797,535	5,826,975
Total Annualized Costs (Point Estimate) .....		37,597,325	39,147,434
Annual Benefits: Number of Cases Prevented			
Fatal Lung Cancer .....	4.0		
CBD-Related Mortality .....	92.0		
Total Beryllium Related Mortality .....	96.0	\$572,981,864	\$253,743,368
Morbidity .....	49.5	2,844,770	1,590,927
Monetized Annual Benefits (midpoint estimate) .....		575,826,633	255,334,295
Net Benefits .....		538,229,308	216,186,861

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.

Initial Regulatory Flexibility Analysis

OSHA has prepared an Initial Regulatory Flexibility Analysis (IRFA) in accordance with the requirements of the Regulatory Flexibility Act, as amended in 1996. Among the contents of the IRFA are an analysis of the potential impact of the proposed rule on small entities and a description and discussion of significant alternatives to the proposed rule that OSHA has considered. The IRFA is presented in its entirety both in Chapter IX of the PEA and in Section IX.I of this preamble.

The remainder of this section (Section IX) of the preamble is organized as follows:

- B. The Need for Regulation
- C. Profile of Affected Industry
- D. Technological Feasibility Analysis
- E. Costs of Compliance
- F. Economic Feasibility Analysis and Regulatory Flexibility Determination
- G. Benefits and Net Benefits
- H. Regulatory Alternatives
- I. Initial Regulatory Flexibility Analysis.

B. Need for Regulation

Employees in work environments addressed by the proposed beryllium 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 PEA in support of the proposed rule, the risks to employees are excessively large due to the existence of various types of market failure, and existing and alternative methods of overcoming these negative consequences—such as workers’ compensation systems, tort liability options, and information dissemination programs—have been

shown to provide insufficient worker protection.

After carefully weighing the various potential advantages and disadvantages of using a regulatory approach to improve upon the current situation, OSHA preliminarily concludes that, in the case of beryllium exposure, the proposed 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

1. Introduction

Chapter III of the PEA presents a profile of industries that use beryllium, beryllium oxide, and/or beryllium alloys. The discussion below summarizes the findings in that chapter. For each industry sector identified, the Agency describes the uses of beryllium and estimates the number of establishments and employees that may be affected by this proposed rulemaking. Employee exposure to beryllium can also occur as a result of certain processes such as welding that are found in many industries. OSHA uses the umbrella term “application group” to refer either to an industrial sector or a cross-industry group with a common process. These groups are all mutually exclusive and are analyzed in separate sections in Chapter III of the PEA. These sections briefly describe each application group and then explain how OSHA estimated the number of establishments working with beryllium and the number of employees exposed

to beryllium. Beryllium is rarely used by all establishments in any particular application group because its unique properties and relatively high cost typically result in only very specific and limited usage within a portion of a group.

The information in Chapter III of the PEA is based on reports prepared under task order by Eastern Research Group (ERG), an OSHA contractor; information collected during OSHA’s Small Business Advocacy Review Panel (OSHA 2008b); and Agency research and analysis. Technological feasibility reports (summarized in Chapter IV of the PEA) for each beryllium-using application group provide a detailed presentation of processes and occupations with beryllium exposure, including available sampling exposure measurements and estimates of how many employees are affected in each specific occupation.

OSHA has identified nine application groups that would be potentially affected by the proposed beryllium standard:

1. Beryllium Production
2. Beryllium Oxide Ceramics and Composites
3. Nonferrous Foundries
4. Secondary Smelting, Refining, and Alloying
5. Precision Turned Products
6. Copper Rolling, Drawing, and Extruding
7. Fabrication of Beryllium Alloy Products
8. Welding
9. Dental Laboratories

These application groups are broadly defined, and some include establishments in several North

American Industrial Classification System (NAICS) codes. For example, the Copper Rolling and Drawing, and Extruding application group is made up both of NAICS 331421 Copper Rolling, Drawing, and Extruding and NAICS 331422 Copper Wire Drawing. While an application group may contain numerous NAICS six-digit industry codes, in most cases only a fraction of the establishments in any individual six-digit NAICS industry use beryllium and would be affected by the proposed rule. For example, not all companies in the above application group work with copper that contains beryllium.

One application group, welding, reflects industrial activities or processes that take place in various industry sectors. All of the industries in which a given activity or process may result in worker exposure to beryllium are

identified in the sections on the application group. The section on each application group describes the production processes where occupational contact with beryllium can occur and contains estimates of the total number of firms, employees, affected establishments, and affected employees.

Chapter III of the PEA presents formulas in the text, usually in parentheses, to help explain the derivation of estimates. Because the values used in the formulas shown in the text are sometimes rounded, while the actual spreadsheet formulas used to create final costs are not, the calculation using the presented formula will sometimes differ slightly from the total presented in the text—which is the actual total as shown in the tables.

At the end of Chapter III in the PEA, OSHA discusses other industry sectors

that have reportedly used beryllium in the past or for which there are anecdotal or informal reports of beryllium use. The Agency was unable to verify beryllium use in these sectors that would be affected by the proposed standard, and seeks further information in this rulemaking on these or other industries where there may be significant beryllium use and employee exposure.

## 2. Summary of Affected Establishments and Employers

As shown in Table IX–2, OSHA estimates that a total of 35,051 workers in 4,088 establishments will be affected by the proposed beryllium standard. Also shown are the estimated annual revenues for these entities.

Table IX-2										
CHARACTERISTICS OF INDUSTRIES AFFECTED BY OSHA'S PROPOSED STANDARD FOR BERYLLIUM--ALL ENTITIES										
NAICS	Industry	Total Entities [a]	Total Establishments [a]	Total Employees [a]	Affected Entities [b]	Affected Establishments	Affected Employees	Total Revenues	Revenues/Entit	Revenues/Establishment (\$1,000)
Beryllium Production										
331419	Primary Smelting and	140	161	8,943	1	1	616	\$8,524,863	\$60,892	\$52,949
Beryllium Oxide Ceramics and Composites										
327113a	Porcelain electrical supply	94	106	4,310	2	2	83	789,731	\$8,401	\$7,450
327113b	Porcelain electrical supply	94	106	4,310	12	14	168	789,731	\$8,401	\$7,450
334220	Cellular telephones	721	810	79,732	9	10	120	35,175,313	\$48,999	\$43,797
334310	Compact disc players	460	464	8,858	5	5	60	3,975,351	\$8,642	\$8,568
334411	Electron Tube	62	79	4,884	16	21	252	1,220,476	\$19,685	\$15,449
334415	Electronic resistor	50	61	3,722	10	12	144	560,967	\$11,219	\$9,196
334419	Other electronic	1,058	1,133	46,836	8	9	108	10,013,730	\$9,165	\$8,838
334510	Electromedical equipment	555	629	66,107	8	9	108	27,480,966	\$49,515	\$43,690
336322b	Other motor vehicle	585	636	38,475	9	10	120	12,152,053	\$20,773	\$19,107
Nonferrous Foundries										
331521	Aluminum die-casting	228	254	18,017	6	7	98	4,310,021	\$18,904	\$16,969
331522	Nonferrous (except	137	140	6,362	37	38	534	1,510,799	\$11,028	\$10,791
331524	Aluminum foundries	366	394	15,178	7	7	98	2,518,097	\$6,880	\$6,391
331525a	Copper foundries (except	201	208	5,123	19	20	281	1,205,574	\$5,998	\$5,796
331525b	Copper foundries (except	201	208	5,123	24	25	393	1,205,574	\$5,998	\$5,796
Secondary Smelting, Refining, and Alloying										
331314	Secondary smelting &	98	122	4,846	1	1	9	4,837,129	\$49,358	\$39,649
331421b	Copper rolling, drawing,	70	96	9,849	1	1	9	12,513,425	\$178,763	\$130,348
331423	Secondary smelting,	23	24	789	3	3	27	723,759	\$31,468	\$30,157
331492	Secondary Smelting,	217	248	9,696	26	30	270	8,195,807	\$37,769	\$33,048
Precision Machining										
332721a	Precision turned product	3,057	3,124	78,749	18	18	222	13,262,706	\$4,338	\$4,245
332721b	Precision turned product	3,057	3,124	78,749	288	294	3,542	13,262,706	\$4,338	\$4,245

Table IX-2, continued										
CHARACTERISTICS OF INDUSTRIES AFFECTED BY OSHA'S PROPOSED STANDARD FOR BERYLLIUM—ALL ENTITIES										
NAICS	Industry	Total Entities [a]	Total Establishments [a]	Total Employees [a]	Affected Entities [b]	Affected Establishments	Affected Employees	Total Revenues	Revenues/Entit	Revenues/Establishment (\$1,000)
Copper Rolling, Drawing and Extruding										
331422	Copper wire (except	84	114	9,847	43	59	5,096	6,471,491	\$77,042	\$56,767
331421a	Copper rolling, drawing,	70	96	9,849	11	15	1,539	12,513,425	\$178,763	\$130,348
Stamping, Spring, and Connector Manufacturing										
332612	Light gauge spring	269	323	10,329	269	323	2,071	2,167,977	\$8,059	\$6,712
332116	Metal stamping	1,413	1,484	48,855	70	74	496	9,749,800	\$6,900	\$6,570
334417	Electronic connector	198	231	19,538	40	46	310	5,029,508	\$25,402	\$21,773
336322a	Other motor vehicle	585	636	38,475	146	159	1,066	12,152,053	\$20,773	\$19,107
Dental Laboratories										
339116	Dental laboratories	6,718	6,995	44,030	1,680	1,749	8,148	4,100,626	\$610	\$586
621210	Offices of dentists	123,322	129,830	846,092	226	238	1,107	100,431,324	\$814	\$774
Arc and Gas Welding										
331111	Iron and Steel Mills	461	587	94,089	5	7	27	\$92,726,004	\$201,141	\$157,966
331221	Rolled Steel Shape	134	161	9,971	1	1	6	8,376,271	\$62,509	\$52,027
331513	Steel Foundries (except	203	220	13,874	1	1	5	4,251,852	\$20,945	\$19,327
332117	Powder Metallurgy Part	121	133	6,707	1	1	4	1,414,108	\$11,687	\$10,632
332212	Hand and Edge Tool	999	1,066	25,098	3	3	12	5,077,868	\$5,083	\$4,763
332312	Fabricated Structural	3,081	3,407	89,728	51	56	224	26,119,614	\$8,478	\$7,666
332313	Plate Work Manufacturing	1,252	1,288	28,400	21	21	85	6,023,356	\$4,811	\$4,677
332322	Sheet Metal Work	3,907	4,173	91,364	64	69	274	17,988,908	\$4,604	\$4,311
332323	Ornamental and	2,314	2,354	30,029	38	39	155	5,708,707	\$2,467	\$2,425
332439	Other Metal Container	321	370	12,553	6	7	27	3,565,875	\$11,109	\$9,638
332919	Other Metal Valve and	240	265	14,688	2	3	11	4,584,082	\$19,100	\$17,298
332999	All Other Miscellaneous	3,195	3,262	65,821	33	33	134	13,963,184	\$4,370	\$4,281
333111	Farm Machinery and	975	1,041	53,133	19	20	80	\$24,067,145	\$24,684	\$23,119
333414a	Heating Equipment	433	460	16,768	6	6	24	4,781,561	\$11,043	\$10,395
333911	Pump and Pumping	445	571	31,272	5	7	27	12,395,387	\$27,855	\$21,708
333922	Conveyor and Conveying	737	776	26,970	9	9	36	6,569,120	\$8,913	\$8,465
333924	Industrial Truck, Tractor,	347	374	19,974	4	4	17	7,444,451	\$21,454	\$19,905
333999	All Other Miscellaneous	1,463	1,524	43,401	17	18	71	10,972,258	\$7,500	\$7,200
336211	Motor Vehicle Body	652	742	38,587	13	15	60	\$9,877,558	\$15,150	\$13,312
336214	Travel Trailer and Camper	602	683	30,803	12	14	55	7,465,024	\$12,400	\$10,930
336399a	All Other Motor Vehicle	1,156	1,350	95,426	6	7	30	\$2,279,766	\$27,824	\$23,911
336510	Railroad Rolling Stock	157	226	24,491	2	3	11	\$11,927,191	\$75,969	\$52,775
336999	All Other Transportation	366	374	10,846	4	4	14	5,250,368	\$14,345	\$14,038
337215	Showcase, Partition,	1,144	1,194	33,195	3	3	13	5,815,404	\$5,083	\$4,871
811310	Commercial and Industrial	20,299	21,960	181,220	132	143	571	31,650,469	\$1,559	\$1,441

Table IX-2, continued										
CHARACTERISTICS OF INDUSTRIES AFFECTED BY OSHA'S PROPOSED STANDARD FOR BERYLLIUM—ALL ENTITIES										
NAICS	Industry	Total Entities [a]	Total Establishments [a]	Total Employees [a]	Affected Entities [b]	Affected Establishments	Affected Employees	Total Revenues	Revenues/Entit	Revenues/Establishment (\$1,000)
Resistance Welding										
333411	Air Purification Equipment	303	358	14,521	21	25	379	3,060,741	\$10,101	\$8,550
333412	Industrial and Commercial	135	151	6,908	9	11	160	1,681,585	\$12,456	\$11,136
333414b	Heating Equipment	433	460	16,768	30	32	487	4,781,561	\$11,043	\$10,395
333415	Air-Conditioning, Warm	695	843	79,651	49	59	893	25,454,383	\$36,625	\$30,195
335211	Electric Housewares and	101	106	5,980	5	5	80	2,209,657	\$21,878	\$20,846
335212	Household Vacuum	29	31	2,577	1	2	26	891,600	\$30,745	\$26,221
335221	Household Cooking	91	96	9,730	5	5	73	3,757,849	\$41,295	\$39,144
335222	Household Refrigerator	16	22	9,731	1	1	17	4,489,845	\$280,615	\$204,084
335224	Household Laundry	9	11	8,051	1	1	8	3,720,514	\$413,390	\$338,229
335228	Other Major Household	34	38	9,023	2	2	29	3,499,273	\$102,920	\$92,086
336311	Carburetor, Piston, Piston	97	109	7,370	5	5	82	1,715,129	\$17,685	\$15,738
336312	Gasoline Engine and	697	742	36,896	35	37	561	20,000,705	\$28,695	\$26,955
336321	Vehicular Lighting	86	93	9,218	4	5	70	2,322,610	\$27,007	\$24,974
336322c	Other Motor Vehicle	585	636	38,475	29	32	481	12,152,053	\$20,773	\$19,107
336330	Motor Vehicle Steering	209	246	26,118	10	12	186	8,856,584	\$42,376	\$36,002
336340	Motor Vehicle Brake	159	199	20,245	8	10	150	8,147,826	\$51,244	\$40,944
336350	Motor Vehicle	397	476	51,171	20	24	360	21,862,014	\$55,068	\$45,929
336360	Motor Vehicle Seating and	305	403	39,805	15	20	305	15,168,862	\$49,734	\$37,640
336370	Motor Vehicle Metal	599	736	66,985	30	37	557	19,809,238	\$33,071	\$26,915
336391	Motor Vehicle Air-	72	80	11,207	4	4	61	3,798,464	\$52,756	\$47,481
336399b	All Other Motor Vehicle	1,156	1,350	95,426	58	68	1,021	32,279,766	\$27,924	\$23,911
Total	All Affected Industries				3,795	4,088	35,051			

[a] US Census Bureau, Statistics of US Businesses, 2010.

[b] OSHA estimates of employees potentially exposed to beryllium and associated entities and establishments. Affected entities and establishments constrained to be less than or equal to the number of affected employees.

[c] Estimates based on 2007 receipts and payroll data from US Census Bureau, Statistics of US Businesses, 2007, and payroll data from the US Census Bureau, Statistics of US Businesses, 2010. Receipts are not reported for 2010 but were estimated assuming the ratio of receipts to payroll remained unchanged from 2007 to 2010.

Source: US Dept. of Labor, OSHA, Directorate of Evaluation and Analysis, Office of Regulatory Analysis, based on ERG, 2012.

### 3. Beryllium Exposure Profile of At-Risk Workers

The technological feasibility analyses presented in Chapter IV of the PEA contain data and discussion of worker exposures to beryllium 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 beryllium and, thus,

the workers for whom beryllium controls would be implemented under the proposed rule.

Table IX-3 summarizes, from the exposure profiles, the number of workers at risk from beryllium exposure and the distribution of 8-hour TWA respirable beryllium exposures by affected job category and sector. Exposures are grouped into the following ranges: Less than  $0.1 \mu\text{g}/\text{m}^3$ ;  $\geq 0.1 \mu\text{g}/\text{m}^3$  and  $\leq 0.2 \mu\text{g}/\text{m}^3$ ;  $> 0.2 \mu\text{g}/\text{m}^3$  and  $\leq 0.5 \mu\text{g}/\text{m}^3$ ;  $> 0.5 \mu\text{g}/\text{m}^3$  and  $\leq 1.0 \mu\text{g}/\text{m}^3$ ;  $> 1.0 \mu\text{g}/\text{m}^3$  and  $\leq 2.0 \mu\text{g}/\text{m}^3$ ; and greater than  $2.0 \mu\text{g}/\text{m}^3$ . These frequencies represent the percentages of production employees in each job

category and sector currently exposed at levels within the indicated range.

Table IX-4 presents data by NAICS code on the estimated number of workers currently at risk from beryllium exposure, as well as the estimated number of workers at risk of beryllium exposure above  $0 \mu\text{g}/\text{m}^3$ , at or above  $0.1 \mu\text{g}/\text{m}^3$ , at or above  $0.2 \mu\text{g}/\text{m}^3$ , at or above  $0.5 \mu\text{g}/\text{m}^3$ , at or above  $1.0 \mu\text{g}/\text{m}^3$ , and at or above  $2.0 \mu\text{g}/\text{m}^3$ . As shown, an estimated 12,101 workers currently have beryllium exposures at or above the proposed action level of  $0.1 \mu\text{g}/\text{m}^3$ ; and an estimated 8,091 workers currently have beryllium exposures above the proposed PEL of  $0.2 \mu\text{g}/\text{m}^3$ .

Table IX-3									
Distribution of Beryllium Exposures by Sector and Job Category or Activity									
Sector	Job Category/Activity	Beryllium Exposure Range					Total		
		≤0.1 μe/m <sup>3</sup>	0.1 - 0.2 μe/m <sup>3</sup>	0.2 - 0.5 μe/m <sup>3</sup>	0.5 - 1.0 μe/m <sup>3</sup>	1.0 - 2.0 μe/m <sup>3</sup>	>2.0 μe/m <sup>3</sup>		
Beryllium Production	Administrative	84.91%	9.17%	3.98%	1.02%	0.61%	0.31%	100.00%	
	Wastewater Treatment	58.70%	17.39%	19.57%	4.35%	0.00%	0.00%	100.00%	
	Boiler Operators	27.78%	27.78%	44.44%	0.00%	0.00%	0.00%	100.00%	
	Decontamination	35.42%	25.00%	14.58%	14.58%	6.25%	4.17%	100.00%	
	Other Site Support	86.31%	9.78%	2.74%	0.78%	0.39%	0.00%	100.00%	
	Mix/Makeup	27.45%	17.65%	33.33%	9.80%	9.80%	1.96%	100.00%	
	Scrap Recycling	12.61%	23.42%	27.03%	12.61%	9.91%	14.41%	100.00%	
	Maintenance/Furnace & Tools	10.34%	8.62%	27.59%	20.69%	8.62%	24.14%	100.00%	
	Other Production Support	70.20%	13.88%	6.55%	3.59%	3.43%	2.34%	100.00%	
	Machining	55.48%	21.23%	15.53%	2.51%	3.20%	2.05%	100.00%	
	Other Cold Work	78.63%	11.97%	5.13%	1.71%	2.56%	0.00%	100.00%	
	Welding	0.00%	26.67%	40.00%	26.67%	0.00%	6.67%	100.00%	
	Other Hot Work	72.70%	18.44%	8.16%	0.71%	0.00%	0.00%	100.00%	
	Impact Grinding	19.23%	3.85%	23.08%	23.08%	26.92%	3.85%	100.00%	
	Compact loading/Sintering	15.79%	31.58%	26.32%	0.00%	15.79%	10.53%	100.00%	
	NNS Operator	0.00%	22.22%	40.74%	29.63%	3.70%	3.70%	100.00%	
	Chemical Operations	5.00%	10.00%	50.00%	20.00%	10.00%	5.00%	100.00%	
	Alloy Arc Furnace	0.00%	2.63%	15.79%	36.84%	18.42%	26.32%	100.00%	
	Alloy Induction Furnace	5.15%	13.40%	31.96%	26.80%	13.40%	9.28%	100.00%	
	Vacuum Cast	0.00%	33.33%	22.22%	11.11%	22.22%	11.11%	100.00%	
	Be Oxide - Primary	Atomization	0.00%	0.00%	0.00%	30.77%	0.00%	69.23%	100.00%
		Beryllium Oxide Furnace	20.00%	20.00%	20.00%	6.67%	20.00%	13.33%	100.00%
		Material preparations operators	12.99%	15.58%	31.17%	19.48%	10.39%	10.39%	100.00%
	Be Oxide - Secondary	Forming operators - pressing	30.96%	25.06%	28.26%	10.57%	3.69%	1.47%	100.00%
		Forming operators - extruding	30.96%	25.06%	28.26%	10.57%	3.69%	1.47%	100.00%
		Kiln operators	0.00%	0.00%	100.00%	0.00%	0.00%	0.00%	100.00%
	Sand foundries	Machining operators	40.00%	22.56%	22.31%	10.26%	2.82%	2.05%	100.00%
		Metallization Workers	55.56%	13.89%	27.78%	2.78%	0.00%	0.00%	100.00%
		Production support	74.79%	13.45%	6.72%	2.52%	0.84%	1.68%	100.00%
		Administrative	93.51%	4.32%	1.08%	0.54%	0.54%	0.00%	100.00%
		Molder	0.00%	0.00%	62.50%	25.00%	0.00%	12.50%	100.00%
		Material Handler	0.00%	0.00%	0.00%	100.00%	0.00%	0.00%	100.00%
Furnace operator		0.00%	18.18%	9.09%	18.18%	18.18%	36.36%	100.00%	
Pouring operator		0.00%	40.00%	0.00%	0.00%	20.00%	40.00%	100.00%	
Shakeout operator		0.00%	0.00%	0.00%	0.00%	100.00%	0.00%	100.00%	
Abrasive blaster		0.00%	100.00%	0.00%	0.00%	0.00%	0.00%	100.00%	
Non Sand foundries	Grinding/finishing operator	6.25%	31.25%	31.25%	6.25%	6.25%	18.75%	100.00%	
	Maintenance	20.51%	29.49%	23.08%	14.10%	8.97%	3.85%	100.00%	
	Molder	0.00%	0.00%	62.50%	25.00%	0.00%	12.50%	100.00%	
	Material Handler	0.00%	0.00%	0.00%	100.00%	0.00%	0.00%	100.00%	
	Furnace operator	0.00%	18.18%	9.09%	18.18%	18.18%	36.36%	100.00%	
Smelting - Be Alloys	Pouring operator	0.00%	40.00%	0.00%	0.00%	20.00%	40.00%	100.00%	
	Abrasive blaster	0.00%	100.00%	0.00%	0.00%	0.00%	0.00%	100.00%	
	Grinding/finishing operator	6.25%	31.25%	31.25%	6.25%	6.25%	18.75%	100.00%	
Smelting - Precious metals	Mechanical processing operator	25.00%	75.00%	0.00%	0.00%	0.00%	0.00%	100.00%	
	Furnace operator	0.00%	0.00%	0.00%	0.00%	25.00%	75.00%	100.00%	
Machining (high)	Mechanical processing operator	25.00%	75.00%	0.00%	0.00%	0.00%	0.00%	100.00%	
Machining (low)	Furnace operator	50.00%	0.00%	50.00%	0.00%	0.00%	0.00%	100.00%	
	Machinist (high)	13.56%	11.86%	44.07%	15.25%	6.78%	8.47%	100.00%	
Rolling	Machinist (low)	73.75%	11.25%	7.50%	2.50%	1.25%	3.75%	100.00%	
	Administrative	98.53%	1.47%	0.00%	0.00%	0.00%	0.00%	100.00%	
	Other Production support	97.96%	2.04%	0.00%	0.00%	0.00%	0.00%	100.00%	
Drawing	Wastewater treatment operator	33.33%	33.33%	33.33%	0.00%	0.00%	0.00%	100.00%	
	Production	92.81%	4.69%	1.88%	0.63%	0.00%	0.00%	100.00%	
	Administrative	98.53%	1.47%	0.00%	0.00%	0.00%	0.00%	100.00%	
Springs	Other Production support	97.96%	2.04%	0.00%	0.00%	0.00%	0.00%	100.00%	
	Wastewater treatment operator	33.33%	33.33%	33.33%	0.00%	0.00%	0.00%	100.00%	
	Production	70.00%	13.33%	10.48%	1.90%	1.90%	2.38%	100.00%	
Stamping	Assembly operator	92.86%	7.14%	0.00%	0.00%	0.00%	0.00%	100.00%	
	Deburring Operator	85.71%	0.00%	14.29%	0.00%	0.00%	0.00%	100.00%	
	Chemical process operator	88.37%	6.98%	4.65%	0.00%	0.00%	0.00%	100.00%	
	Assembly operator	92.86%	7.14%	0.00%	0.00%	0.00%	0.00%	100.00%	
	Deburring Operator	85.71%	0.00%	14.29%	0.00%	0.00%	0.00%	100.00%	
Dental labs	Chemical process operator	88.37%	6.98%	4.65%	0.00%	0.00%	0.00%	100.00%	
Welding_GI	Mechanical processing operator	25.00%	75.00%	0.00%	0.00%	0.00%	0.00%	100.00%	
Resistance Welding	Dental technicians	30.43%	21.74%	13.04%	17.39%	4.35%	13.04%	100.00%	
	Welder	56.76%	13.51%	16.22%	10.81%	0.00%	2.70%	100.00%	
	Welder	100.00%	0.00%	0.00%	0.00%	0.00%	0.00%	100.00%	

Source: OSHA Office of Regulatory Analysis-Health

NAICs	Industry	No. of Establishments	No. of Employees	Numbers Exposed to Beryllium					
				> 0	>=0.1 $\mu\text{g}/\text{m}^3$	>=0.2 $\mu\text{g}/\text{m}^3$	>=0.5 $\mu\text{g}/\text{m}^3$	>=1.0 $\mu\text{g}/\text{m}^3$	>=2.0 $\mu\text{g}/\text{m}^3$
327113	Porcelain Electrical Supply	106	4,310	251	117	80	23	8	3
331111	Iron and Steel Mills	587	94,089	27	11	8	4	1	1
331221	Rolled Steel Shape Manufacturing	161	9,971	6	2	2	1	0	0
331314	Secondary Smelting and Alloying of	122	4,846	9	8	6	6	6	5
331419	Primary Smelting and Refining of	161	8,943	616	250	166	91	53	28
331421	Copper Rolling, Drawing, and Extruding	96	9,849	1,548	97	35	12	6	5
331422	Copper Wire (except Mechanical)	114	9,847	5,096	995	531	190	132	73
331423	Secondary Smelting, Refining, and	24	789	27	25	18	18	18	14
331492	Secondary Smelting, Refining, and	248	9,696	270	158	90	0	0	0
331513	Steel Foundries (except Investment)	220	13,874	5	2	2	1	0	0
331521	Aluminum Die-Casting Foundries	254	18,017	98	94	72	40	21	15
331522	Nonferrous (except Aluminum) Die-	140	6,362	534	512	393	219	115	83
331524	Aluminum Foundries (except Die-	394	15,178	98	94	72	40	21	15
331525	Copper Foundries (except Die-Casting)	208	5,123	674	647	507	300	177	99
332116	Metal Stamping	1,484	48,855	496	58	45	0	0	0
332117	Powder Metallurgy Part Manufacturing	133	6,707	4	2	1	0	0	0
332212	Hand and Edge Tool Manufacturing	1,066	25,098	12	5	3	2	0	0
332312	Fabricated Structural Metal	3,407	89,728	224	97	67	30	6	6
332313	Plate Work Manufacturing	1,288	28,400	85	37	25	11	2	2
332322	Sheet Metal Work Manufacturing	4,173	91,364	274	119	81	37	7	7
332323	Ornamental and Architectural Metal	2,354	30,029	155	67	46	21	4	4
332439	Other Metal Container Manufacturing	370	12,553	27	12	8	4	1	1
332612	Spring (Light Gauge) Manufacturing	323	10,329	2,071	185	74	0	0	0
332721	Precision Turned Product Manufacturing	3,124	78,749	3,764	1,122	697	333	211	152
332919	Other Metal Valve and Pipe Fitting	265	14,688	11	5	3	1	0	0
332999	All Other Miscellaneous Fabricated	3,262	65,821	134	58	40	18	4	4
333111	Farm Machinery and Equipment	1,041	53,133	80	34	24	11	2	2
333411	Air Purification Equipment	358	14,521	379	0	0	0	0	0
333412	Industrial and Commercial Fan and	151	6,908	160	0	0	0	0	0
333414	Heating Equipment (except Warm Air	460	16,768	511	10	7	3	1	1
333415	Air-Conditioning, Warm Air Heating, and	843	79,651	893	0	0	0	0	0
333911	Pump and Pumping Equipment	571	31,272	27	11	8	4	1	1
333922	Conveyor and Conveying Equipment	776	26,970	36	16	11	5	1	1
333924	Industrial Truck, Tractor, Trailer, and	374	19,974	17	8	5	2	0	0
333999	All Other Miscellaneous General	1,524	43,401	71	31	21	10	2	2
334220	Radio and Television Broadcasting and	810	79,732	120	37	22	8	3	1
334310	Audio and Video Equipment	464	8,858	60	19	11	4	1	1
334411	Electron Tube Manufacturing	79	4,884	252	79	46	18	6	3
334415	Electronic Resistor Manufacturing	61	3,722	144	45	26	10	3	1
334417	Electronic Connector Manufacturing	231	19,538	310	36	28	0	0	0
334419	Other Electronic Component	1,133	46,836	108	34	20	8	3	1
334510	Electromedical and Electrotherapeutic	629	66,107	108	34	20	8	3	1
335211	Electric Housewares and Household Fan	106	5,980	80	0	0	0	0	0
335212	Household Vacuum Cleaner	34	2,577	26	0	0	0	0	0
335221	Household Cooking Appliance	96	9,730	73	0	0	0	0	0



**Table IX-4, continued**  
**Numbers of Workers Exposed to Beryllium (by Affected Industry and Exposure Level ( $\mu\text{g}/\text{m}^3$ ))**

NAICS	Industry	No. of Establishments	No. of Employees	Numbers Exposed to Beryllium					
				> 0	$\geq 0.1 \mu\text{g}/\text{m}^3$	$> 0.2 \mu\text{g}/\text{m}^3$	$\geq 0.5 \mu\text{g}/\text{m}^3$	$> 1.0 \mu\text{g}/\text{m}^3$	$\geq 2.0 \mu\text{g}/\text{m}^3$
335222	Household Refrigerator and Home	22	9,731	17	0	0	0	0	0
335224	Household Laundry Equipment	11	8,051	8	0	0	0	0	0
335228	Other Major Household Appliance	38	9,023	29	0	0	0	0	0
336211	Motor Vehicle Body Manufacturing	742	38,587	60	26	18	8	2	2
336214	Travel Trailer and Camper	683	30,803	55	24	16	7	1	1
336311	Carburetor, Piston, Piston Ring, and	109	7,370	82	0	0	0	0	0
336312	Gasoline Engine and Engine Parts	742	36,896	561	0	0	0	0	0
336321	Vehicular Lighting Equipment	93	9,218	70	0	0	0	0	0
336322	Other Motor Vehicle Electrical and	636	38,475	1,667	163	120	8	3	1
336330	Motor Vehicle Steering and Suspension	246	26,118	186	0	0	0	0	0
336340	Motor Vehicle Brake System	199	20,245	150	0	0	0	0	0
336350	Motor Vehicle Transmission and Power	476	51,171	360	0	0	0	0	0
336360	Motor Vehicle Seating and Interior Trim	403	39,805	305	0	0	0	0	0
336370	Motor Vehicle Metal Stamping	736	66,985	557	0	0	0	0	0
336391	Motor Vehicle Air Conditioning	80	11,207	61	0	0	0	0	0
336399	All Other Motor Vehicle Parts	1,350	95,426	1,051	13	9	4	1	1
336510	Railroad Rolling Stock Manufacturing	226	24,491	11	5	3	1	0	0
336999	All Other Transportation Equipment	374	10,846	14	6	4	2	0	0
337215	Showcase, Partition, Shelving, and	1,194	33,195	13	6	4	2	0	0
339116	Dental Laboratories	6,995	44,030	8,148	5,668	3,897	2,834	1,417	1,063
621210	Offices of Dentists	129,830	846,092	1,107	770	529	385	192	144
811310	Commercial and Industrial Machinery	21,960	181,220	571	247	170	77	15	15
	Totals	200,970	2,892,762	35,051	12,101	8,091	4,822	2,454	1,761

Source: County Business Patterns, 2010.

**D. Technological Feasibility Analysis of the Proposed Permissible Exposure Limit to Beryllium Exposures**

This section summarizes the technological feasibility analysis presented in Chapter IV of the PEA (OSHA, 2014). The technological feasibility analysis includes information on current exposures, descriptions of engineering controls and other measures to reduce exposures, and a preliminary assessment of the technological

feasibility of compliance with the proposed standard, including a reduction in OSHA's permissible exposure limits (PELs) in nine affected application groups. The current PELs for beryllium are  $2.0 \mu\text{g}/\text{m}^3$  as an 8-hour time weighted average (TWA), and  $5.0 \mu\text{g}/\text{m}^3$  as an acceptable ceiling concentration. OSHA is proposing a PEL of  $0.2 \mu\text{g}/\text{m}^3$  as an 8-hour TWA and is additionally considering alternative TWA PELs of 0.1 and  $0.5 \mu\text{g}/\text{m}^3$ . OSHA

is also proposing a 15-minute short-term exposure limit (STEL) of  $2.0 \mu\text{g}/\text{m}^3$ , and is considering alternative STELs of 0.5, 1.0 and  $2.5 \mu\text{g}/\text{m}^3$ .

The technological feasibility analysis includes nine application groups that correspond to specific industries or production processes that OSHA has preliminarily determined fall within the scope of the proposed standard. Within each of these application groups, exposure profiles have been developed

that characterize the distribution of the available exposure measurements by job title or group of jobs. Descriptions of existing engineering controls for operations that create sources of beryllium exposure, and of additional engineering and work practice controls that can be used to reduce exposure are also provided. For each application group, a preliminary determination is made regarding the feasibility of achieving the proposed permissible exposure limits. For application groups in which the median exposures for some jobs exceed the proposed TWA PEL, a more detailed analysis is presented by job or group of jobs within the application group. The analysis is based on the best information currently available to the Agency, including a comprehensive review of the industrial hygiene literature, National Institute for Occupational Safety and Health (NIOSH) Health Hazard Evaluations and case studies of beryllium exposure, site visits conducted by an OSHA contractor (Eastern Research Group (ERG)), submissions to OSHA's rulemaking docket, and inspection data from OSHA's Integrated Management Information System (IMIS). OSHA also obtained information on production processes, worker exposures, and the effectiveness of existing control measures from the primary beryllium producer in the United States, Materion Corporation, and from interviews with industry experts.

The nine application groups included in this analysis were identified based on information obtained during preliminary rulemaking activities that included a SBRFA panel, a comprehensive review of the published literature, stakeholder input, and an analysis of IMIS data collected during OSHA workplace inspections where detectable airborne beryllium was found. The nine application groups and their corresponding section numbers in Chapter IV of the PEA are:

- Section 3—Beryllium Production, Ceramics and Composites,
- Section 4—Beryllium Oxide Ceramics and Composites,
- Section 5—Nonferrous Foundries, Refining, and Alloying,
- Section 6—Secondary Smelting Products,
- Section 7—Precision Turned Products,
- Section 8—Copper Rolling, Drawing, and Extruding,
- Section 9—Fabrication of Beryllium Alloy Products,
- Section 10—Welding, and
- Section 11—Dental Laboratories.

OSHA developed exposure profiles by job or group of jobs using exposure data at the application, operation or task level to the extent that such data were

available. In those instances where there were insufficient exposure data to create a profile, OSHA used analogous operations to characterize the operations. The exposure profiles represent baseline conditions with existing controls for each operation with potential exposure. For job groups where exposures were above the proposed TWA PEL of 0.2  $\mu\text{g}/\text{m}^3$ , OSHA identified additional controls that could be implemented to reduce employee exposures to beryllium. These included engineering controls, such as process containment, local exhaust ventilation and wet methods for dust suppression, and work practices, such as improved housekeeping and the prohibition of compressed air for cleaning beryllium-contaminated surfaces.

For the purposes of this technological feasibility assessment, these nine application groups can be divided into three general categories based on current exposure levels:

- (1) application groups in which current exposures for most jobs are already below the proposed PEL of 0.2  $\mu\text{g}/\text{m}^3$ ;
- (2) application groups in which exposures for most jobs are below the current PEL, but exceed the proposed PEL of 0.2  $\mu\text{g}/\text{m}^3$ , and therefore additional controls would be required; and
- (3) application groups in which exposures in one or more jobs routinely exceed the current PEL, and therefore substantial reductions in exposure would be required to achieve the proposed PEL.

The majority of exposure measurements taken in the application groups in the first category are already at or below the proposed PEL of 0.2  $\mu\text{g}/\text{m}^3$ , and most of the jobs with exposure to beryllium in these four application groups have median exposures below the alternative PEL of 0.1  $\mu\text{g}/\text{m}^3$  (See Table IX-5). These four application groups include rolling, drawing, and extruding; fabrication of beryllium alloy products; welding; and dental laboratories.

The two application groups in the second category include: precision turned products and secondary smelting. For these two groups, the median exposures in most jobs are below the current PEL, but the median exposure levels for some job groups currently exceed the proposed PEL. Additional exposure controls and work practices could be implemented that the Agency has preliminarily concluded would reduce exposures to or below the proposed PEL for most jobs most of the time. One exception is furnace operations in secondary smelting, in

which the median exposure exceeds the current PEL. Furnace operations involve high temperatures that produce significant amounts of fumes and particulate that can be difficult to contain. Therefore, the proposed PEL may not be feasible for most furnace operations involved with secondary smelting, and in some cases, respiratory protection would be required to adequately protect furnace workers when exposures exceed 0.2  $\mu\text{g}/\text{m}^3$  despite the implementation of all feasible controls.

Exposures in the third category of application groups routinely exceed the current PEL for several jobs. The three application groups in this category include: Beryllium production, beryllium oxide ceramics production, and nonferrous foundries. The individual job groups for which exposures exceed the current PEL are discussed in the application group specific sections later in this summary, and described in greater detail in the PEA. For the jobs that routinely exceed the current PEL, OSHA identified additional exposure controls and work practices that the Agency preliminarily concludes would reduce exposures to or below the proposed PEL most of the time, with three exceptions: Furnace operations in primary beryllium production and nonferrous foundries, and shakeout operations at nonferrous foundries. For these jobs, OSHA recognizes that even after installation of feasible controls, respiratory protection may be needed to adequately protect workers.

In conclusion, the preliminary technological feasibility analysis shows that for the majority of the job groups evaluated, exposures are either already at or below the proposed PEL, or can be adequately controlled with additional engineering and work practice controls. Therefore, OSHA preliminarily concludes that the proposed PEL of 0.2  $\mu\text{g}/\text{m}^3$  is feasible for most operations most of the time. The preliminary feasibility determination for the proposed PEL is also supported by Materion Corporation, the sole primary beryllium production company in the U.S., and by the United Steelworkers, who jointly submitted a draft proposed standard that specified an exposure limit of 0.2  $\mu\text{g}/\text{m}^3$  to OSHA (Materion and USW, 2012). The technological feasibility analysis conducted for each application group is briefly summarized below, and a more detailed discussion is presented in Sections 3 through 11 of Chapter IV of the PEA (OSHA, 2014).

Based on the currently available evidence, it is more difficult to determine whether an alternative PEL of

0.1  $\mu\text{g}/\text{m}^3$  would also be feasible in most operations. For some application groups, such as fabrication of beryllium alloy products, a PEL of 0.1  $\mu\text{g}/\text{m}^3$  would almost certainly be feasible. In other application groups, such as precision turned products, a PEL of 0.1  $\mu\text{g}/\text{m}^3$  appears feasible, except for establishments working with high beryllium content alloys. For application groups with the highest exposure, the exposure monitoring data necessary to more fully evaluate the effectiveness of exposure controls adopted after 2000 are not currently available to OSHA, which makes it difficult to determine the feasibility of achieving exposure levels at or below 0.1  $\mu\text{g}/\text{m}^3$ .

OSHA also evaluated the feasibility of a STEL of 2.0  $\mu\text{g}/\text{m}^3$ , and alternative STELs of 0.5 and 1.0  $\mu\text{g}/\text{m}^3$ . An analysis of the available short-term exposure measurements indicates that elevated exposures can occur during short-term tasks such as those associated with the operation and maintenance of furnaces at primary beryllium production facilities, at nonferrous foundries, and at secondary smelting operations. Peak exposure can also occur during the transfer and handling of beryllium oxide powders. OSHA believes that in many cases, reducing short-term exposures will be necessary to reduce workers' TWA exposures to or below the proposed PEL. The majority of the available short-term measurements are below 2.0  $\mu\text{g}/\text{m}^3$ , therefore OSHA preliminarily concludes that the proposed STEL of 2.0  $\mu\text{g}/\text{m}^3$  can be achieved for most operations most of the time. OSHA recognizes that for a small number of tasks, short-term exposures may exceed the proposed STEL, even after feasible control measures to reduce TWA exposure to below the proposed PEL have been implemented, and therefore assumes that the use of respiratory protection will continue to be required for some short-term tasks. It is more difficult based on the currently available evidence to determine whether the alternative STEL of 1.0  $\mu\text{g}/\text{m}^3$  would also be feasible in most operations based on lack of detail in the activities of the workers presented in the data. OSHA expects additional use of respiratory protection would be required for tasks in which peak exposures can be reduced to less than 2.0  $\mu\text{g}/\text{m}^3$  but not less than 1.0  $\mu\text{g}/\text{m}^3$ . Due to limitations in the available sampling data and the higher detection limits for short term measurements, OSHA could not determine the percentage of the STEL measurements that are less than or equal to 0.5  $\mu\text{g}/\text{m}^3$ . A detailed discussion of

the STELs being considered by OSHA is presented in Section 12 of Chapter IV of the PEA (OSHA, 2014).

OSHA requests available exposure monitoring data and comments regarding the effectiveness of currently implemented control measures and the feasibility of the PELs under consideration, particularly the proposed TWA PEL of 0.2  $\mu\text{g}/\text{m}^3$ , the alternative TWA PEL of 0.1  $\mu\text{g}/\text{m}^3$ , the proposed STEL of 2.0  $\mu\text{g}/\text{m}^3$ , and the alternative STEL of 1.0  $\mu\text{g}/\text{m}^3$  to inform the Agency's final feasibility determinations.

#### Application Group Summaries

This section summarizes the technological feasibility analysis for each of the nine application groups affected by the proposed standard. Chapter IV of the PEA, Technological Feasibility Analysis, identifies specific jobs or job groups with potential exposure to beryllium, and presents exposure profiles for each of these job groups (OSHA, 2014). Control measures and work practices that OSHA believes can reduce exposures are described along with preliminary conclusions regarding the feasibility of the proposed PEL. Table IX-5, located at the end of this summary, presents summary statistics for the personal breathing zone samples taken to measure full-shift exposures to beryllium in each application group. For the five application groups in which the median exposure level for at least one job group exceeds the proposed PEL, the sampling results are presented by job group. Table IX-5 displays the number of measurements; the range, the mean and the median of the measurement results; and the percentage of measurements less than 0.1  $\mu\text{g}/\text{m}^3$ , less than or equal to the proposed PEL of 0.2  $\mu\text{g}/\text{m}^3$ , and less than or equal to the current PEL of 2.0  $\mu\text{g}/\text{m}^3$ . A more detailed discussion of exposure levels by job or job group for each application group is provided in Chapter IV of the PEA, sections 3 through 11, along with a description of the available exposure measurement data, existing controls, and additional controls that would be required to achieve the proposed PEL.

#### Beryllium Production

Only one primary beryllium production facility is currently in operation in the United States, a plant owned and operated by Materion Corporation,<sup>15</sup> located in Elmore, Ohio.

<sup>15</sup> Materion Corporation was previously named Brush Wellman. In 2011, subsequent to the collection of the information presented in this chapter, the name changed. "Brush Wellman" is

OSHA identified eight job groups at this facility in which workers are exposed to beryllium. These include: Chemical operations, powdering operations, production support, cold work, hot work, site support, furnace operations, and administrative work.

The Agency developed an exposure profile for each of these eight job groups to analyze the distribution of exposure levels associated with primary beryllium production. The job exposure profiles are based primarily on full-shift personal breathing zone (PBZ) (lapel-type) sample results from air monitoring conducted by Brush Wellman's primary production facility in 1999 (Brush Wellman, 2004). Starting in 2000, the company developed the Materion Worker Protection Program (MWPP), a multi-faceted beryllium exposure control program designed to reduce airborne exposures for the vast majority of workers to less than an internally established exposure limit of 0.2  $\mu\text{g}/\text{m}^3$ . According to information provided by Materion, a combination of engineering controls, work practices, and housekeeping were used together to reduce average exposure levels to below 0.2  $\mu\text{g}/\text{m}^3$  for the majority of workers (Materion Information Meeting, 2012). Also, two operations with historically high exposures, the wet plant and pebble plants, were decommissioned in 2000, thereby reducing average exposure levels. Therefore, the samples taken prior to 2000 may overestimate current exposures.

Additional exposure samples were taken by NIOSH at the Elmore facility from 2007 through 2008 (NIOSH, 2011). This dataset, which was made available to OSHA by Materion, contains fewer samples than the 1999 survey. OSHA did not incorporate these samples into the exposure profile due to the limited documentation associated with the sampling data. The lack of detailed information for individual samples has made it difficult for OSHA to correlate job classifications and identify the working conditions associated with the samples. Sampling data provided by Materion for 2007 and 2008 were not incorporated into the exposure profiles because the data lacked specific information on jobs and workplace conditions. In a meeting in May 2012 held between OSHA and Materion Corporation at the Elmore facility, the Agency was able to obtain some general information on the exposure control modifications that Materion Corporation made between 1999 and 2007, but has been unable to determine what specific

used whenever the data being discussed pre-dated the name change.

controls were in place at the time NIOSH conducted sampling (Materion Information Meeting, 2012).

In five of the primary production job groups (*i.e.*, hot work, cold work, production support, site support, and administrative work), the baseline exposure profile indicates that exposures are already lower than the proposed PEL of 0.2  $\mu\text{g}/\text{m}^3$ . Median exposure values for these job groups range from nondetectable to 0.08  $\mu\text{g}/\text{m}^3$ .

For three of the job groups involved with primary beryllium production, (*i.e.*, chemical operations, powdering, and furnace operations), the median exposure level exceeds the proposed PEL of 0.2  $\mu\text{g}/\text{m}^3$ . Median exposure values for these job groups are 0.47, 0.37, and 0.68  $\mu\text{g}/\text{m}^3$  respectively, and only 17 percent to 29 percent of the available measurements are less than or equal to 0.2  $\mu\text{g}/\text{m}^3$ . Therefore, additional control measures for these job groups would be required to achieve compliance with the proposed PEL. OSHA has identified several engineering controls that the Agency preliminarily concludes can reduce exposures in chemical processes and powdering operations to less than or equal to 0.2  $\mu\text{g}/\text{m}^3$ . In chemical processes, these include fail-safe drum-handling systems, full enclosure of drum-handling systems, ventilated enclosures around existing drum positions, automated systems to prevent drum overflow, and automated systems for container cleaning and disposal such as those designed for hazardous powders in the pharmaceutical industry. Similar engineering controls would reduce exposures in powdering operations. In addition, installing remote viewing equipment (or other equally effective engineering controls) to eliminate the need for workers to enter the die-loading hood during die filling will reduce exposures associated with this powdering task and reduce powder spills. Based on the availability of control methods to reduce exposures for each of the major sources of exposure in chemical operations, OSHA preliminarily concludes that exposures at or below the proposed 0.2  $\mu\text{g}/\text{m}^3$  PEL can be achieved in most chemical and powdering operations most of the time. OSHA believes furnace operators' exposures can be reduced using appropriate ventilation, including fume capture hoods, and other controls to reduce overall beryllium levels in foundries, but is not certain whether the exposures of furnace operators can be reduced to the proposed PEL with currently available technology. OSHA requests additional information on current exposure levels and the

effectiveness of potential control measures for primary beryllium production operations to further refine this analysis.

#### Beryllium Oxide Ceramics Production

OSHA identified seven job groups involved with beryllium oxide ceramics production. These include: Material preparation operator, forming operator, machining operator, kiln operator, production support, metallization, and administrative work. Four of these jobs (material preparation, forming operator, machining operator and kiln operator) work directly with beryllium oxides, and therefore these jobs have a high potential for exposure. The other three job groups (production support work, metallization, and administrative work) have primarily indirect exposure that occurs only when workers in these job groups enter production areas and are exposed to the same sources to which the material preparation, forming, machining and kiln operators are directly exposed. However, some production support and metallization activities do require workers to handle beryllium directly, and workers performing these tasks may at times be directly exposed to beryllium.

The Agency developed exposure profiles for these jobs based on air sampling data from four sources: (1) Samples taken between 1994 and 2003 at a large beryllium oxide ceramics facility, (2) air sampling data obtained during a site visit to a primary beryllium oxide ceramics producer, (3) a published report that provides information on beryllium oxide ceramics product manufacturing for a slightly earlier time period, and (4) exposure data from OSHA's Integrated Management Information System (OSHA, 2009). The exposure profile indicates that the three job groups with mostly indirect exposure (production support work, metallization, and administrative work) already achieve the proposed PEL of 0.2  $\mu\text{g}/\text{m}^3$ . Median exposure sample values for these job groups did not exceed 0.06  $\mu\text{g}/\text{m}^3$ .

The four job groups with direct exposure had higher exposures. In forming operations and machining operations, the median exposure levels of 0.18 and 0.15  $\mu\text{g}/\text{m}^3$ , respectively, are below the proposed PEL, while the median exposure levels for material preparation and kiln operations of 0.41  $\mu\text{g}/\text{m}^3$  and 0.25  $\mu\text{g}/\text{m}^3$ , respectively, exceed the proposed PEL.

The profile for the directly exposed jobs may overestimate exposures due to the preponderance of data from the mid-1990s, a time period prior to the implementation of a variety of exposure

control measures introduced after 2000. In forming operations, 44 percent of sample values in the exposure profile exceeded 0.2  $\mu\text{g}/\text{m}^3$ . However, the median exposure levels for some tasks, such as small-press and large-press operation, based on sampling conducted in 2003 were below 0.1  $\mu\text{g}/\text{m}^3$ . The exposure profile for kiln operation was based on three samples taken from a single facility in 1995, and are all above 0.2  $\mu\text{g}/\text{m}^3$ . Since then, exposures at the facility have declined due to changes in operations that reduced the amount of time kiln operators spend in the immediate vicinity of the kilns, as well as the discontinuation of a nearby high-exposure process. More recent information communicated to OSHA suggests that current exposures for kiln operators at the facility are currently below 0.1  $\mu\text{g}/\text{m}^3$ . Exposures in machining operations, most of which were already below 0.2  $\mu\text{g}/\text{m}^3$  during the 1990s, may have been further reduced since then through improved work practices and exposure controls (PEA Chapter IV, Section 7). For forming, kiln, and machining operations, OSHA preliminarily concludes that the installation of additional controls such as machine interlocks (for forming) and improved enclosures and ventilation will reduce exposures to or below the proposed PEL most of the time. OSHA requests information on recent exposure levels and controls in beryllium oxide forming and kiln operations to help the Agency evaluate the effectiveness of available exposure controls for this application group.

In the exposure profile for material preparation, 73 percent of sample values exceeded 0.2  $\mu\text{g}/\text{m}^3$ . As with other parts of the exposure profile, exposure values from the mid-1990s may overestimate airborne beryllium levels for current operations. During most material preparation tasks, such as material loading, transfer, and spray drying, OSHA preliminarily concludes that exposures can be reduced to or below 0.2  $\mu\text{g}/\text{m}^3$  with process enclosures, ventilation hoods, and improved housekeeping procedures. However, OSHA acknowledges that peak exposures from some short-term tasks such as servicing of the spray chamber might continue to drive the TWA exposures above 0.2  $\mu\text{g}/\text{m}^3$  on days when these material preparation tasks are performed. Respirators may be needed to protect workers from exposures above the proposed TWA PEL

during these tasks.<sup>16</sup> OSHA notes that material preparation for production of beryllium oxide ceramics currently takes place at only two facilities in the United States.

#### Nonferrous Foundries

OSHA identified eight job groups in aluminum and copper foundries with beryllium exposure: Molding, material handling, furnace operation, pouring, shakeout operation, abrasive blasting, grinding/finishing, and maintenance. The Agency developed exposure profiles based on an air monitoring survey conducted by NIOSH in 2007, a Health Hazard Evaluation (HHE) conducted by NIOSH in 1975, a site visit by ERG in 2003, a site visit report from 1999 by the California Cast Metals Association (CCMA); and two sets of data from air monitoring surveys obtained from Materion in 2004 and 2010.

The exposure profile indicates that in foundries processing beryllium alloys, six of the eight job groups have median exposures that exceed the proposed PEL of 0.2  $\mu\text{g}/\text{m}^3$  with baseline working conditions. One exception is grinding/finishing operations, where the median value is 0.12  $\mu\text{g}/\text{m}^3$  and 73 percent of exposure samples are below 0.2  $\mu\text{g}/\text{m}^3$ . The other exception is abrasive blasting. The samples for abrasive blasting used in the exposure profile were obtained during blasting operations using enclosed cabinets, and all 5 samples were below 0.2  $\mu\text{g}/\text{m}^3$ . Exposures for other job groups ranged from just below to well above the proposed PEL, including molder (all samples above 0.2  $\mu\text{g}/\text{m}^3$ ), material handler (1 sample total, above 0.2  $\mu\text{g}/\text{m}^3$ ), furnace operator (81.8 percent of samples above 0.2  $\mu\text{g}/\text{m}^3$ ), pouring operator (60 percent of samples above 0.2  $\mu\text{g}/\text{m}^3$ ), shakeout operator (1 sample total, above 0.2  $\mu\text{g}/\text{m}^3$ ), and maintenance worker (50 percent of samples above 0.2  $\mu\text{g}/\text{m}^3$ ).

In some of the foundries at which the air samples included in the exposure profile were collected, there are indications that the ventilation systems were not properly used or maintained, and dry sweeping or brushing and the use of compressed air systems for cleaning may have contributed to high dust levels. OSHA believes that exposures in foundries can be substantially reduced by improving and properly using and maintaining the ventilation systems; switching from dry brushing, sweeping and compressed air to wet methods and use of HEPA-

filtered vacuums for cleaning molds and work areas; enclosing processes; automation of high-exposure tasks; and modification of processes (e.g., switching from sand-based to alternative casting methods). OSHA preliminarily concludes that these additional engineering controls and modified work practices can be implemented to achieve the proposed PEL most of the time for molding, material handling, maintenance, abrasive blasting, grinding/finishing, and pouring operations at foundries that produce aluminum and copper beryllium alloys.

The Agency is less confident that exposure can be reliably reduced to the proposed PEL for furnace and shakeout operators. Beryllium concentrations in the proximity of the furnaces are typically higher than in other areas due to the fumes generated and the difficulty of controlling emissions during furnace operations. The exposure profile for furnace operations shows a median beryllium exposure level of 1.14  $\mu\text{g}/\text{m}^3$ . OSHA believes that furnace operators' exposures can be reduced using local exhaust ventilation and other controls to reduce overall beryllium levels in foundries, but it is not clear that they can be reduced to the proposed PEL with currently available technology. In foundries that use sand molds, the shakeout operation typically involves removing the freshly cast parts from the sand mold using a vibrating grate that shakes the sand from castings. The shakeout equipment generates substantial amounts of airborne dust that can be difficult to contain, and therefore shakeout operators are typically exposed to high dust levels. During casting of beryllium alloys, the dust may contain beryllium and beryllium oxide residues dislodged from the casting during the shakeout process. The exposure profile for the shakeout operations contains only one result of 1.3  $\mu\text{g}/\text{m}^3$ . This suggests that a substantial reduction would be necessary to achieve compliance with a proposed PEL of 0.2  $\mu\text{g}/\text{m}^3$ . OSHA requests additional information on recent employee exposure levels and the effectiveness of dust controls for shakeout operations for copper and aluminum alloy foundries.

#### Secondary Smelting, Refining, and Alloying

OSHA identified two job groups in this application group with exposure to beryllium: Mechanical process operators and furnace operations workers. Mechanical operators handle and treat source material, and furnace operators run heating processes for refining, melting, and casting metal alloy. OSHA

developed exposure profiles for these jobs based on exposure data from ERG site visits to a precious/base metals recovery facility and a facility that melts and casts beryllium-containing alloys, both conducted in 2003. The available exposure data for this application group are limited, and therefore, the exposure profile is supplemented in part by summary data presented in secondary sources of information on beryllium exposures in this application group.

The exposure profile for mechanical processing operators indicates low exposures (3 samples less than 0.2  $\mu\text{g}/\text{m}^3$ ), even though these samples were collected at a facility where the ventilation system was allowing visible emissions to escape exhaust hoods. Summary data from studies and reports published in 2005–2009 showed that mechanical processing operator exposures averaged between 0.01 and 0.04  $\mu\text{g}/\text{m}^3$  at facilities where mixed or electronic waste including beryllium alloy parts were refined. Based on these results, OSHA preliminarily concludes that the proposed PEL is already achieved for most mechanical processing operations most of the time, and exposures could be further reduced through improved ventilation system design and other measures, such as process enclosures.

As with furnace operations examined in other application groups, the exposure profile indicates higher worker exposures for furnace operators in the secondary smelting, refining, and alloying application group (six samples with a median of 2.15  $\mu\text{g}/\text{m}^3$ , and 83.3 percent above 0.2  $\mu\text{g}/\text{m}^3$ ). The two lowest samples in this job's exposure profile (0.03 and 0.5  $\mu\text{g}/\text{m}^3$ ) were collected at a facility engaged in recycling and recovery of precious metals where work with beryllium-containing material is incidental. At this facility, the furnace is enclosed and fumes are ducted into a filtration system. The four higher samples, ranging from 1.92 to 14.08  $\mu\text{g}/\text{m}^3$ , were collected at a facility engaged primarily in beryllium alloying operations, where beryllium content is significantly higher than in recycling and precious metal recovery activities, the furnace is not enclosed, and workers are positioned directly in the path of the exhaust ventilation over the furnace. OSHA believes these exposures could be reduced by enclosing the furnace and repositioning the worker, but is not certain whether the reduction achieved would be enough to bring exposures down to the proposed PEL. Based on the limited number of samples in the exposure profile and surrogate data from furnace operations, the proposed PEL

<sup>16</sup> One facility visited by ERG has reportedly modified this process to reduce worker exposures, but OSHA has no data to quantify the reduction.

may not be feasible for furnace work in beryllium recovery and alloying, and respirators may be necessary to protect employees performing these tasks.

#### Precision Turned Products

OSHA's preliminary feasibility analysis for precision turned products focuses on machinists who work with beryllium-containing alloys. The Agency also examined the available exposure data for non-machinists and has preliminarily concluded that, in most cases, controlling the sources of exposures for machinists will also reduce exposures for other job groups with indirect exposure when working in the vicinity of machining operations.

OSHA developed exposure profiles based on exposure data from four NIOSH surveys conducted between 1976 and 2008; ERG site visits to precision machining facilities in 2002, 2003, and 2004; case study reports from six facilities machining copper-beryllium alloys; and exposure data collected between 1987 and 2001 by the U.S. Navy Environmental Health Center (NEHC). Analysis of the exposure data showed a substantial difference between the median exposure level for workers machining pure beryllium and/or high-beryllium alloys compared to workers machining low-beryllium alloys. Most establishments in the precision turned products application group work only with low-beryllium alloys, such as copper-beryllium. A relatively small number of establishments (estimated at 15) specialize in precision machining of pure beryllium and/or high-beryllium alloys.

The exposure profile indicates that machinists working with low-beryllium alloys have mostly low exposure to airborne beryllium. Approximately 85 percent of the 80 exposure results are less than or equal to  $0.2 \mu\text{g}/\text{m}^3$ , and 74 percent are less than or equal to  $0.1 \mu\text{g}/\text{m}^3$ . Some of the results below  $0.1 \mu\text{g}/\text{m}^3$  were collected at a facility where machining operations were enclosed, and metal cutting fluids were used to control the release of airborne contaminants. Higher results ( $0.1 \mu\text{g}/\text{m}^3$ – $1.07 \mu\text{g}/\text{m}^3$ ) were found at a facility where cutting and grinding operations were conducted in partially enclosed booths equipped with LEV, but some LEV was not functioning properly. A few very high results ( $0.77 \mu\text{g}/\text{m}^3$ – $24 \mu\text{g}/\text{m}^3$ ) were collected at a facility where exposure controls were reportedly inadequate and poor work practices were observed (e.g., improper use of downdraft tables, use of compressed air for cleaning). Based on these results, OSHA preliminarily concludes that exposures below  $0.2 \mu\text{g}/\text{m}^3$  can be

achieved most of the time for most machinists at facilities dealing primarily with low-beryllium alloys. OSHA recognizes that higher exposures may sometimes occur during some tasks where exposures are difficult to control with engineering methods, such as cleaning, and that respiratory protection may be needed at these times.

Machinists working with high-beryllium alloys have higher exposure than those working with low-beryllium alloys. This difference is reflected in the exposure profile for this job, where the median of exposure is  $0.31 \mu\text{g}/\text{m}^3$  and 75 percent of samples exceed the proposed PEL of  $0.2 \mu\text{g}/\text{m}^3$ . The exposure profile was based on two machining facilities at which LEV was used and machining operations were performed under a liquid coolant flood. Like most facilities where pure beryllium and high-beryllium alloys are machined, these facilities also used some combination of full or partial enclosures, as well as work practices to minimize exposure such as prohibiting the use of compressed air and dry sweeping and implementing dust migration control practices to prevent the spread of beryllium contamination outside production areas. At one facility machining high-beryllium alloys, where all machining operations were fully enclosed and ventilated, exposures were mostly below  $0.1 \mu\text{g}/\text{m}^3$  (median  $0.035 \mu\text{g}/\text{m}^3$ , range  $0.02$ – $0.11 \mu\text{g}/\text{m}^3$ ). Exposures were initially higher at the second facility, where some machining operations were not enclosed, existing LEV system were in need of upgrades, and some exhaust systems were improperly positioned. Samples collected there in 2003 and 2004 were mostly below the proposed PEL in 2003 (median  $0.1 \mu\text{g}/\text{m}^3$ ) but higher in 2004 (median  $0.25 \mu\text{g}/\text{m}^3$ ), and high exposure means in both years ( $1.65$  and  $0.68 \mu\text{g}/\text{m}^3$  respectively) show the presence of high exposure spikes in the facility. However, the facility reported that measures to reduce exposure brought almost all machining exposures below  $0.2 \mu\text{g}/\text{m}^3$  in 2006. With the use of fully enclosed machines and LEV and work practices that minimize worker exposures, OSHA preliminarily concludes that the proposed PEL is feasible for the vast majority of machinists working with pure beryllium and high-beryllium alloys. OSHA recognizes that higher exposures may sometimes occur during some tasks where exposures are difficult to control with engineering methods, such as machine cleaning and maintenance, and that respiratory protection may be needed at these times.

Copper Rolling, Drawing, and Extruding

OSHA's exposure profile for copper rolling, drawing, and extruding includes four job groups with beryllium exposure: strip metal production, rod and wire production, production support, and administrative work. Exposure profiles for these jobs are based on personal breathing zone lapel sampling conducted at the Brush Wellman Reading, Pennsylvania, rolling and drawing facility from 1977 to 2000.

Prior to 2000, the Reading facility had limited engineering controls in place. Equipment in use included LEV in some operations, HEPA vacuums for general housekeeping, and wet methods to control loose dust in some rod and wire production operations. The exposure profile shows very low exposures for all four job groups. All had median exposure values below  $0.1 \mu\text{g}/\text{m}^3$ , and in strip metal production, production support, and administrative work, over 90 percent of samples were below  $0.1 \mu\text{g}/\text{m}^3$ . In rod and wire production, 70 percent of samples were below  $0.1 \mu\text{g}/\text{m}^3$ .

To characterize exposures in extrusion, OSHA examined the results of an industrial hygiene survey of a copper-beryllium extruding process conducted in 2000 at another facility. The survey reported eight PBZ samples, which were not included in the exposure profile because of their short duration (2 hours). Samples for three of the four jobs involved with the extrusion process (press operator, material handler, and billet assembler) were below the limit of detection (LOD) (level not reported). The two samples for the press operator assistant, taken when the assistant was buffing, sanding, and cleaning extrusion tools, were very high ( $1.6$  and  $1.9 \mu\text{g}/\text{m}^3$ ). Investigators recommended a ventilated workstation to reduce exposure during these activities.

In summary, exposures at or below  $0.2 \mu\text{g}/\text{m}^3$  have already been achieved for most jobs in rolling, drawing, and extruding operations, and OSHA preliminarily concludes that the proposed PEL of  $0.2 \mu\text{g}/\text{m}^3$  is feasible for this application group. For jobs or tasks with higher exposures, such as tool refinishing, use of exposure controls such as local exhaust ventilation can help reduce workers' exposures. The Agency recognizes the limitations of the available data, which were drawn from two facilities and did not include full-shift PBZ samples for extrusion. OSHA requests additional exposure data from other facilities in this application group, especially data from facilities where extrusion is performed.

#### Fabrication of Beryllium Alloy Products

This application group includes the fabrication of beryllium alloy springs, stampings, and connectors for use in electronics. The exposure profile is based on a study conducted at four precision stamping companies; a NIOSH report on a spring and stamping company; an ERG site visit to a precision stamping, forming, and plating establishment; and exposure monitoring results from a stamping facility presented at the American Industrial Hygiene Conference and Exposition in 2007. The exposure profiles for this application group include three jobs: chemical processing operators, deburring operators, and assembly operators. Other jobs for which all samples results were below  $0.1 \mu\text{g}/\text{m}^3$  are not shown in the profile.

For the three jobs in the profile, the majority of exposure samples were below  $0.1 \mu\text{g}/\text{m}^3$  (deburring operators, 79 percent; chemical processing operators, 81 percent; assembly operators, 93 percent). Based on these results, OSHA preliminarily concludes that the proposed PEL is feasible for this application group. The Agency notes that a few exposures above the proposed PEL were recorded for the chemical processing operator (in plating and bright cleaning) and for deburring (during corn cob deburring in an open tumbling mill). OSHA believes the use of LEV, improved housekeeping, and work practice modifications would reduce the frequency of excursions above the proposed PEL.

#### Welding

Most of the samples in OSHA's exposure profile for welders in general industry were collected between 1994 and 2001 at two of Brush Wellman's alloy strip distribution centers, and in 1999 at Brush Wellman's Elmore facility. At these facilities, tungsten inert gas (TIG) welding was conducted on beryllium alloy strip. Seven samples in the exposure profile came from a case study conducted at a precision stamping

facility, where airborne beryllium levels were very low (see previous summary, Fabrication of Beryllium Alloy Products). At this facility, resistance welding was performed on copper-beryllium parts, and welding processes were automated and enclosed.

Most of the sample results in the welding exposure profile were below  $0.2 \mu\text{g}/\text{m}^3$ . Of the 44 welding samples in the profile, 75 percent were below  $0.2 \mu\text{g}/\text{m}^3$  and 64 percent were below  $0.1 \mu\text{g}/\text{m}^3$ , with most values between 0.01 and  $0.05 \mu\text{g}/\text{m}^3$ . All but one of the 16 exposure samples above  $0.1 \mu\text{g}/\text{m}^3$  were collected in Brush Wellman's Elmore facility in 1999. According to company representatives, these higher exposure levels may have been due to beryllium oxide that can form on the surface of the material as a result of hot rolling. All seven samples from the precision stamping facility were below the limit of detection. Based on these results, OSHA preliminarily concludes that the proposed PEL of  $0.2 \mu\text{g}/\text{m}^3$  is feasible for most welding operations in general industry.

#### Dental Laboratories

OSHA's exposure profile for dental technicians includes sampling results from a site visit conducted by ERG in 2003; a study of six dental laboratories published by Rom *et al.* in 1984; a data set of exposure samples collected between 1987 and 2001, on dental technicians working for the U.S. Navy; and a docket submission from CMP Industries including two samples from a large commercial dental laboratory using nickel-beryllium alloy. Information on exposure controls in these facilities suggests that controls in some cases may have been absent or improperly used.

The exposure profile indicates that 52 percent of samples are less than or equal to  $0.2 \mu\text{g}/\text{m}^3$ . However, the treatment of nondetectable samples in the feasibility analysis may overestimate many of the sample values in the exposure profile. Twelve of the samples in the profile are

nondetectable for beryllium. In the exposure profile, these were assigned the highest possible value, the limit of detection (LOD). For eight of the nondetectable samples, the LOD was reported as  $0.2 \mu\text{g}/\text{m}^3$ . For the other four nondetectable samples, the LOD was between 0.23 and  $0.71 \mu\text{g}/\text{m}^3$ . If the true values for these four nondetectable samples are actually less than or equal to the assigned value of  $0.2 \mu\text{g}/\text{m}^3$ , then the true percentage of profile sample values less than or equal to  $0.2 \mu\text{g}/\text{m}^3$  is between 52 and 70 percent. Of the sample results with detectable beryllium above  $0.2 \mu\text{g}/\text{m}^3$ , some were collected in 1984 at facilities studied by Rom *et al.*, who reported that they occurred during grinding with LEV that was improperly used or, in one case, not used at all. Others were collected at facilities where little contextual information was available to determine what control equipment or work practices might have reduced exposures.

Based on this information, OSHA preliminarily concludes that beryllium exposures for most dental technicians are already below  $0.2 \mu\text{g}/\text{m}^3$  most of the time. OSHA furthermore believes that exposure levels can be reduced to or below  $0.1 \mu\text{g}/\text{m}^3$  most of the time via material substitution, engineering controls, and work practices. Beryllium-free alternatives for casting dental appliances are readily available from commercial sources, and some alloy suppliers have stopped carrying alloys that contain beryllium. For those dental laboratories that continue to use beryllium alloys, exposure control options include properly designed, installed, and maintained LEV systems (equipped with HEPA filters) and enclosures; work practices that optimize LEV system effectiveness; and housekeeping methods that minimize beryllium contamination in the workplace. In summary, OSHA preliminarily concludes that the proposed PEL is feasible for dental laboratories.

TABLE IX-5—BERYLLIUM FULL-SHIFT PBZ SAMPLES BY APPLICATION/JOB GROUP ( $\mu\text{g}/\text{m}^3$ )

Application/Job group	N	Range	Mean	Median	%<0.1	%≤0.2	%≤2.0
Be Production Operations (Section 3)							
Furnace Operations .....	172	0.05 to 254	3.80	0.68	5	17	82
Chemical Operations .....	20	0.05 to 9.6	1.02	0.47	5	15	95
Powdering Operations .....	72	0.06 to 11.5	0.82	0.37	11	29	94
Production Support .....	861	0.02 to 22.7	0.51	0.08	56	71	94
Cold Work .....	555	0.04 to 24.9	0.31	0.08	61	80	98
Hot Work .....	297	0.01 to 2.21	0.12	0.06	69	88	99
Site Support .....	879	0.05 to 4.22	0.11	0.05	81	92	99
Administrative .....	981	0.05 to 4.54	0.10	0.05	85	94	99
Be Oxide Ceramics (Section 4)							
Material Preparation Operator .....	77	0.02 to 10.6	1.01	0.41	13	27	90
Forming Operator .....	408	0.02 to 53.2	0.48	0.18	27	56	99
Machining Operator .....	355	0.01 to 5.0	0.32	0.15	37	63	98
Kiln Operator .....	3	0.22 to 0.36	0.28	0.25	0	0	100
Production Support Worker .....	119	0.02 to 7.7	0.21	0.05	68	88	98
Metallization Worker .....	36	0.02 to 0.62	0.15	0.06	55	69	100
Administrative .....	185	0.02 to 1.2	0.06	0.05	93	98	100
Aluminum and Copper Foundries (Section 5)							
Furnace Operator .....	11	0.2 to 19.76	4.41	1.14	0	18	64
Pouring Operator .....	5	0.2 to 2.2	1.21	1.40	0	40	60
Shakeout Operator .....	1	1.3	1.30	1.30	0	0	100
Material Handler .....	1	0.93	0.93	0.93	0	0	100
Molder .....	8	0.24 to 2.29	0.67	0.45	0	0	88
Maintenance .....	78	0.05 to 22.71	0.87	0.21	15	50	96
Abrasive Blasting Operator .....	5	0.05 to 0.15	0.11	0.12	40	100	100
Grinding/finishing Operator .....	56	0.01 to 4.79	0.31	0.05	59	73	95
Secondary Smelting (Section 6)							
Furnace operations worker .....	6	0.03 to 14.1	3.85	2.15	17	17	50
Mechanical processing operator .....	3	0.03 to 0.2	0.14	0.20	33	100	100
Precision Turned Products (Section 7)							
High Be Content Alloys .....	80	0.02 to 7.2	0.72	0.31	14	25	92
Low Be Content Alloys .....	59	0.005 to 24	0.45	0.01	74	85	96
Rolling, Drawing, and Extruding (Section 8)	650	0.006 to 7.8	0.11	0.024	86	93	99
Alloy Fabrication (Section 9)	71	0.004 to 0.42	0.056	0.025	83	94	100
Welding: Beryllium Alloy (Section 10)	44	0.005 to 2.21	0.19	0.02	64	75	98
Dental Laboratories (Section 11)	23	0.02 to 4.4	0.74	0.2	13	52	87

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.



### E. Costs of Compliance

Chapter V of the PEA in support of the proposed beryllium rule provides a detailed assessment of the costs to establishments in all affected application groups of reducing worker exposures to beryllium to an eight-hour time-weighted average (TWA) permissible exposure limit (PEL) of 0.2  $\mu\text{g}/\text{m}^3$  and to the proposed short-term exposure limit (STEL) of 2.0  $\mu\text{g}/\text{m}^3$ , as well as of complying with the proposed standard's ancillary provisions. OSHA describes its methodology and sources in more detail in Chapter V. OSHA's preliminary cost assessment is based on the Agency's technological feasibility analysis presented in Chapter IV of the PEA; analyses of the costs of the proposed standard conducted by OSHA's contractor, Eastern Research Group (ERG); and the comments submitted to the docket in response to the request for information (RFI) and as part of the SBREFA process.

As shown in Table IX-7 at the end of this section, OSHA estimates that the proposed standard would have an annualized cost of \$37.6 million. All cost estimates are expressed in 2010 dollars and were annualized using a discount rate of 3 percent, which—along with 7 percent—is one of the discount rates recommended by OMB.<sup>17</sup> Annualization periods for expenditures on equipment are based on equipment life, and one-time costs are annualized over a 10-year period.

The estimated costs for the proposed beryllium rule represent the additional costs necessary for employers to achieve full compliance. They do not include costs associated with current compliance that may already have been achieved with regard to existing beryllium requirements or costs necessary to achieve compliance with existing beryllium requirements, to the extent that some employers may currently not be fully complying with applicable regulatory requirements.

Throughout this section and in the PEA, OSHA presents cost formulas in the text, usually in parentheses, to help explain the derivation of cost estimates for individual provisions. Because the values used in the formulas shown in the text are shown only to the second decimal place, while the actual spreadsheet formulas used to create final costs are not limited to two decimal places, the calculation using the presented formula will sometimes

differ slightly from the presented total in the text, which is the actual and mathematically correct total as shown in the tables.

#### 1. Compliance With the Proposed PEL/STEL

OSHA's estimate of the costs for affected employers to comply with the proposed PEL of 0.2  $\mu\text{g}/\text{m}^3$  and the proposed STEL of 2.0  $\mu\text{g}/\text{m}^3$  consists of two parts. First, costs are estimated for the engineering controls, additional studies and custom design requirements to implement those controls, work practices, and specific training required for those work practices (as opposed to general training in compliance with the rule) needed for affected employers to meet the proposed PEL and STEL, as well as opportunity costs (lost productivity) that may result from working with some of the new controls. In most cases, the PEA breaks out these costs, but in other instances some or all of the costs are shortened simply to "engineering controls" in the text, for convenience. Second, for employers unable to meet the proposed PEL and STEL using engineering controls and work practices alone, costs are estimated for respiratory protection sufficient to reduce worker exposure to the proposed PEL and STEL or below.

In the technological feasibility analysis presented in Chapter IV of the PEA, OSHA concluded that implementing all engineering controls and work practices necessary to reach the proposed PEL will, except for a small residual group (accounting for about 6 percent of all exposures above the STEL), also reduce exposures below the STEL. However, based on the nature of the processes this residual group is likely to be engaged in, the Agency expects that employees would already be using respirators to comply with the PEL under the proposed standard. Therefore, with the proposed STEL set at ten times the proposed PEL, the Agency has preliminarily determined that engineering controls, work practices, and (when needed) respiratory protection sufficient to meet the proposed PEL are also sufficient to meet the proposed STEL. For that reason, OSHA has taken no additional costs for affected employers to meet the proposed STEL. The Agency invites comment and requests that the public provide data on this issue.

#### a. Engineering Controls

For this preliminary cost analysis, OSHA estimated the necessary engineering controls and work practices for each affected application group according to the exposure profile of

current exposures by occupation presented in Chapter III of the PEA. Under the requirements of the proposed standard, employers would be required to implement engineering or work practice controls whenever beryllium exposures exceed the proposed PEL of 0.2  $\mu\text{g}/\text{m}^3$  or the proposed STEL of 2.0  $\mu\text{g}/\text{m}^3$ .

In addition, even if employers are not exposed above the proposed PEL or proposed STEL, paragraph (f)(2) of the proposed standard would require employers at or above the action level to use at least one engineering or work practice control to minimize worker exposure. Based on the technological feasibility analysis presented in Chapter IV of the PEA, OSHA has determined that, for only two job categories in two application groups—chemical process operators in the Stamping, Spring and Connection Manufacture application group and machinists in the Machining application group—do the majority of facilities at or above the proposed action level, but below the proposed PEL, lack the baseline engineering or work controls required by paragraph (f)(2). Therefore, OSHA has estimated costs, where appropriate, for employers in these two application groups to comply with paragraph (f)(2).

By assigning controls based on application group, the Agency is best able to identify those workers with exposures above the proposed PEL and to design a control strategy for, and attribute costs specifically to, these groups of workers. By using this approach, controls are targeting those specific processes, emission points, or procedures that create beryllium exposures. Moreover, this approach allows OSHA to assign costs for technologies that are demonstrated to be the most effective in reducing exposures resulting from a particular process.

In developing cost estimates, OSHA took into account the wide variation in the size or scope of the engineering or work practice changes necessary to minimize beryllium exposures based on technical literature, judgments of knowledgeable consultants, industry observers, and other sources. The resulting cost estimates reflect the representative conditions for the affected workers in each application group and across all work settings. In all but a handful of cases (with the exceptions noted in the PEA), all wage costs come from the 2010 Occupational Employment Statistics (OES) of the Bureau of Labor Statistics (BLS, 2010a) and utilize the median wage for the appropriate occupation. The wages used include a 30.35 percent markup for fringe benefits as a percentage of total

<sup>17</sup> Appendix V-A of the PEA presents costs by NAICS industry and establishment size categories using, as alternatives, a 7 percent discount rate—shown in Table V-A-1—and a 0 percent discount rate—shown in Table V-A-2.

compensation, which is the average percentage markup for fringe benefits for all civilian workers from the 2010 Employer Costs for Employee Compensation of the BLS (BLS, 2010b). All descriptions of production processes are drawn from the relevant sections of Chapter IV of the PEA.

The specific engineering costs for each of the applications groups, and the NAICS industries that contain those application groups, are discussed in Chapter V of the PEA. Like the industry profile and technological feasibility analysis presented in other PEA chapters, Chapter V of the PEA presents engineering control costs for the following application groups:

- Beryllium Production
- Beryllium Oxide, Ceramics & Composites Production
- Nonferrous Foundries
- Stamping, Spring and Connection Manufacture
- Secondary Smelting, Refining, and Alloying
- Copper Rolling, Drawing, and Extruding
- Secondary Smelting, Refining, and Alloying
- Precision Machining
- Welding
- Dental Laboratories

The costs within these application groups are estimated by occupation and/or operation. One application group could have multiple occupations, operations, or activities where workers are exposed to levels of beryllium above the proposed PEL, and each will need its own set of controls. The major types of engineering controls needed to achieve compliance with the proposed PEL include ventilation equipment, pharmaceutical-quality high-containment isolators, decontainment chambers, equipment with controlled water sprays, closed-circuit remote televisions, enclosed cabs, conveyor enclosures, exhaust hoods, and portable local-exhaust-ventilation (LEV) systems. Capital costs and annual operation and maintenance (O&M) costs, as well as any other annual costs, are estimated for the set of engineering controls estimated to be necessary for limiting beryllium exposures for each occupation or operation within each application group.

Tables V-2 through V-10 in Chapter V of the PEA summarize capital, maintenance, and operating costs for each application group disaggregated by NAICS code. Table IX-7 at the end of this section breaks out the costs of engineering controls/work practices by application group and NAICS code.

Some engineering control costs are estimated on a per-worker basis and then multiplied by the estimated number of affected workers—as identified in Chapter III: Profile of

Affected Industries in the PEA—to arrive at a total cost for a particular control within a particular application group. This worker-based method is necessary because—even though OSHA has data on the number of firms in each affected industry, the occupations and industrial activities that result in worker exposure to beryllium, and the exposure profile of at-risk occupations—the Agency does not have a way to match up these data at the firm level. Nor does the Agency have establishment-specific data on worker exposure to beryllium for all establishments, or even establishment-specific data on the level of activity involving worker exposure to beryllium. Thus, OSHA could not always directly estimate per-affected-establishment costs, but instead first had to estimate aggregate compliance costs (using an estimated per-worker cost multiplied by the number of affected workers) and then calculate the average per-affected-establishment costs by dividing those aggregate costs by the number of affected establishments. This method, while correct on average, may under- or over-state costs for certain firms. For other controls that are implemented on a fixed-cost basis per establishment (e.g., creating a training program, writing a control program), the costs are estimated on an establishment basis, and these costs were multiplied by the number of affected establishments in the given application group to obtain total control costs.

In developing cost estimates, the Agency sometimes had to make case-specific judgments about the number of workers affected by each engineering control. Because work environments vary within occupations and across establishments, there are no definitive data on how many workers are likely to have their exposures reduced by a given set of controls. In the smallest establishments, especially those that might operate only one shift per day, some controls would limit exposures for only a single worker in one specific affected occupation. More commonly, however, several workers are likely to benefit from each enhanced engineering control. Many controls were judged to reduce exposure for employees in multi-shift work or where workstations are used by more than one worker per shift.

In general, improving work practices involves operator training, actual work practice modifications, and better enforcement or supervision to minimize potential exposures. The costs of these process improvements consist of the supervisor and worker time involved and would include the time spent by supervisors to develop a training program.

Unless otherwise specified, OSHA viewed the extent to which exposure controls are already in place to be reflected in the distribution of exposures at levels above the proposed PEL among affected workers. Thus, for example, if 50 percent of workers in a given occupation are found to be exposed to beryllium at levels above the proposed PEL, OSHA judged this equivalent to 50 percent of facilities lacking adequate exposure controls. The facilities may have, for example, the correct equipment installed but without adequate ventilation to provide protection to workers exposed to beryllium. In this example, the Agency would expect that the remaining 50 percent of facilities to either have installed the relevant controls to reduce beryllium exposures below the PEL or that they engage in activities that do not require that the exposure controls be in place (for example, they do not perform any work with beryllium-containing materials). To estimate the need for incremental controls on a per-worker basis, OSHA used the exposure profile information as the best available data. OSHA recognizes that a very small percentage of facilities might have all the relevant controls in place but are still unable, for whatever reason, to achieve the proposed PEL through controls alone. ERG's review of the industrial hygiene literature and other source materials (ERG, 2007b), however, suggest that the large majority of workplaces where workers are exposed to high levels of beryllium lack at least some of the relevant controls. Thus, in estimating the costs associated with the proposed standard, OSHA has generally assumed that high levels of exposure to beryllium occur due to the absence of suitable controls. This assumption likely results in an overestimate of costs since, in some cases, employers may not need to install and maintain new controls in order to meet the proposed PEL but merely need to upgrade or better maintain existing controls, or to improve work practices.

#### b. Respiratory Protection Costs

Based on the findings of the technological feasibility analysis, a small subset of employees working with a few processes in a handful of application groups will need to use respirators, in addition to required engineering controls and improved work practices, to reduce employee exposures to meet the proposed PEL. Specifically, furnace operators—both in non-ferrous foundries (both sand and non-sand) and in secondary smelting, refining, and alloying—as well as welders in a few other processes, will

need to wear half-mask respirators. In beryllium production, workers who rebuild or otherwise maintain furnaces and furnace tools will need to wear full-face powered air-purifying respirators. Finally, the Agency recognizes the possibility that, after all feasible engineering and other controls are in place, there may still be a residual group with potential exposure above the proposed PEL and/or STEL. To account for these residual cases, OSHA estimates that 10 percent of the workers, across all application groups and job categories, who are above the proposed PEL before the beryllium proposed standard is in place (according to the baseline exposure profile presented in Chapter III of the PEA), would still be above the PEL after all feasible controls are implemented and, hence, would need to use half-mask respirators to achieve compliance with the proposed PEL.

There are five primary costs for respiratory protection. First, there is a cost per establishment to set up a written respirator program in accordance with the respiratory protection standard (29 CFR 1910.134). The respiratory protection standard requires written procedures for the proper selection, use, cleaning, storage, and maintenance of respirators. As derived in the PEA, OSHA estimates that, when annualized over 10 years, the annualized per-establishment cost for a written respirator program is \$207.

For reasons unrelated to the proposed standard, certain establishments will already have a respirator program in place. Table V-11 in Chapter V of the PEA presents OSHA's estimates, by application group, of current levels of compliance with the respirator program provision of the proposed rule.

The four other major costs of respiratory protection are the per-employee costs for all aspects of respirator use: equipment, training, fit-testing, and cleaning. Table V-12 of Chapter V in the PEA breaks out OSHA's estimate of the unit costs for the two types of respirators needed: A half-mask respirator and a full-face powered air-purifying respirator. As derived in the PEA, the annualized per-employee cost for a half-mask respirator would be \$524 and the annualized per-employee cost for a full-face powered air-purifying respirator would be \$1,017.

Table V-13 in Chapter V of the PEA presents the number of additional employees, by application group and NAICS code, that would need to wear respirators to comply with the proposed standard and the cost to industry to comply with the respirator protection provisions in the proposed rule. OSHA judges that only workers in Beryllium

Production work with processes that would require a full-face respirator and estimates that there are 23 of those workers. Three hundred and eighteen workers in other assorted application groups are estimated to need half-mask respirators. A total of 341 employees would need to wear some type of respirator, resulting in a total annualized cost of \$249,684 for affected industries to comply with the respiratory protection requirements of the proposed standard. Table IX-7 at the end of this section breaks out the costs of respiratory protection by application group and NAICS code.

## 2. Ancillary Provisions

This section presents OSHA's estimated costs for ancillary beryllium control programs required under the proposed rule. Based on the program requirements contained in the proposed standard, OSHA considered the following cost elements in the following employer duties: (a) Assess employees' exposure to airborne beryllium, (b) establish regulated areas, (c) develop a written exposure control plan, (d) provide protective work clothing, (e) establish hygiene areas and practices, (f) implement housekeeping measures, (g) provide medical surveillance, (h) provide medical removal for employees who have developed CBD or been confirmed positive for beryllium sensitization, and (i) provide appropriate training.

The worker population affected by each program element varies by several criteria discussed in detail in each subsection below. In general, some elements would apply to all workers exposed to beryllium at or above the action level. Other elements would apply to a smaller set of workers who are exposed above the PEL. The training requirements would apply to all employees who work in a beryllium work area (e.g., an area with any level of exposure to airborne beryllium). The regulated area program elements triggered by exposures exceeding the proposed PEL of 0.2  $\mu\text{g}/\text{m}^3$  would apply to those workers for whom feasible controls are not adequate. In the earlier discussion of respiratory protection, OSHA estimated that 10 percent of all affected workers with current exposures above the proposed PEL would fall in this category.

Costs for each program requirement are aggregated by employment and by industry. For the most part, unit costs do not vary by industry, and any variations are specifically noted. The estimated compliance rate for each provision of the proposed standard by

application group is presented in Table V-15 of the PEA.

## a. Exposure Assessment

Most establishments wishing to perform exposure monitoring would require the assistance of an outside consulting industrial hygienist (IH) to obtain accurate results. While some firms might already employ or train qualified staff, OSHA judged that the testing protocols are fairly challenging and that few firms have sufficiently skilled staff to eliminate the need for outside consultants.

The proposed standard requires that, after receiving the results of any exposure monitoring where exposures exceed the TWA PEL or STEL, the employer notify each such affected employee in writing of suspected or known sources of exposure, and the corrective action(s) being taken to reduce exposure to or below the PEL. Those workers exposed at or above the action level and at or below the PEL must have their exposure levels monitored annually.

For costing purposes, OSHA estimates that, on average, there are four workers per work area. OSHA interpreted the initial exposure assessment 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 beryllium at or above the action level.

The proposed standard requires that whenever there is a change in the production, process, control equipment, personnel, or work practices that may result in new or additional exposures, or when the employer has any reason to suspect that a change may result in new or additional exposures, the employer must conduct additional monitoring. The Agency has estimated that this provision would require an annual sampling of 10 percent of the affected workers.

OSHA estimates that an industrial hygienist (IH) would spend 1 day each year to sample 2 workers, for a per worker IH fee of \$257. This exposure monitoring requires that three samples be taken per worker: One TWA and two STEL for an annual IH fee per sample of \$86. Based on the 2000 EMSL Laboratory Testing Catalog (ERG, 2007b), OSHA estimated that analysis of each sample would cost \$137 in lab fees. When combined with the IH fee, OSHA estimated the annual cost to obtain a TWA sample to be \$223 per sampled worker and the annual cost to obtain the two STEL samples to be \$445 per sampled worker. The direct exposure monitoring unit costs are

summarized in Table V–16 in Chapter V of the PEA.

The cost of the sample also incorporates a productivity loss due to the additional time for the worker to participate in the sampling (30 minutes per worker sampled) as well as for the associated recordkeeping time incurred by a manager (15 minutes per worker sampled). The STEL samples are assumed to be taken along with the TWA sample and, thus, labor costs were not added to both unit costs. Including the costs related to lost productivity, OSHA estimates the total annual cost of a TWA sample to be \$251, and 2 STEL samples, \$445. The total annual cost per worker for all sampling taken is then \$696. OSHA estimates the total annualized cost of this provision to be \$2,208,950 for all affected industries. The annualized cost of this provision for each affected NAICS industry is shown in Table IX–6.

#### b. Beryllium Work Areas and Regulated Areas

The proposed beryllium standard requires the employer to establish and maintain a regulated area wherever employees are, or can reasonably be expected to be, exposed to airborne beryllium at levels above the TWA PEL or STEL. Regulated areas require specific provisions that both limit employee exposure within its boundaries and curb the migration of beryllium outside the area. The Agency judged, based on the preliminary findings of the technological feasibility analysis, that companies can reduce establishment-wide exposure by ensuring that only authorized employees wearing proper protective equipment have access to areas of the establishment where such higher concentrations of beryllium exist, or can be reasonably expected to exist. Workers in other parts of the establishment are also likely to see a reduction in beryllium exposures due to these measures since fewer employees would be traveling through regulated areas and subsequently carrying beryllium residue to other work areas on their clothes and shoes.

Requirements in the proposed rule for a regulated area include: Demarcating the boundaries of the regulated area as separate from the rest of the workplace, limiting access to the regulated area, providing an appropriate respirator to each person entering the regulated area and other protective clothing and equipment as required by paragraph (g) and paragraph (h), respectively.

OSHA estimated that the total annualized cost per regulated area, including set-up costs (\$76), respirators

(\$1,768) and protective clothing (\$4,500), is \$6,344.

When establishments are in full compliance with the standard, regulated areas would be required only for those workers for whom controls could not feasibly reduce their exposures to or below the 0.2 µg/m<sup>3</sup> TWA PEL and the 2 µg/m<sup>3</sup> STEL. Based on the findings of the technological feasibility analysis, OSHA estimated that 10 percent of the affected workers would be exposed above the TWA PEL or STEL after implementation of engineering controls and thus would require regulated areas (with one regulated area, on average, for every four workers exposed above the proposed TWA PEL or STEL).

The proposed standard requires that all beryllium work areas are adequately established and demarcated. ERG estimated that one work area would need to be established for every 12 at-risk workers. OSHA estimates that the annualized cost would be \$33 per work area.

OSHA estimates the total annualized cost of the regulated areas and work areas is \$629,031 for all affected industries. The cost for each affected application group and NAICS code is shown in Table IX–6.

#### c. Written Exposure Control Plan

The proposed standard requires that employers must establish and maintain a written exposure control plan for beryllium work areas. The written program must contain:

1. An inventory of operations and job titles reasonably expected to have exposure.
2. An inventory of operations and job titles reasonably expected to have exposure at or above the action level.
3. An inventory of operations and job titles reasonably expected to have exposure above the TWA PEL or STEL.
4. Procedures for minimizing cross-contamination, including but not limited to preventing the transfer of beryllium between surfaces, equipment, clothing, materials and articles within beryllium work areas.
5. Procedures for keeping surfaces in the beryllium work area free as practicable of beryllium.
6. Procedures for minimizing the migration of beryllium from beryllium work areas to other locations within or outside the workplace.
7. An inventory of engineering and work practice controls required by paragraph (f)(2) of this standard.

8. Procedures for removal, laundering, storage, cleaning, repairing, and disposal of beryllium-contaminated personal protective clothing and equipment, including respirators.

The unit cost estimates take into account the judgment that (1) most establishments have an awareness of beryllium risks and, thus, should be able to develop or modify existing safeguards in an expeditious fashion, and (2) many operations have limited beryllium activities and these establishments need to make only modest changes in procedures to create the necessary exposure control plan. ERG's experts estimated that managers would spend eight hours per establishment to develop and implement such a written exposure control plan, yielding a total cost per establishment to develop and implement the written control plan of \$563.53 and an annualized cost of \$66. In addition, because larger firms with more affected workers will need to develop more complicated written control plans, the development of a plan would require an extra thirty minutes of a manager's time per affected employee, for a cost of \$35 per affected employee and an annualized cost of \$4 per employee. Managers would also need 12 minutes (0.2 hours) per affected employee per quarter, or 48 minutes per affected employee per year to review and update the plan, for a recurring cost of \$56 per affected employee per year to maintain and update the plan. Five minutes of clerical time would also be needed per employee for providing each employee with a copy of the written exposure control plan—yielding an annualized cost of \$2 per employee. The total annual per-employee cost for development, implementation, review, and update of a written exposure control plan is then \$62. The Agency estimates the total annualized cost of this provision to be \$1,769,506 for all affected establishments. The breakdown of these costs by application group and NAICS code is presented in Table IX–6.

#### d. Personal Protective Clothing and Equipment

The proposed standard requires personal protective clothing and equipment for workers:

1. Whose exposure can reasonably be expected to exceed the TWA PEL or STEL.
2. When work clothing or skin may become visibly contaminated with beryllium, including during maintenance and repair activities or during non-routine tasks.
3. Where employees' skin can reasonably be expected to be exposed to soluble beryllium compounds.

OSHA has determined that it would be necessary for employers to provide reusable overalls and/or lab coats at a

cost of \$284 and \$86, respectively, for operations in the following application groups:

Beryllium Production  
Beryllium Oxide, Ceramics & Composites  
Nonferrous Foundries  
Fabrication of Beryllium Alloy Products  
Copper Rolling, Drawing & Extruding  
Secondary Smelting, Refining and Alloying  
Precision Turned Products  
Dental Laboratories

Chemical process operators in the spring and stamping application group would require chemical resistant protective clothing at an annual cost of \$849. Gloves and/or shoe covers would be required when performing operations in several different application groups, depending on the process being performed, at an annual cost of \$50 and \$78, respectively.

The proposed standard requires that all reusable protective clothing and equipment be cleaned, laundered, repaired, and replaced as needed to maintain their effectiveness. This includes such safeguards as transporting contaminated clothing in sealed and labeled impermeable bags and informing any third party businesses coming in contact with such materials of the risks associated with beryllium exposure. OSHA estimates that the lowest cost alternative to satisfy this provision is for an employer to rent and launder reusable protective clothing—at an estimated annual cost per employee of \$49. Ten minutes of clerical time would also be needed per establishment with laundry needs to notify the cleaners in writing of the potentially harmful effects of beryllium exposure and how the protective clothing and equipment must be handled in accordance with this standard—at a per establishment cost of \$3.

The Agency estimates the total annualized cost of this provision to be \$1,407,365 for all affected establishments. The breakdown of these costs by application group and NAICS code is shown in Table IX–6.

#### e. Hygiene Areas and Practices

The proposed standard requires employers to provide readily accessible washing facilities to remove beryllium from the hands, face, and neck of each employee working in a beryllium work area and also to provide a designated change room in workplaces where employees would have to remove their personal clothing and don the employer-provided protective clothing. The proposed standard also requires that employees shower at the end of the work shift or work activity if the employee reasonably could have been exposed to beryllium at levels above the

PEL or STEL, and if those exposures could reasonably be expected to have caused contamination of the employee's hair or body parts other than hands, face, and neck.

In addition to other forms of PPE costed previously, for processes where hair may become contaminated, head coverings can be purchased at an annual cost of \$28 per employee. This could satisfy the requirement to avoid contaminated hair. If workers are covered by protective clothing such that no body parts (including their hair where necessary, but not including their hands, face, and neck) could reasonably be expected to have been contaminated by beryllium, and they could not reasonably be expected to be exposed to beryllium while removing their protective clothing, they would not need to shower at the end of a work shift or work activity. OSHA notes that some facilities already have showers, and the Agency judges that all employers either already have showers where needed or will have sufficient measures in place to ensure that employees could not reasonably be expected to be exposed to beryllium while removing protective clothing. Therefore, OSHA has preliminarily determined that employers will not need to provide any new shower facilities to comply with the standard.

The Agency estimated the costs for the addition of a change room and segregated lockers based on the costs for acquisition of portable structures. The change room is presumed to be used in providing a transition zone from general working areas into beryllium-using regulated areas. OSHA estimated that portable building, adequate for 10 workers per establishment can be rented annually for \$3,251, and that lockers could be procured for a capital cost of \$407—or \$48 annualized—per establishment. This results in an annualized cost of \$3,299 per facility to rent a portable change room with lockers. OSHA estimates that the 10 percent of affected establishments unable to meet the proposed TWA PEL would require change rooms. The Agency estimated that a worker using a change room would need 2 minutes per day to change clothes. Assuming 250 days per year, this annual time cost for changing clothes is \$185 per employee.

The Agency estimates the total annualized cost of the provision on hygiene areas and practices to be \$389,241 for all affected establishments. The breakdown of these costs by application group and NAICS code can be seen in Table IX–6.

#### f. Housekeeping

The proposed rule specifies requirements for cleaning and disposing of beryllium-contaminated wastes. The employer shall maintain all surfaces in beryllium work areas as free as practicable of accumulations of beryllium and shall ensure that all spills and emergency releases of beryllium are cleaned up promptly, in accordance with the employer's written exposure control plan and using a HEPA-filtered vacuum or other methods that minimize the likelihood and level of exposure. The employer shall not allow dry sweeping or brushing for cleaning surfaces in beryllium work areas unless HEPA-filtered vacuuming or other methods that minimize the likelihood and level of exposure have been tried and were not effective.

ERG's experts estimated that each facility would need to purchase a single vacuum at a cost of \$2,900 for every five affected employees in order to successfully integrate housekeeping into their daily routine. The per-employee cost would be \$580, resulting in an annualized cost of \$68 per worker. ERG's experts also estimated that all affected workers would require an additional five minutes per work day (.083 hours) to complete vacuuming tasks and to label and dispose of beryllium-contaminated waste. While this allotment is modest, OSHA judged that the steady application of this incremental additional cleaning, when combined with currently conducted cleaning, would be sufficient in average establishments to address dust or surface contamination hazards. Assuming that these affected workers would be working 250 days per year, OSHA estimates that the annual labor cost per employee for additional time spent cleaning in order to comply with this provision is \$462.

The proposed standard requires each disposal bag with contaminated materials to be properly labeled. ERG estimated a cost of 10 cents per label with one label needed per day for every five workers. With the disposal of one labeled bag each day and 250 working days, the per-employee annual cost would be \$5. The annualized cost of a HEPA-filtered vacuum, combined with the additional time needed to perform housekeeping and the labeling of disposal bags, results in a total annualized cost of \$535 per employee.

The Agency estimates the total annualized cost of this provision to be \$12,574,921 for all affected establishments. The breakdown of these costs by application group and NAICS code is shown in Table IX–6.

#### g. Medical Surveillance

The proposed standard requires the employer to make medical surveillance available at no cost to the employee, and at a reasonable time and place, for the following employees:

1. Employees who have worked in a regulated area for more than 30 days in the last 12 months
2. Employees showing signs or symptoms of chronic beryllium disease (CBD)
3. Employees exposed to beryllium during an emergency; and
4. Employees exposed to airborne beryllium above  $0.2 \mu\text{g}/\text{m}^3$  for more than 30 days in a 12-month period for 5 years or more.

As discussed in the regulated areas section of this analysis of program costs, the Agency estimates that approximately 10 percent of affected employees would have exposure in excess of the PEL after the standard goes into effect and would therefore be placed in regulated areas. The Agency further estimates that a very small number of employees will be affected by emergencies in a given year, likely less than 0.1 percent of the affected population, representing a small additional cost. The number of workers who would suffer signs and symptoms of CBD after the rule takes effect is difficult to estimate, but would likely substantially exceed those with actual cases of CBD.

While the symptoms of CBD vary greatly, the first to appear are usually chronic dry cough (generally defined as a nonproductive cough, without phlegm or sputum, lasting two months or more) and shortness of breath during exertion. Ideally, in developing these costs estimates, OSHA would first estimate the percent of affected workers who might be presenting with a chronic cough and/or experiencing shortness of breath.

Studies have found the prevalence of a chronic cough ranging from 10 to 38 percent across various community populations, with smoking accounting for up to 18 percent of cough prevalence (Irwin, 1990; Barbee, 1991). However, these studies are over 20 years old, and the number of smokers has decreased substantially since then. It's also not clear whether the various segments of the U.S. population studied are similar enough to the population of workers exposed to beryllium such that results of these studies could be generalized to the affected worker population.

A more recent study from a plant in Cullman, Alabama that works with beryllium alloy found that about five percent of employees said they were

current smokers, with roughly 52 percent saying they were previous smokers and approximately 43 percent stating they had never smoked (Newman et al., 2001). This study does not, however, report on the prevalence of chronic cough in this workplace.

OSHA was unable to identify any studies on the general prevalence of the other common early symptom of CBD, shortness of breath. Lacking any better data to base an estimate on, the Agency used the studies cited above (Irwin, 1990; Barbee, 1991) showing the prevalence of chronic cough in the general population, adjusted to account for the long term decrease in smoking prevalence (and hence, the amount of overall cases of chronic cough), and estimated that 15 percent of the worker population with beryllium exposure would exhibit a chronic cough or other sign or symptom of CBD that would trigger medical surveillance. The Agency welcomes comment and further data on this question.

According to the proposed rule, the initial (baseline) medical examination would consist of the following:

1. A medical and work history, with emphasis on past and present exposure, smoking history and any history of respiratory system dysfunction;
2. A physical examination with emphasis on the respiratory tract;
3. A physical examination for skin breaks and wounds;
4. A pulmonary function test;
5. A standardized beryllium lymphocyte proliferation test (BeLPT) upon the first examination and within every two years from the date of the first examination until the employee is confirmed positive for beryllium sensitization;
6. A CT scan, offered every two years for the duration of the employee's employment, if the employee was exposed to airborne beryllium at levels above  $0.2 \mu\text{g}/\text{m}^3$  for more than 30 days in a 12-month period for at least 5 years. This obligation begins on the start-up date of this standard, or on the 15th year after the employee's first exposure above for more than 30 days in a 12-month period, whichever is later; and
7. Any other test deemed appropriate by the Physician or other Licensed Health Care Professional (PLHCP).

Table V-17 in Chapter V of the PEA lists the direct unit costs for initial medical surveillance activities including: Work and medical history, physical examination, pulmonary function test, BeLPT, CT scan, and costs of additional tests. In OSHA's cost model, all of the activities will take place during an employee's initial visit and on an annual basis thereafter and

involve a single set of travel costs, except that: (1) The BeLPT tests will only be performed at two-year intervals after the initial test, but will be conducted in conjunction with the annual general examination (no additional travel costs); and (2) the CT scans will typically involve different specialists and are therefore treated as separate visits not encompassed by the general exams (therefore requiring separate travel costs). Not all employees would require CT scans, and employers would only be required to offer them every other year.

In addition to the fees for the annual medical exam, employers may also incur costs for lost work time when their employees are unavailable to perform their jobs. This includes time for traveling, a health history review, the physical exam, and the pulmonary function test. Each examination would require 15 minutes (or 0.25 hours) of a human resource manager's time for recording the results of the exam and tests and the PLHCP's written opinion for each employee and any necessary post-exam consultation with the employee. There is also a cost of 15 minutes of supervisor time to provide information to the physician, five minutes of supervisor time to process a licensed physician's written medical opinion, and five minutes for an employee to receive a licensed physician's written medical opinion. The total unit annual cost for the medical examinations and tests, excluding the BeLPT test, and the time required for both the employee and the supervisor is \$297.

The estimated fee for the BeLPT is \$259. With the addition of the time incurred by the worker to undergo the test, the total cost for a BeLPT is \$261. The standard requires a biennial BeLPT for each employee covered by the medical surveillance provision, so most workers would receive between two and five BeLPT tests over a ten year period (including the BeLPT performed during the initial examination), depending on whether the results of these tests were positive. OSHA therefore estimates a net present value (NPV) of \$1,417 for all five tests. This NPV annualized over a ten year period is \$166.

Together, the annualized net present value of the BeLPT and the annualized cost of the remaining medical surveillance produce an annual cost of \$436 per employee.

The proposed standard requires that a helical tomography (CT scan) be offered to employees exposed to airborne beryllium above  $0.2 \mu\text{g}/\text{m}^3$  for more than 30 days in a 12-month period, for a period of 5 years or more. The five years

do not need to be consecutive, and the exposure does not need to occur after the effective date of the standard. The CT scan shall be offered every 2 years starting on the 15th year after the first year the employee was exposed above  $0.2 \mu\text{g}/\text{m}^3$  for more than 30 days in a 12-month period, for the duration of their employment. The total yearly cost for biennial CT scans consists of medical costs totaling \$1,020, comprised of a \$770 fee for the scan and the cost of a specialist to review the results, which OSHA estimates would cost \$250. The Agency estimates an additional cost of \$110 for lost work time, for a total of \$1,131. The annualized yearly cost for biennial CT scans is \$574.

Based on OSHA's estimates explained earlier in this section, all workers in regulated areas, workers exposed in emergencies, and an estimated 15 percent of workers not in regulated areas who exhibit signs and symptoms of CBD will be eligible for medical surveillance other than CT scans. The estimate for the number of workers eligible to receive CT scans is 25 percent of workers who are exposed above 0.2 in the exposure profile. The estimate of 25 percent is based on the facts that roughly this percentage of workers have 15-plus years of job tenure in the durable manufacturing sector and the estimate that all those with 15-plus years of job tenure and current exposure over 0.2 would have had at least 5 years of such exposure in the past.

The costs estimated for this provision are likely to be significantly overestimated, since not all affected employees offered medical surveillance would necessarily accept the offer. At Department of Energy facilities, only about 50 percent of eligible employees participate in the voluntary medical surveillance tests, and a report on an initial medical surveillance program at four aluminum manufacture facilities found participation rates to be around 57 percent (Taiwo et al., 2008). Where employers already offer equivalent health surveillance screening, no new costs are attributable to the proposed standard.

Within 30 days after an employer learns that an employee has been confirmed positive for beryllium sensitization, the employer's designated licensed physician shall consult with the employee to discuss referral to a CBD diagnostic center that is mutually agreed upon by the employer and the employee. If, after this consultation, the employee wishes to obtain a clinical evaluation at a CBD diagnostic center, the employer must provide the evaluation at no cost to the employee. OSHA estimates this consultation will

take 15 minutes, with an estimated total cost of \$33.

Table V-18 in Chapter V of the PEA lists the direct unit costs for a clinical evaluation with a specialist at a CBD diagnostic center. To estimate these costs, ERG contacted a healthcare provider who commonly treats patients with beryllium-related disease, and asked them to provide both the typical tests given and associated costs of an initial examination for a patient with a positive BeLPT test, presented in Table V-18 in Chapter V of the PEA. Their typical evaluation includes bronchoscopy with lung biopsy, a pulmonary stress test, and a chest CAT scan. The total cost for the entire suite of tests is \$6,305.

In addition, there are costs for lost productivity and travel. The Agency has estimated the clinical evaluation would take three days of paid time for the worker to travel to and from one of two locations: Penn Lung Center at the Cleveland Clinic Foundation in Cleveland, Ohio or National Jewish Medical Center in Denver, Colorado. OSHA estimates lost work time is 24 hours, yielding total cost for the 3 days of \$532.

OSHA estimates that roundtrip airfare would be available for most facilities at \$400, and the cost of a hotel room would be approximately \$100 per night, for a total cost of \$200 for the hotel room. OSHA estimates a per diem cost of \$50 for three days, for a total of \$150. The total cost per trip for traveling expenses is therefore \$750.

The total cost of a clinical evaluation with a specialist at a CBD diagnostic center is equal to the cost of the examination plus the cost of lost work-time and the cost for the employee to travel to the CBD diagnostic center, or \$7,620.

Based on the data from the exposure profile and the prevalence of beryllium sensitization observed at various levels of cumulative exposure,<sup>18</sup> OSHA estimated the number of workers eligible for BeLPT testing (4,181) and the percentage of workers who will be confirmed positive for sensitization (two positive BeLPT tests, as specified in the proposed standard) and referred to a CBD diagnostic center. During the first year that the medical surveillance provisions are in effect, OSHA estimates that 9.4 percent of the workers who are tested for beryllium sensitization will be identified as sensitized. This percentage is an average based on: (1) The number of employees in the baseline exposure profile that are in a given cumulative

exposure range; (2) the expected prevalence for a given cumulative exposure range (from Table VI-6 in Section VI of the preamble); and (3) an assumed even distribution of employees by cumulative years of exposure at a given level—20 percent having exposures at a given level for 5 years, 20 percent for 15 years, 20 percent for 25 years, 20 percent for 30 years, and 20 percent for 40 years.

OSHA did not assume that all workers with confirmed sensitization would choose to undergo evaluation at a CBD diagnostic center, which may involve invasive procedures and/or travel. For purposes of this cost analysis, OSHA estimates that approximately two-thirds of workers who are confirmed positive for beryllium sensitization will choose to undergo evaluation for CBD. OSHA requests comment on the CBD evaluation participation rate. OSHA estimates that about 264 of all non-dental lab workers will go to a diagnostic center for CBD evaluation in the first year.

The calculation method described above applies to all workers except dental technicians, who were analyzed with one modification. The rates for dental technicians are calculated differently due to the estimated 75 percent beryllium-substitution rate at dental labs, where the 75 percent of labs that eliminate all beryllium use are those at higher exposure levels. None of the remaining labs affected by this standard had exposures above  $0.1 \mu\text{g}/\text{m}^3$ . For the dental labs, the same calculation was done as presented in the previous paragraph, but only the remaining 25 percent of employees (2,314) who would still face beryllium exposures were included in the baseline cumulative exposure profile. With that one change, and all other elements of the calculation the same, OSHA estimates that 9 percent of dental lab workers tested for beryllium sensitization will be identified as sensitized. The predicted prevalence of sensitization among those dental lab workers tested in the first year after the standard takes effect is slightly lower than the predicted prevalence among all other tested workers combined. This slightly lower rate is not surprising because only dental lab workers with exposures below  $0.1 \mu\text{g}/\text{m}^3$  are included (after adjusting for substitution), and OSHA's exposure profile indicates that the vast majority of non-dental workers exposed to beryllium are also exposed at  $0.1 \mu\text{g}/\text{m}^3$  or lower. OSHA estimates that 20 dental lab workers (out of 347 tested for sensitization) would go to a diagnostic center for CBD evaluation in the first year.

<sup>18</sup> See Table VI-6 in Section VI of the preamble, Preliminary Risk Assessment.

In each year after the first year, OSHA relied on a 10 percent worker turnover rate in a steady state (as discussed in Chapter VII of the PEA) to estimate that the annual sensitization incidence rate is 10 percent of the first year's incidence rate. Based on that rate and the number of workers in the medical surveillance program, the CBD evaluation rate for workers other than those in dental labs would drop to 0.63 percent ( $.063 \times .10$ ). The evaluation rate for dental labs technicians is similarly estimated to drop to 0.58 percent ( $.058 \times .10$ ).

Based on these unit costs and the number of employees requiring medical surveillance estimated above, OSHA estimates that the medical surveillance and referral provisions would result in an annualized total cost of \$2,882,706. These costs are presented by application group and NAICS code in Table IX-7.

#### h. Medical Removal Provision

Once a licensed physician diagnoses an employee with CBD or the employee is confirmed positive for sensitization to beryllium, that employee is eligible for medical removal and has two choices:

- (a) Removal from current job, or
- (b) Remain in a job with exposure above the action level while wearing a respirator pursuant to 29 CFR 1910.134.

To be eligible for removal, the employee must accept comparable work if such is available, but if not available the employer would be required to place the employee on paid leave for six months or until such time as comparable work becomes available, whichever comes first. During that six-month period, whether the employee is re-assigned or placed on paid leave, the employer must continue to maintain the employee's base earnings, seniority and other rights, and benefits that existed at the time of the first test.

For purposes of this analysis, OSHA has conservatively estimated the costs as if all employees will choose removal, rather than remaining in the current job while wearing a respirator. In practice, many workers may prefer to continue working at their current job while wearing a respirator, and the employer would only incur the respirator costs identified earlier in this chapter. The removal costs are significantly higher over the same six-month period, so this analysis likely overestimates the total costs for this provision.

OSHA estimated that the majority of firms would be able to reassign the

worker to a job at least at the clerical level. The employer will often incur a cost for re-assigning the worker because this provision requires that, regardless of the comparable work the medically removed worker is performing, the employee must be paid the full base earnings for the previous position for six months. The cost per hour of reassigning a worker to a clerical job is based on the wage difference of a production worker of \$22.16 and a clerical worker of \$19.97, for a difference of \$2.19. Over the six-month period, the incremental cost of reassigning a worker to a clerical position would be \$2,190 per employee. This estimate is based on the employee remaining in a clerical position for the entire 6-month period, but the actual cost would be lower if there is turnover or if the employee is placed in any alternative position (for any part of the six-month period) that is compensated at a wage closer to the employee's previous wage.

Some firms may not have the ability to place the worker in an alternate job. If the employee chooses not to remain in the current position, the additional cost to the employer would be at most the cost of equipping that employee with a respirator, which would be required if the employee would continue to face exposures at or above the action level. Based on the earlier discussion of respirator costs, that option would be significantly cheaper than the alternative of providing the employee with six months of paid leave. Therefore, in order to estimate the maximum potential economic cost of the remaining alternatives, the Agency has conservatively estimated the cost per worker based on the cost of 6 months paid leave.

Using the wage rate of a production worker of \$22.16 for 6 months (or 8 hours a day for 125 days), the total per-worker cost for this provision when a firm cannot place a worker in an alternate job is \$22,161.

OSHA has estimated an average medical removal cost per worker assuming 75 percent of firms are able to find the employee an alternate job, and the remaining 25 percent of firms would not. The weighted average of these costs is \$7,183. Based on these unit costs, OSHA estimates that the medical removal provision would result in an annualized total cost of \$148,826. The

breakdown of these costs by application group and NAICS code is shown in Table IX-6.

#### i. Training

As specified in the proposed standard and existing OSHA standard 29 CFR 1910.1200 on hazard communication, training is required for all employees where there is potential exposure to beryllium. In addition, newly hired employees would require training before starting work.

OSHA anticipates that training in accordance with the requirements of the proposed rule, which includes hazard communication training, would be conducted by in-house safety or supervisory staff with the use of training modules or videos. ERG estimated that this training would last, on average, eight hours. (Note that this estimate does not include the time taken for hazard communication training that is already required by 29 CFR 1910.1200.) The Agency judged that establishments could purchase sufficient training materials at an average cost of \$2 per worker, encompassing the cost of handouts, video presentations, and training manuals and exercises. For initial and periodic training, ERG estimated an average class size of five workers with one instructor over an eight hour period. The per-worker cost of initial training totals to \$239.

Annual retraining of workers is also required by the standard. OSHA estimates the same unit costs as for initial training, so retraining would require the same per-worker cost of \$239.

Finally, to calculate training costs, the Agency needs the turnover rate of affected workers to know how many workers are receiving initial training versus retraining. Based on a 26.3 percent new hire rate in manufacturing, OSHA calculated a total net present value (NPV) of ten years of initial and annual retraining of \$2,101 per employee. Annualizing this NPV gives a total annual cost for training of \$246.

Based on these unit costs, OSHA estimates that the training requirements in the standard would result in an annualized total cost of \$5,797,535. The breakdown of these costs by application group and NAICS code is presented in Table IX-6.



Table IX-6

## Annualized Cost of Program Requirements for Industries Affected by the Proposed Beryllium Standard by Application Group and Six-Digit NAICS Industry (in 2010 dollars)

NAICS Code	Industry	Exposure Assessment	Regulated Areas and Beryllium Work Areas	Medical Surveillance	Medical Removal Provision	Written Exposure Control Plan	Protective Work Clothing & Equipment	Hygiene Areas and Practices	House-keeping	Training	Total Program Costs
Beryllium Production											
331419	Primary smelting and refining of nonferrous metals	\$0	\$1,683	\$11,121	\$6,359	\$0	\$17,801	\$8,112	\$0	\$0	\$45,075
Beryllium Oxide Ceramics and Composites											
327113a	Porcelain electrical supply manufacturing (primary)	\$6,959	\$4,162	\$9,205	\$1,912	\$2,645	\$2,761	\$2,432	\$22,189	\$10,230	\$62,495
327113b	Porcelain electrical supply manufacturing (secondary)	\$17,311	\$5,303	\$20,307	\$1,276	\$11,365	\$4,938	\$1,959	\$67,370	\$31,060	\$160,889
334220	Cellular telephones manufacturing	\$12,365	\$3,788	\$14,505	\$911	\$8,118	\$8,526	\$1,399	\$48,122	\$22,186	\$119,920
334310	Compact disc players manufacturing	\$6,183	\$1,894	\$7,252	\$456	\$4,059	\$864	\$830	\$24,061	\$11,093	\$56,692
334411	Electron tube manufacturing	\$25,967	\$7,955	\$30,460	\$1,914	\$17,048	\$11,252	\$2,938	\$101,055	\$46,590	\$245,179
334415	Electronic resistor manufacturing	\$14,838	\$4,545	\$17,406	\$1,094	\$9,742	\$6,346	\$1,679	\$57,746	\$26,623	\$140,019
334419	Other electronic component manufacturing	\$11,129	\$3,409	\$13,054	\$820	\$7,306	\$3,227	\$1,292	\$43,309	\$19,967	\$103,514
334510	Electromedical equipment manufacturing	\$11,129	\$3,409	\$13,054	\$820	\$7,306	\$8,193	\$1,292	\$43,309	\$19,967	\$108,480
336322b	Other motor vehicle electrical and electronic equipment manufacturing	\$12,365	\$3,788	\$14,505	\$911	\$8,118	\$5,243	\$1,399	\$48,122	\$22,186	\$116,637
Aluminum and Copper Foundries											
331521	Aluminum die-casting foundries	\$18,965	\$11,764	\$22,386	\$2,948	\$6,580	\$14,421	\$3,882	\$39,473	\$18,199	\$138,616
331522	Nonferrous (except aluminum) die-casting foundries	\$102,953	\$63,860	\$121,522	\$16,003	\$35,718	\$50,165	\$20,536	\$214,281	\$98,792	\$723,831
331524	Aluminum foundries (except die-casting)	\$18,965	\$11,764	\$22,386	\$2,948	\$6,580	\$7,835	\$3,882	\$39,473	\$18,199	\$132,030
331525a	Copper foundries (except die-casting) (non-sand casting foundries)	\$54,186	\$33,610	\$63,959	\$8,423	\$18,799	\$14,318	\$10,808	\$112,780	\$51,996	\$368,879
331525b	Copper foundries (except die-casting) (sand casting foundries)	\$75,706	\$48,627	\$91,350	\$11,940	\$26,047	\$31,197	\$15,520	\$157,416	\$72,575	\$530,377
Secondary Smelting, Refining, and Alloying											
331314	Secondary smelting & alloying of aluminum	\$1,687	\$984	\$1,926	\$251	\$625	\$284	\$294	\$3,609	\$1,664	\$11,325
331421b	Copper rolling, drawing, and extruding	\$1,687	\$984	\$1,926	\$251	\$625	\$733	\$294	\$3,609	\$1,664	\$11,774
331423	Secondary smelting, refining, & alloying of copper	\$5,062	\$2,953	\$5,779	\$752	\$1,876	\$706	\$882	\$10,827	\$4,992	\$33,829
331492	Secondary smelting, refining, & alloying of nonferrous metal (except copper & aluminum)	\$38,355	\$15,256	\$40,496	\$4,129	\$18,761	\$9,889	\$4,411	\$108,274	\$49,918	\$289,489
Precision Turned Products											
332721a	Precision turned product manufacturing (high beryllium content)	\$19,773	\$20,306	\$39,419	\$6,022	\$11,265	\$22,809	\$8,725	\$59,373	\$27,373	\$215,066
332721b	Precision turned product manufacturing (low beryllium content)	\$339,855	\$93,938	\$406,491	\$22,244	\$239,550	\$363,790	\$35,735	\$1,420,434	\$654,876	\$5,576,912
Copper Rolling, Drawing and Extruding											
331422	Copper wire (except mechanical) drawing	\$330,266	\$77,096	\$426,151	\$23,234	\$240,458	\$349,147	\$27,975	\$2,043,664	\$942,210	\$4,460,202
331421a	Copper rolling, drawing, and extruding	\$77,074	\$7,662	\$109,469	\$1,983	\$72,471	\$105,427	\$1,919	\$617,121	\$284,517	\$1,277,644

Table IX-6, continued

Annualized Cost of Program Requirements for Industries Affected by the Proposed Beryllium Standard by Application Group and Six-Digit NAICS Industry (in 2010 dollars)											
NAICS Code	Industry	Exposure Assessment	Regulated Areas and Beryllium Work Areas	Medical Surveillance	Medical Removal Provision	Written Exposure Control Plan	Protective Work Clothing & Equipment	Hygiene Areas and Practices	House-keeping	Training	Total Program Costs
Fabrication of Beryllium Alloy Products											
332612	Light gauge spring manufacturing	\$147,766	\$22,281	\$192,128	\$4,170	\$150,032	\$80,612	\$3,613	\$1,107,234	\$510,479	\$2,218,314
332116	Metal stamping	\$37,074	\$9,640	\$51,382	\$1,355	\$35,726	\$11,246	\$2,229	\$265,310	\$122,318	\$536,280
334417	Electronic connector manufacturing	\$23,146	\$6,018	\$32,079	\$846	\$22,304	\$18,014	\$1,392	\$165,639	\$76,366	\$345,805
336322a	Other motor vehicle electrical & electronic equipment	\$79,660	\$20,712	\$110,402	\$2,911	\$76,762	\$44,357	\$4,789	\$570,058	\$262,819	\$1,172,471
Arc and Gas Welding											
331111	Iron and steel mills	\$3,167	\$1,467	\$3,792	\$295	\$2,085	\$0	\$3,685	\$14,171	\$6,533	\$35,195
331221	Rolled steel shape manufacturing	\$658	\$305	\$788	\$61	\$433	\$0	\$3,379	\$2,945	\$1,338	\$9,926
331513	Steel foundries (except investment)	\$647	\$300	\$775	\$60	\$426	\$0	\$3,378	\$2,897	\$1,336	\$9,819
332117	Powder metallurgy part manufacturing	\$435	\$201	\$521	\$41	\$286	\$0	\$3,352	\$1,946	\$897	\$7,679
332212	Hand and edge tool manufacturing	\$1,394	\$646	\$1,669	\$130	\$918	\$0	\$3,469	\$6,239	\$2,876	\$17,341
332312	Fabricated structural metal manufacturing	\$26,737	\$12,383	\$32,010	\$2,493	\$17,601	\$0	\$21,713	\$119,636	\$55,157	\$287,730
332313	Plate work manufacturing	\$10,108	\$4,681	\$12,101	\$942	\$6,654	\$0	\$8,208	\$45,228	\$20,852	\$108,775
332322	Sheet metal work manufacturing	\$32,749	\$15,168	\$39,207	\$3,053	\$21,538	\$0	\$26,594	\$146,534	\$67,538	\$352,421
332323	Ornamental and architectural metal work manufacturing	\$18,474	\$8,556	\$22,117	\$1,722	\$12,161	\$0	\$15,002	\$82,660	\$38,110	\$198,802
332439	Other metal container manufacturing	\$3,206	\$1,485	\$3,838	\$299	\$2,111	\$0	\$3,690	\$14,346	\$6,614	\$35,589
332919	Other metal valve and pipe fitting manufacturing	\$1,300	\$602	\$1,556	\$121	\$856	\$0	\$3,457	\$5,816	\$2,681	\$16,389
332999	All other miscellaneous fabricated metal product manufacturing	\$16,000	\$7,410	\$19,155	\$1,492	\$10,532	\$0	\$12,993	\$71,590	\$33,006	\$172,178
333111	Farm machinery and equipment manufacturing	\$9,531	\$4,414	\$11,411	\$889	\$6,274	\$0	\$7,740	\$42,647	\$19,662	\$102,568
333414a	Heating equipment (except warm air furnaces) manufacturing	\$2,858	\$1,324	\$3,421	\$266	\$1,881	\$0	\$3,647	\$12,788	\$5,836	\$32,081
333911	Pump and pumping equipment manufacturing	\$3,174	\$1,470	\$3,800	\$296	\$2,089	\$0	\$3,686	\$14,202	\$6,548	\$35,266
333922	Conveyor and conveying equipment manufacturing	\$4,314	\$1,978	\$5,164	\$402	\$2,840	\$0	\$3,825	\$19,301	\$8,809	\$46,743
333924	Industrial truck, tractor, trailer, and stacker machinery manufacturing	\$2,079	\$963	\$2,489	\$194	\$1,369	\$0	\$3,552	\$9,303	\$4,289	\$24,237
333999	All other miscellaneous general purpose machinery manufacturing	\$8,472	\$3,924	\$10,142	\$790	\$5,577	\$0	\$6,880	\$37,906	\$17,476	\$91,167
336211	Motor vehicle body manufacturing	\$7,157	\$3,315	\$8,569	\$667	\$4,712	\$0	\$5,812	\$32,026	\$14,765	\$77,024
336214	Travel trailer and camper manufacturing	\$6,588	\$3,051	\$7,888	\$614	\$4,337	\$0	\$5,350	\$29,480	\$13,591	\$70,900
336399a	All other motor vehicle parts manufacturing	\$3,531	\$1,636	\$4,228	\$329	\$2,325	\$0	\$3,729	\$15,802	\$7,285	\$38,865
336510	Railroad rolling stock	\$1,293	\$599	\$1,548	\$121	\$851	\$0	\$3,456	\$5,787	\$2,668	\$16,323
336999	All other transportation equipment manufacturing	\$1,712	\$793	\$2,050	\$160	\$1,127	\$0	\$3,508	\$7,661	\$3,532	\$20,542
337215	Showcase, partition, shelving, and locker manufacturing	\$1,562	\$723	\$1,870	\$146	\$1,028	\$0	\$3,489	\$6,988	\$3,222	\$19,027
811310	Commercial and industrial machinery and equipment repair	\$68,217	\$31,594	\$81,669	\$6,360	\$44,906	\$0	\$55,397	\$305,236	\$140,726	\$734,105

Table IX-6, continued

Annualized Cost of Program Requirements for Industries Affected by the Proposed Beryllium Standard by Application Group and Six-Digit NAICS Industry (in 2010 dollars)											
NAICS Code	Industry	Exposure Assessment	Regulated Areas and Beryllium Work Areas	Medical Surveillance	Medical Removal Provision	Written Exposure Control Plan	Protective Work Clothing & Equipment	Hygiene Areas and Practices	House-keeping	Training	Total Program Costs
Resistance Welding											
333411	Air purification equipment manufacturing	\$22,068	\$1,036	\$32,575	\$0	\$25,212	\$0	\$0	\$202,669	\$93,438	\$376,997
333412	Industrial and commercial fan and blower manufacturing	\$9,308	\$437	\$13,740	\$0	\$10,634	\$0	\$0	\$85,483	\$39,411	\$159,013
333414b	Heating equipment (except warm air furnaces) manufacturing	\$28,356	\$1,331	\$41,856	\$0	\$32,395	\$0	\$0	\$260,413	\$120,061	\$484,410
333415	Air-conditioning, warm air heating, and industrial refrigeration equipment manufacturing	\$51,965	\$2,439	\$76,705	\$0	\$59,367	\$0	\$0	\$477,235	\$220,024	\$887,734
335211	Electric housewares and household fan manufacturing	\$4,667	\$219	\$6,889	\$0	\$5,332	\$0	\$0	\$42,863	\$19,762	\$79,732
335212	Household vacuum cleaner manufacturing	\$1,497	\$70	\$2,210	\$0	\$1,710	\$0	\$0	\$13,748	\$6,339	\$25,574
335221	Household cooking appliance manufacturing	\$4,227	\$198	\$6,239	\$0	\$4,829	\$0	\$0	\$38,819	\$17,897	\$72,210
335222	Household refrigerator and home freezer manufacturing	\$969	\$45	\$1,430	\$0	\$1,107	\$0	\$0	\$8,896	\$4,101	\$16,548
335224	Household laundry equipment manufacturing	\$484	\$23	\$715	\$0	\$553	\$0	\$0	\$4,448	\$2,051	\$8,274
335228	Other major household appliance manufacturing	\$1,673	\$79	\$2,470	\$0	\$1,912	\$0	\$0	\$15,366	\$7,084	\$28,583
336311	Carburetor, piston, piston ring, and valve manufacturing	\$4,799	\$225	\$7,084	\$0	\$5,483	\$0	\$0	\$44,076	\$20,321	\$81,989
336312	Gasoline engine and engine parts manufacturing	\$32,671	\$1,533	\$48,225	\$0	\$37,325	\$0	\$0	\$300,041	\$138,331	\$558,125
336321	Vehicular lighting equipment manufacturing	\$4,095	\$192	\$6,044	\$0	\$4,678	\$0	\$0	\$37,606	\$17,338	\$69,954
336322c	Other motor vehicle electrical and electronic equipment manufacturing	\$28,004	\$1,314	\$41,336	\$0	\$31,993	\$0	\$0	\$257,178	\$118,569	\$478,393
336330	Motor vehicle steering and suspension components (except spring) manufacturing	\$10,832	\$508	\$15,988	\$0	\$12,374	\$0	\$0	\$99,474	\$45,862	\$185,039
336340	Motor vehicle brake system manufacturing	\$8,762	\$411	\$12,934	\$0	\$10,010	\$0	\$0	\$80,469	\$37,099	\$149,686
336350	Motor vehicle transmission and power train parts manufacturing	\$20,959	\$984	\$30,937	\$0	\$23,944	\$0	\$0	\$192,479	\$88,740	\$358,042
336360	Motor vehicle seating and interior trim manufacturing	\$17,744	\$833	\$26,192	\$0	\$20,272	\$0	\$0	\$162,960	\$75,131	\$303,132
336370	Motor vehicle metal stamping	\$32,407	\$1,521	\$47,835	\$0	\$37,023	\$0	\$0	\$297,614	\$137,212	\$553,612
336391	Motor vehicle air-conditioning manufacturing	\$3,522	\$165	\$5,199	\$0	\$4,024	\$0	\$0	\$32,349	\$14,914	\$60,175
336399b	All other motor vehicle parts manufacturing	\$59,441	\$2,789	\$87,741	\$0	\$67,909	\$0	\$0	\$545,896	\$251,680	\$1,015,456
Dental Laboratories											
339116	Dental laboratories	\$118,601	\$14,334	\$172,420	\$0	\$155,480	\$187,007	\$0	\$816,900	\$376,623	\$1,841,363
621210	Offices of dentists	\$16,107	\$1,947	\$23,417	\$0	\$21,116	\$26,293	\$0	\$110,944	\$51,150	\$250,973
<b>Total</b>		<b>\$2,208,950</b>	<b>\$629,031</b>	<b>\$2,882,076</b>	<b>\$148,826</b>	<b>\$1,769,506</b>	<b>\$1,407,365</b>	<b>\$389,241</b>	<b>\$12,574,921</b>	<b>\$5,797,535</b>	<b>\$27,807,451</b>

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.

## Total Annualized Cost

As shown in Table IX-7, the total annualized cost of the proposed rule is estimated to be about \$37.6 million. As shown, at \$27.8 million, the program

costs represent about 74 percent of the total annualized costs of the proposed rule. The annualized cost of complying with the PEL accounts for the remaining 26 percent, almost all of which is for engineering controls and work practices.

Respiratory protection, at about \$237,600, represents only 3 percent of the annualized cost of complying with the PEL and less than 1 percent of the annualized cost of the proposed rule.

**Table IX-7**  
**Annualized Costs to Industries Affected by the Proposed Beryllium Standard, by Application Group and Six-Digit NAICS**

NAICS code	Industry	Engineering Controls and Work Practices	Respirator Costs	Program Costs	Total Costs
Beryllium Production					
331419	Primary smelting and refining of nonferrous metals	\$1,188,758	\$23,381	\$45,075	\$1,257,214
Beryllium Oxide Ceramics and Composites					
327113a	Porcelain electrical supply manufacturing (primary)	\$175,546	\$2,702	\$62,495	\$240,744
327113b	Porcelain electrical supply manufacturing (secondary)	\$72,102	\$1,744	\$160,889	\$234,736
334220	Cellular telephones manufacturing	\$51,502	\$1,246	\$119,920	\$172,668
334310	Compact disc players manufacturing	\$25,751	\$675	\$56,692	\$83,118
334411	Electron tube manufacturing	\$108,154	\$2,617	\$245,179	\$355,950
334415	Electronic resistor manufacturing	\$61,802	\$1,495	\$140,019	\$203,316
334419	Other electronic component manufacturing	\$46,352	\$1,132	\$103,514	\$150,998
334510	Electromedical equipment manufacturing	\$46,352	\$1,132	\$108,480	\$155,964
336322b	Other motor vehicle electrical and electronic equipment manufacturing	\$51,502	\$1,246	\$116,637	\$169,385
Nonferrous Foundries					
331521	Aluminum die-casting foundries	\$182,887	\$3,899	\$138,616	\$325,402
331522	Nonferrous (except aluminum) die-casting foundries	\$992,813	\$20,999	\$723,831	\$1,737,643
331524	Aluminum foundries (except die-casting)	\$182,887	\$3,899	\$132,030	\$318,816
331525a	Copper foundries (except die-casting) (non-sand casting foundries)	\$522,533	\$11,052	\$368,879	\$902,464
331525b	Copper foundries (except die-casting) (sand casting foundries)	\$682,229	\$15,962	\$530,377	\$1,228,568
Secondary Smelting, Refining, and Alloying					
331314	Secondary smelting & alloying of aluminum	\$19,186	\$3,246	\$11,325	\$33,757
331421b	Copper rolling, drawing, and extruding	\$19,186	\$3,246	\$11,775	\$34,207
331423	Secondary smelting, refining, & alloying of copper	\$57,558	\$9,820	\$33,831	\$101,209
331492	Secondary smelting, refining, & alloying of nonferrous metal (except copper & aluminum)	\$287,789	\$5,024	\$289,489	\$582,301
Precision Turned Products					
332721a	Precision turned product manufacturing (high beryllium content)	\$162,739	\$8,864	\$215,066	\$386,669
332721b	Precision turned product manufacturing (low beryllium content)	\$888,502	\$30,866	\$3,576,912	\$4,496,280
Copper Rolling, Drawing and Extruding					
331421a	Copper rolling, drawing, and extruding	\$23,656	\$1,677	\$1,277,644	\$1,302,977
331422	Copper wire (except mechanical) drawing	\$96,231	\$28,425	\$4,460,202	\$4,584,858
Fabrication of Beryllium Alloy Products					
332612	Light gauge spring manufacturing	\$588,200	\$8,874	\$2,218,314	\$2,815,387
332116	Metal stamping	\$134,748	\$3,531	\$536,280	\$674,558
334417	Electronic connector manufacturing	\$84,126	\$2,204	\$345,805	\$432,136
336322a	Other motor vehicle electrical & electronic equipment	\$289,526	\$7,586	\$1,172,471	\$1,469,583
Arc and Gas Welding					
331111	Iron and steel mills	\$18,123	\$679	\$35,195	\$53,997
331221	Rolled steel shape manufacturing	\$3,766	\$679	\$9,926	\$14,371
331513	Steel foundries (except investment)	\$3,705	\$679	\$9,819	\$14,203
332117	Powder metallurgy part manufacturing	\$2,489	\$679	\$7,679	\$10,846
332212	Hand and edge tool manufacturing	\$7,979	\$679	\$17,341	\$25,998
332312	Fabricated structural metal manufacturing	\$153,001	\$4,352	\$287,730	\$445,083
332313	Plate work manufacturing	\$57,841	\$1,645	\$108,775	\$168,261
332322	Sheet metal work manufacturing	\$187,400	\$5,330	\$352,421	\$545,151
332323	Ornamental and architectural metal work manufacturing	\$105,713	\$3,007	\$198,802	\$307,521
332439	Other metal container manufacturing	\$18,347	\$679	\$35,589	\$54,614
332919	Other metal valve and pipe fitting manufacturing	\$7,438	\$679	\$16,389	\$24,506
332999	All other miscellaneous fabricated metal product manufacturing	\$91,556	\$2,604	\$172,178	\$266,338
333111	Farm machinery and equipment manufacturing	\$54,540	\$1,551	\$102,568	\$158,660

IX-7, continued					
Annualized Costs to Industries Affected by the Proposed Beryllium Standard, by Application Group and Six-Digit NAICS					
NAICS code	Industry	Engineering Controls and Work Practices	Respirator Costs	Program Costs	Total Costs
Arc and Gas Welding					
333414a	Heating equipment (except warm air furnaces) manufacturing	\$16,354	\$679	\$32,081	\$49,114
333911	Pump and pumping equipment manufacturing	\$18,163	\$679	\$35,266	\$54,108
333922	Conveyor and conveying equipment manufacturing	\$24,684	\$717	\$47,006	\$72,407
333924	Industrial truck, tractor, trailer, and stacker machinery	\$11,897	\$679	\$24,237	\$36,813
333999	All other miscellaneous general purpose machinery manufacturing	\$48,478	\$1,379	\$91,167	\$141,023
336211	Motor vehicle body manufacturing	\$40,958	\$1,165	\$77,024	\$119,147
336214	Travel trailer and camper manufacturing	\$37,701	\$1,072	\$70,900	\$109,673
336399a	All other motor vehicle parts manufacturing	\$20,208	\$679	\$38,865	\$59,753
336510	Railroad rolling stock	\$7,400	\$679	\$16,323	\$24,403
336999	All other transportation equipment manufacturing	\$9,797	\$679	\$20,542	\$31,018
337215	Showcase, partition, shelving, and locker manufacturing	\$8,937	\$679	\$19,027	\$28,643
811310	Commercial and industrial machinery and equipment repair	\$390,361	\$11,103	\$734,105	\$1,135,568
Resistance Welding					
333411	Air purification equipment manufacturing	\$0	\$0	\$376,997	\$376,997
333412	Industrial and commercial fan and blower manufacturing	\$0	\$0	\$159,013	\$159,013
333414b	Heating equipment (except warm air furnaces) manufacturing	\$0	\$0	\$484,410	\$484,410
333415	Air-conditioning, warm air heating, and industrial refrigeration equipment manufacturing	\$0	\$0	\$887,734	\$887,734
335211	Electric housewares and household fan manufacturing	\$0	\$0	\$79,732	\$79,732
335212	Household vacuum cleaner manufacturing	\$0	\$0	\$25,574	\$25,574
335221	Household cooking appliance manufacturing	\$0	\$0	\$72,210	\$72,210
335222	Household refrigerator and home freezer manufacturing	\$0	\$0	\$16,548	\$16,548
335224	Household laundry equipment manufacturing	\$0	\$0	\$8,274	\$8,274
335228	Other major household appliance manufacturing	\$0	\$0	\$28,583	\$28,583
336311	Carburetor, piston, piston ring, and valve manufacturing	\$0	\$0	\$81,989	\$81,989
336312	Gasoline engine and engine parts manufacturing	\$0	\$0	\$558,125	\$558,125
336321	Vehicular lighting equipment manufacturing	\$0	\$0	\$69,954	\$69,954
336322c	Other motor vehicle electrical and electronic equipment	\$0	\$0	\$478,393	\$478,393
336330	Motor vehicle steering and suspension components (except spring) manufacturing	\$0	\$0	\$185,039	\$185,039
336340	Motor vehicle brake system manufacturing	\$0	\$0	\$149,686	\$149,686
336350	Motor vehicle transmission and power train parts manufacturing	\$0	\$0	\$358,042	\$358,042
336360	Motor vehicle seating and interior trim manufacturing	\$0	\$0	\$303,132	\$303,132
336370	Motor vehicle metal stamping	\$0	\$0	\$553,612	\$553,612
336391	Motor vehicle air-conditioning manufacturing	\$0	\$0	\$60,175	\$60,175
336399b	All other motor vehicle parts manufacturing	\$0	\$0	\$1,015,456	\$1,015,456
Dental Laboratories					
339116	Dental laboratories	\$1,013,143	\$0	\$1,841,363	\$2,854,507
621210	Offices of dentists	\$137,596	\$0	\$250,973	\$388,569
<b>Total</b>		<b>\$9,487,239</b>	<b>\$237,571</b>	<b>\$27,807,451</b>	<b>\$37,597,325</b>

Note-For Dental Laboratories, "Engineering Controls and Work Practices" represents the substitution costs of switching to non-Beryllium alloys.  
Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.

**F. Economic Feasibility Analysis and Regulatory Flexibility Determination**

Chapter VI of the PEA, summarized here, investigates the economic impacts of the proposed beryllium rule on affected employers. This impact investigation has two overriding objectives: (1) To establish whether the proposed rule is economically feasible for all affected application groups/industries, and (2) to determine if the Agency can certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

In the discussion below, OSHA first presents its approach for achieving these objectives and next applies this approach to industries with affected employers. The Agency invites

comment on any aspect of the methods, data, or preliminary findings presented here or in Chapter VI of the PEA.

- 1. Analytic Approach
  - a. Economic Feasibility

Section 6(b)(5) of the OSH Act directs the Secretary of Labor to set standards based on the available evidence where no employee, over his/her working life time, will suffer from material impairment of health or functional capacity, even if such employee has regular exposure to the hazard, "to the extent feasible" (29 U.S.C. 655(b)(5)). OSHA interpreted the phrase "to the extent feasible" to encompass economic feasibility and was supported in this view by the U.S. Court of Appeals for the D.C. Circuit, which has long held

that OSHA standards would satisfy the economic feasibility criterion even if they imposed significant costs on regulated industries and forced some marginal firms out of business, so long as they did not cause massive economic dislocations within a particular industry or imperil the existence of that industry. *Am. Iron and Steel Inst. v. OSHA*, 939 F.2d 975, 980 (D.C. Cir. 1991); *United Steelworkers of Am., AFL-CIO-CLC v. Marshall*, 647 F.2d 1189, 1265 (D.C. Cir. 1980); *Indus. Union Dep't v. Hodgson*, 499 F.2d 467 (D.C. Cir. 1974).

- b. The Price Elasticity of Demand and Its Relationship to Economic Feasibility

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 the establishment has to absorb compliance costs in the form of reduced profits. When demand is inelastic, establishments can recover most of the costs of compliance by raising the prices they charge; under this scenario, 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. 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 *Am. Dental Ass'n v. Sec'y 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. Over time, because of rising real incomes and productivity increases, firms in most industries are able to ensure an adequate profit. 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, or a combination of the two, 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 one percent of revenues for each firm in the industry would be a one percent increase in the price of the product, with no decline in quantity demanded. Such a situation 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.

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 proposed standard) if the industry attempted to maintain production at the same level as previously. 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 in the industry with hope of an adequate return on investment, then some or all of the firms in the industry would close. This scenario is highly unlikely to occur, however, because it can only arise when there are other products—unaffected by the proposed rule—that are, in the eyes of their customers, perfect substitutes for the products the affected establishments make.

A commonly-discussed intermediate case would be a price elasticity of demand of one (in absolute terms). In this situation, if the costs of compliance amount to one percent of revenues, then production would decline by one percent and prices would rise by one percent. As a result, industry revenues would remain the same, with somewhat lower production, but with similar profit rates per unit of output (in most situations where the marginal costs of production net of regulatory costs would fall as well). 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*, is the more typical case.

### c. Variable Costs Versus Fixed Costs

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 expanding industry, new entry may be delayed until demand equals supply. In some situations, there could be a combination of these three effects. Which possibility is most likely depends on the form that the costs of the regulation take. 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 overall output will be the result of reductions in output at each affected facility, with few, if any, plant closures. If, on the other hand, 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), then reductions in overall output are more likely to 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 PEA, are variable costs in the sense that they will tend to vary by production levels and/or employment levels. 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. Finally, the costs of operating and maintaining engineering controls tend to vary by usage—which typically closely tracks 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 and certain initial costs. The capital costs of engineering controls due to the standard—many of which are scaled to production and/or employment levels—constitute a relatively small share of the total costs, representing 10 percent of total annualized costs (or approximately \$870 per year per affected establishment).

Some ancillary provisions require initial costs that are fixed in the sense that they do not vary by production activity or the number of employees. Some examples are the costs to develop a training plan for general training not currently required and to develop a written exposure control plan.

As a result of these considerations, OSHA expects it to be quite likely that any reductions in total industry output would be due to reductions in output at each affected facility rather than as a result of plant closures. However, closures of some marginal plants or poorly performing facilities are always possible.

#### d. Economic Feasibility Screening Analysis

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,<sup>19</sup> particularly since most industries have at least some ability to raise prices to reflect increased costs, and normal price variations for products typically exceed three percent a year.

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. OSHA also considered whether this threshold would be adequate to assure that upfront costs would not create major

credit problems for affected employers. To do this, OSHA examined a worst case scenario in which annualized costs were ten percent of profits and all of the annualized costs were the result of upfront costs. In this scenario, assuming a three percent discount rate and a ten year life of equipment, total costs would be 85 percent of profits<sup>20</sup> in the year in which these upfront costs were incurred. Because upfront costs would be less than one year's profits in the year they were incurred, this means that an employer could pay for all of these costs from that year's profits and would not necessarily have to incur any new borrowing. As a result, it is unlikely that these costs would create a credit crunch or other major credit problems. It would be true, however, that paying regulatory costs from profits might reduce investment from profits in that year. 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—assuming a three percent discount rate and a ten-year time period—would be no more than 85 percent of first-year profits and thus would be affordable from profits without 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 markets and otherwise being threatened with short-term insolvency.

In general, because it is usually the case that firms would be able to pass on to their customers some or all of the costs of the proposed rule in the form of higher prices, OSHA 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 proposed 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, 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 proposed 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 annualized costs of an OSHA standard were equal to 10 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 might reasonably be concluded that the competitive structure of the industry had been altered. For this reason, OSHA also calculates compliance costs by size of firm and conducts its economic feasibility screening analysis for small and very small entities.

#### e. 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 proposed rulemaking will have on small entities. The RFA states that whenever a Federal agency is required to publish general notice of proposed rulemaking for any proposed rule, the agency must prepare and make available for public comment an initial regulatory flexibility analysis (IRFA). 5 U.S.C. 603(a). Pursuant to section 605(b), in lieu of an IRFA, the head of an agency may certify that the proposed 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 proposed rulemaking or at the time of publication of the final rule. 5 U.S.C. 605(b).

To determine if the Assistant Secretary of Labor for OSHA can certify that the proposed beryllium rule 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 proposed rule on

<sup>19</sup> See OSHA's Web page, <http://www.osha.gov/daa/lookback.html#Completed>, for a link to all completed OSHA lookback reviews.

<sup>20</sup> At a discount rate of 3 percent over a life of investment of 10 years, the present value of that stream of annualized costs would be 8.53 times a single year's annualized costs. Hence, if yearly annualized costs are 10 percent of profits, upfront costs would be 85 percent of the profits in that first year. As a simple example, assume annualized costs are \$1 for each of the 10 years. If annualized costs are 10 percent of profits, this translates to a yearly profit of \$10. The present value of that stream of \$1 for each year is \$8.53. (The formula for this calculation is  $(\$1 * (1.03 \wedge 10) - 1) / ((.03) * (1.03) \wedge 10)$ .)

small entities. These screening tests do not constitute hard and fast rules and are similar in concept to those OSHA developed above to identify minimum threshold effects for purposes of demonstrating economic feasibility.

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 SBA) and also to very small entities (as defined by OSHA as 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. 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 IRFA will not be prepared, only if OSHA can be highly confident that a proposed rule will not have a significant economic impact on a substantial number of small entities or very small entities in any affected industry.

Furthermore, certification will not be made, and an IRFA will be prepared, if OSHA believes the proposed rule might otherwise have a significant economic impact on a substantial number of small entities, even if the minimum threshold levels are not exceeded for revenues or profitability for small entities or very small entities in all affected industries.

## 2. Impacts on Affected Industries

In this section, OSHA applies its screening criteria and other analytic methods, as needed, to determine (1) whether the proposed rule is economically feasible for all affected industries within the scope of this proposed rule, and (2) whether the Agency can certify that the proposed rule will not have a significant economic impact on a substantial number of small entities.

### a. Economic Feasibility Screening Analysis: All Establishments

To determine whether the proposed 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 are presented in

Table IX–8. Shown in the table for each affected industry are the total number of establishments, 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 3 percent discount rate. The annualized cost of the proposed rule for the average affected establishment is estimated at \$9,197 in 2010 dollars. It is clear from Table IX–8 that the estimates of the annualized costs per affected establishment vary widely from industry to industry. These estimates range from \$1,257,214 for NAICS 331419 (Beryllium Production) and \$120,372 for NAICS 327113a (Porcelain Electrical Supply Manufacturing (primary)) to \$1,636 for NAICS 621210 (Offices of Dentists) and \$1,632 for NAICS 339116 (Dental Laboratories).



Table IX-8  
 Screening Analysis for Establishments Affected by the Proposed Beryllium Standard  
 With Costs Calculated Using a Three Percent Discount Rate

NAICS Code	Industry	Total		Revenues		Profit		Compliance Costs		
		Establishments	Total Affected Establishments	Total (\$1,000)	Per Establishment (\$)	Rate	Per Establishment (\$)	Per Establishment (\$)	As a Percent of Revenues	As a Percent of Profits
Beryllium Production										
331419	Primary smelting and refining of nonferrous metals	161	1	\$8,524,863	--	--	--	\$1,257,214	--	--
Beryllium Oxide Ceramics and Composites										
327113a	Porcelain electrical supply manufacturing (primary)	106	2	\$789,731	--	--	--	\$120,372	--	--
327113b	Porcelain electrical supply manufacturing (secondary)	106	14	\$789,731	7,450,295	5.01%	373,542	\$16,767	0.23%	4.49%
334220	Cellular telephones manufacturing	810	10	\$35,475,343	43,796,720	6.08%	2,663,922	\$17,267	0.04%	0.65%
334310	Compact disc players manufacturing	464	5	\$3,975,351	8,567,567	4.39%	376,456	\$16,624	0.19%	4.42%
334411	Electron tube manufacturing	79	21	\$1,220,476	15,449,068	7.85%	1,212,421	\$16,950	0.11%	1.40%
334415	Electronic resistor manufacturing	61	12	\$560,967	9,196,181	7.85%	721,703	\$16,943	0.18%	2.35%
334419	Other electronic component manufacturing	1,133	9	\$10,013,730	8,838,244	7.85%	693,613	\$16,778	0.19%	2.42%
334510	Electromedical equipment manufacturing	629	9	\$27,480,966	43,689,930	6.75%	2,947,904	\$17,329	0.04%	0.59%
336322b	Other motor vehicle electrical and electronic equipment manufacturing	636	10	\$12,152,053	19,107,002	1.83%	348,832	\$16,939	0.09%	4.86%
Nonferrous Foundries										
331521	Aluminum die-casting foundries	254	7	\$4,310,021	16,968,585	5.22%	885,603	\$46,486	0.27%	5.25%
331522	Nonferrous (except aluminum) die-casting foundries	140	38	\$1,510,799	10,791,418	5.22%	563,212	\$45,727	0.42%	8.12%
331524	Aluminum foundries (except die-casting)	394	7	\$2,518,097	6,391,108	5.22%	333,557	\$45,545	0.71%	13.65%
331525a	Copper foundries (except die-casting) (non-sand casting foundries)	208	20	\$1,205,574	5,796,031	5.22%	302,499	\$45,123	0.78%	14.92%
331525b	Copper foundries (except die-casting) (sand casting foundries)	208	25	\$1,205,574	5,796,031	5.22%	302,499	\$49,143	0.85%	16.25%
Secondary Smelting, Refining, and Alloying										
331314	Secondary smelting & alloying of aluminum	122	1	\$4,837,129	39,648,599	4.54%	1,802,008	\$33,757	0.09%	1.87%
331421b	Copper rolling, drawing, and extruding	96	1	\$12,513,425	130,348,178	4.79%	6,248,900	\$34,206	0.03%	0.55%
331423	Secondary smelting, refining, & alloying of copper	24	3	\$723,759	30,156,619	4.79%	1,445,710	\$33,639	0.11%	2.33%
331492	Secondary smelting, refining, & alloying of nonferrous metal (except copper & aluminum)	248	30	\$8,195,807	33,047,610	4.79%	1,584,305	\$19,410	0.06%	1.23%
Precision Turned Products										
332721a	Precision turned product manufacturing (high beryllium content)	3,124	18	\$13,262,706	4,245,425	5.82%	247,032	\$20,979	0.49%	8.49%
332721b	Precision turned product manufacturing (low beryllium content)	3,124	294	\$13,262,706	4,245,425	5.82%	247,032	\$15,295	0.36%	6.19%
Copper Rolling, Drawing and Extruding										
331421a	Copper rolling, drawing, and extruding	96	15	\$12,513,425	130,348,178	4.79%	6,248,900	\$86,865	0.07%	1.39%
331422	Copper wire (except mechanical) drawing	114	59	\$6,471,491	56,767,462	4.79%	2,721,436	\$77,709	0.14%	2.86%
Fabrication of Beryllium Alloy Products										
332612	Light gauge spring manufacturing	323	323	\$2,167,977	6,712,003	5.61%	376,763	\$8,716	0.13%	2.31%
332116	Metal stamping	1,484	74	\$9,749,800	6,569,946	5.12%	336,300	\$9,116	0.14%	2.71%
334417	Electronic connector manufacturing	231	46	\$5,029,508	21,772,761	7.85%	1,708,696	\$9,354	0.04%	0.55%
336322a	Other motor vehicle electrical & electronic equipment	636	159	\$12,152,053	19,107,002	1.83%	348,832	\$9,243	0.05%	2.65%
Arc and Gas Welding										
331111	Iron and steel mills	587	7	\$92,726,004	157,965,934	5.41%	8,542,604	\$8,149	0.01%	0.10%
331221	Rolled steel shape manufacturing	161	1	\$8,376,271	52,026,531	5.41%	2,813,531	\$10,438	0.02%	0.37%
331513	Steel foundries (except investment)	220	1	\$4,251,852	19,326,599	5.22%	1,008,670	\$10,486	0.05%	1.04%
332117	Powder metallurgy part manufacturing	133	1	\$1,414,108	10,632,394	5.12%	544,246	\$11,921	0.11%	2.19%
332212	Hand and edge tool manufacturing	1,066	3	\$5,077,868	4,763,479	5.61%	267,387	\$8,913	0.19%	3.33%
332312	Fabricated structural metal manufacturing	3,407	56	\$26,119,614	7,666,455	4.74%	363,273	\$7,957	0.10%	2.19%
332313	Plate work manufacturing	1,288	21	\$6,023,356	4,676,519	4.74%	221,596	\$7,957	0.17%	3.59%
332322	Sheet metal work manufacturing	4,173	69	\$17,988,908	4,310,786	4.74%	204,266	\$7,957	0.18%	3.90%
332323	Ornamental and architectural metal work manufacturing	2,354	39	\$5,708,707	2,425,109	4.74%	114,913	\$7,957	0.33%	6.92%
332439	Other metal container manufacturing	370	7	\$3,565,875	9,637,500	4.30%	414,839	\$8,142	0.08%	1.96%
332919	Other metal valve and pipe fitting manufacturing	265	3	\$4,584,082	17,298,424	7.00%	1,211,086	\$9,012	0.05%	0.74%
332999	All other miscellaneous fabricated metal product manufacturing	3,262	33	\$13,963,184	4,280,559	7.00%	299,688	\$7,957	0.19%	2.66%
333111	Farm machinery and equipment manufacturing	1,041	20	\$24,067,145	23,119,255	6.36%	1,471,196	\$7,957	0.03%	0.54%

**Table IX-8, continued**  
**Screening Analysis for Establishments Affected by the Proposed Beryllium Standard**  
**With Costs Calculated Using a Three Percent Discount Rate**

NAICS Code	Industry	Total Establishments	Total Affected Establishments	Revenues		Profit		Compliance Costs		
				Total (\$1,000)	Per Establishment (\$)	Rate	Per Establishment (\$)	Per Establishment (\$)	As a Percent of Revenues	As a Percent of Profits
333414a	Heating equipment (except warm air furnaces) manufacturing	460	6	\$4,781,561	10,394,697	4.68%	486,402	\$8,214	0.08%	1.69%
333911	Pump and pumping equipment manufacturing	571	7	\$12,395,387	21,708,209	5.36%	1,163,538	\$8,148	0.04%	0.70%
333922	Conveyor and conveying equipment manufacturing	776	9	\$6,569,120	8,465,361	5.36%	453,735	\$7,994	0.09%	1.76%
333924	Industrial truck, tractor, trailer, and stacker machinery manufacturing	374	4	\$7,444,451	19,904,948	5.36%	1,066,885	\$8,464	0.04%	0.79%
333999	All other miscellaneous general purpose machinery manufacturing	1,524	18	\$10,972,258	7,199,644	5.36%	385,894	\$7,957	0.11%	2.06%
336211	Motor vehicle body manufacturing	742	15	\$9,877,558	13,312,072	1.83%	243,036	\$7,957	0.06%	3.27%
336214	Travel trailer and camper manufacturing	683	14	\$7,465,024	10,929,757	1.83%	199,542	\$7,957	0.07%	3.99%
336399a	All other motor vehicle parts manufacturing	1,350	7	\$32,279,766	23,910,938	1.83%	436,537	\$8,087	0.03%	1.85%
336510	Railroad rolling stock	226	3	\$11,927,191	52,775,180	5.47%	2,887,552	\$9,019	0.02%	0.31%
336999	All other transportation equipment manufacturing	374	4	\$5,250,368	14,038,417	6.56%	921,324	\$8,660	0.06%	0.94%
337215	Showcase, partition, shelving, and locker manufacturing	1,194	3	\$5,815,404	4,870,523	4.26%	207,405	\$8,766	0.18%	4.23%
811310	Commercial and industrial machinery and equipment repair	21,960	143	\$31,650,469	1,441,278	5.42%	78,080	\$7,957	0.55%	10.19%
Resistance Welding										
333411	Air purification equipment manufacturing	358	25	\$3,060,744	8,549,565	4.68%	400,062	\$15,044	0.18%	3.76%
333412	Industrial and commercial fan and blower manufacturing	151	11	\$1,681,585	11,136,327	4.68%	521,106	\$15,044	0.14%	2.89%
333414b	Heating equipment (except warm air furnaces) manufacturing	460	32	\$4,781,561	10,394,697	4.68%	486,402	\$15,044	0.14%	3.09%
333415	Air-conditioning, warm air heating, and industrial refrigeration equipment manufacturing	843	59	\$25,454,383	30,194,998	4.68%	1,412,924	\$15,044	0.05%	1.06%
335211	Electric housewares and household fan manufacturing	106	5	\$2,209,657	20,845,825	4.03%	840,119	\$15,044	0.07%	1.79%
335212	Household vacuum cleaner manufacturing	34	2	\$891,600	26,223,543	4.03%	1,056,849	\$15,044	0.06%	1.42%
335221	Household cooking appliance manufacturing	96	5	\$3,757,849	39,144,257	4.03%	1,577,573	\$15,044	0.04%	0.95%
335222	Household refrigerator and home freezer manufacturing	22	1	\$4,489,845	204,083,854	4.03%	8,224,892	\$15,044	0.01%	0.18%
335224	Household laundry equipment manufacturing	11	1	\$3,720,514	338,228,505	4.03%	13,631,126	\$15,044	0.00%	0.11%
335228	Other major household appliance manufacturing	38	2	\$3,499,273	92,086,126	4.03%	3,711,212	\$15,044	0.02%	0.41%
336311	Carburetor, piston, piston ring, and valve manufacturing	109	5	\$1,715,429	15,737,881	1.83%	287,323	\$15,044	0.10%	5.24%
336312	Gasoline engine and engine parts manufacturing	742	37	\$20,000,705	26,955,128	1.83%	492,114	\$15,044	0.06%	3.06%
336321	Vehicular lighting equipment manufacturing	93	5	\$2,322,610	24,974,299	1.83%	455,950	\$15,044	0.06%	3.30%
336322c	Other motor vehicle electrical and electronic equipment manufacturing	636	32	\$12,152,053	19,107,002	1.83%	348,832	\$15,044	0.08%	4.31%
336330	Motor vehicle steering and suspension components (except spring) manufacturing	246	12	\$8,856,584	36,002,374	1.83%	657,287	\$15,044	0.04%	2.29%
336340	Motor vehicle brake system manufacturing	199	10	\$8,147,826	40,943,850	1.83%	747,503	\$15,044	0.04%	2.01%
336350	Motor vehicle transmission and power train manufacturing	476	24	\$21,862,014	45,928,600	1.83%	838,508	\$15,044	0.03%	1.79%
336360	Motor vehicle seating and interior trim manufacturing	403	20	\$15,168,862	37,639,856	1.83%	687,183	\$15,044	0.04%	2.19%
336370	Motor vehicle metal stamping	736	37	\$19,809,238	26,914,725	1.83%	491,376	\$15,044	0.06%	3.06%
336391	Motor vehicle air-conditioning manufacturing	80	4	\$3,798,464	47,480,804	1.83%	866,847	\$15,044	0.03%	1.74%
336399b	All other motor vehicle parts manufacturing	1,350	68	\$32,279,766	23,910,938	1.83%	436,537	\$15,044	0.06%	3.45%
Dental Laboratories										
339116	Dental laboratories	6,995	1,749	\$4,100,626	586,222	10.55%	61,873	\$1,632	0.28%	2.64%
621210	Offices of dentists	129,830	238	\$100,431,324	773,560	8.47%	65,557	\$1,636	0.21%	2.50%
Totals / Averages		207,586	4,088	\$877,101,106	8,145,219	7.42%	604,340	\$9,197	0.11%	1.52%

"-" indicates areas where data are not available. (While the average revenues and implied profits for the Beryllium Production (NAICS 331419) and Beryllium Oxide (NAICS 327113a) industries can be calculated, they would in no way reflect the actual revenues and profits of the affected facilities)

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.

As previously discussed, OSHA has established a minimum threshold level of annualized costs equal to one percent of annual revenues—and, secondarily, annualized costs equal to 10 percent of annual profits—below which the

Agency has concluded that costs are unlikely to threaten the economic viability of an affected industry. The results of OSHA's threshold tests for all affected establishments are displayed in Table IX-8. For all affected establishments, the estimated annualized cost of the proposed rule is, on average, equal to 0.11 percent of annual revenue and 1.52 percent of annual profit.

As Table IX-8 shows, there are no industries in which the annualized costs of the proposed rule exceed one percent of annual revenues. However there are three six-digit NAICS industries where annualized costs exceed ten percent of annual profits.

NAICS 331525 (Copper foundries except die-casting) has the highest cost impact as a percentage of profits. NAICS 331525 is made up of two types of copper foundries: sand casting foundries and non-sand casting foundries, incurring an annualized cost as a percent of profit of 16.25 percent and 14.92 percent, respectively. The other two six-digit NAICS industries where annualized costs exceed ten percent of annual profits are NAICS 331534: Aluminum foundries (except die-casting), 13.65 percent; and NAICS 811310: Commercial and industrial machinery and equipment repair, 10.19 percent.

OSHA believes that the beryllium-containing inputs used by these industries have a relatively inelastic demand for three reasons. First, beryllium has rare and unique characteristics, including low mass, high melting temperature, dimensional stability over a wide temperature range, strength, stiffness, light weight, and high elasticity ("springiness") that can significantly improve the performance of various alloys. These characteristics cannot easily be replicated by other materials. In economic terms, this means that the elasticity of substitution between beryllium and non-beryllium inputs will be low. Second, products which contain beryllium or beryllium-alloy components typically have high-performance applications (whose performance depends on the use of higher-cost beryllium). The lack of available competing products with these performance characteristics suggests that the price elasticity of demand for products containing beryllium or beryllium-alloy components will be low. Third, components made of beryllium or beryllium-containing alloys typically account for only a small portion of the overall cost of the finished goods that these parts are used to make. For example, the cost of brakes made of a beryllium-alloy used in the

production of a jet airplane represents a trivial percentage of the overall cost to produce that airplane. As economic theory indicates, the elasticity of derived demand for a factor of production (such as beryllium) varies directly with the elasticity of substitution between the input in question and other inputs; the price elasticity of demand for the final product that the input is used to produce; and, in general, the share of the cost of the final product that the input accounts for. Applying these three conditions to beryllium points to the relative inelastic derived demand for this factor of production and the likelihood that cost increases resulting from the proposed rule would be passed on to the consumer in the form of higher prices.

A secondary point is that the establishments in an industry that use beryllium may be more profitable than those that don't. This follows from the prior arguments about beryllium's rare and desirable characteristics and its valuable applications. For example, of the 208 establishments that make up NAICS 331525, OSHA estimated that 45 establishments (or 21 percent) work with beryllium. Of the 394 establishments that make up NAICS 331524, OSHA estimated that only 7 establishments (less than 2 percent) work with beryllium. Of the 21,960 establishments that make up NAICS 811310, OSHA estimated that 143 (0.7 percent) work with beryllium. However, when OSHA calculated the cost-to-profit ratio, it used the average profit per firm for the entire NAICs industry, not the average profit per firm for firms working with beryllium.

#### (1) 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 increase in industry revenues or prices of one percent or more are common. Examples of year-to-year changes in an industry that could cause such an increase in revenues or prices include increases in fuel, material, real estate, or other costs; tax increases; and shifts in demand.

To demonstrate the normal year-to-year variation in prices for all the manufacturers in general industry affected by the proposed rule, OSHA developed in the PEA year-to-year producer price indices and year-to-year percentage changes in producer prices, by industry, for the years 1999-2010. For all of the industries estimated to be affected by this proposed standard over the 12-year period, the average change in producer prices was 4.4 percent a

year—which is over 4 times as high as OSHA's 1 percent cost-to-revenue threshold. For the industries found to have the largest estimated potential annual cost impact as a percentage of revenue shown in Chapter VI of the PEA are—NAICS 331524: Aluminum Foundries (except Die-Casting), (0.71 percent); NAICS 331525(a and b): Copper Foundries (except Die-Casting) (average of 0.81 percent); NAICS 332721a: Precision Turned Product Manufacturing of high content beryllium (0.49 percent);<sup>21</sup> and NAICS 811310: Commercial and Industrial Machinery and Equipment (Except Automotive and Electronic) Repair and Maintenance (0.55 percent)—the average annual changes in producer prices in these industries over the 12-year period analyzed were 3.1 percent, 8.2 percent, 3.6 percent and 2.3 percent, respectively.

Based on these data, it is clear that the potential price impacts of the proposed rule in affected industries are all well within normal year-to-year variations in prices in those industries. The maximum cost impact of the proposed rule as a percentage of revenue in any affected industry is 0.84 percent, while, as just noted, the average annual change in producer prices for affected industries was 4.4 percent for the period 1999-2010. In fact, Chapter VI of the PEA shows two of the industries within the secondary smelting, refining, and alloying group, for example, the prices rose over 60 percent in one year without imperiling the existence of those industries. Thus, OSHA preliminarily concludes that the potential price impacts of the proposal would not threaten the economic viability of any industries affected by this proposed standard.

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 affected by the proposed rule, OSHA presented data in the PEA on year-to-year profit rates and year-to-year percentage changes in profit rates, by industry, for the years 2002-2009. For the industries that OSHA has estimated will be affected by this

<sup>21</sup> By contrast, NAICS 332721b: Precision Turned Product Manufacturing of low content beryllium alloys has a cost to revenue ratio below 0.4 percent.

proposed standard over the 8-year period, the average change in profit rates is calculated to be 39 percent per year. For the industries with the largest estimated potential annual cost impacts as a percentage of profit—NAICS 331524: Aluminum foundries (except die-casting), (14 percent); NAICS 331525(a and b): Copper foundries (except die-casting) (16 percent); NAICS 332721a: Precision Turned Product Manufacturing of high content beryllium (8 percent);<sup>22</sup> and NAICS 811310 Commercial and Industrial Machinery and Equipment (Except Automotive and Electronic) Repair and Maintenance (10 percent)—the average annual changes in profit rates in these industries over the eight-year period were 35 percent, 35 percent, 11 percent, and 5 percent, respectively.

A longer-term loss of profits in excess of 10 percent a year could be more problematic for some affected industries and might conceivably, under sufficiently adverse circumstances, threaten an industry's economic viability. However, as previously discussed, OSHA's analysis indicates that affected industries would generally *not* absorb the costs of the proposed rule in reduced profits but, instead, would be able to pass on most or all of those costs in the form of higher prices (due to the relative price inelasticity of demand for beryllium and beryllium-containing inputs). It is possible that such price increases 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. The only realistic circumstance where an entire industry would be significantly affected by small potential price increases would be where there is a very close or perfect substitute product available not subject to OSHA regulation. In most cases where beryllium is used, there is no substitute product that could be used in place of beryllium and achieve the same level of performance. The main potential concern would be substitution by foreign competition, but the following discussion reveals why such competition is not likely.

## (2) International Trade Effects

World production of beryllium is a thin market, with only a handful of countries known to process beryllium ores and concentrates into beryllium products, and characterized by a high degree of variation and uncertainty. The United States accounts for

approximately 65 percent of world beryllium deposits and 90 percent of world production, but there is also a significant stockpiling of beryllium materials in Kazakhstan, Russia, China, and possibly other countries (USGS, 2013a). For the individual years 2008–2012, the United States' net import reliance as a percentage of apparent consumption (that is, imports minus exports net of industry and government stock adjustments) ranged from 10 percent to 61 percent (USGS, 2013b). To assure an adequate stockpile of beryllium materials to support national defense interests, the U.S. Department of Defense, in 2005, under the Defense Production Act, Title III, invested in a public-private partnership with the leading U.S. beryllium producer to build a new \$90.4 million primary beryllium facility in Elmore, Ohio. Construction of that facility was completed in 2011 (USGS, 2013b).

One factor of importance to firms working with beryllium and beryllium alloys is to have a reliable supply of beryllium materials. U.S. manufacturers can have a relatively high confidence in the availability of beryllium materials relative to manufacturers in many foreign countries, particularly those that do not have economic or national security partnerships with the United States.

Firms using beryllium in production must consider not just the cost of the chemical itself but also the various regulatory costs associated with the use, transport, and disposal of the material. For example, for marine transport, metallic beryllium powder and beryllium compounds are classified by the International Maritime Organization (IMO) as poisonous substances, presenting medical danger. Beryllium is also classified as flammable. The United Nations classification of beryllium and beryllium compounds for the transport of dangerous goods is "poisonous substance" and, for packing, a "substance presenting medium danger" (WHO, 1990). Because of beryllium's toxicity, the material is subject to various workplace restrictions as well as international, national, and State requirements and guidelines regarding beryllium content in environmental media (USGS, 2013a).

As the previous discussion indicates, the production and use of beryllium and beryllium alloys in the United States and foreign markets appears to depend on the availability of production facilities; beryllium stockpiles; national defense and political considerations; regulations limiting the shipping of beryllium and beryllium products; international, national, and State

regulations and guidelines regarding beryllium content in environmental media; and, of course, the special performance properties of beryllium and beryllium alloys in various applications. Relatively small changes in the price of beryllium would seem to have a minor effect on the location of beryllium production and use. In particular, as a result of this proposed rule, OSHA would expect that, if all compliance costs were passed through in the form of higher prices, a price increase of 0.11 percent, on average, for firms manufacturing or using beryllium in the United States—and not exceeding 1 percent in any affected industry—would have a negligible effect on foreign competition and would therefore not threaten the economic viability of any affected domestic industries.

## (b) 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 proposed 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 such as by small entities exiting from the industry as a result of the proposed standard.

To address this possibility, OSHA examined the annualized costs of the proposed standard per affected small entity, and per affected very small entity, for each affected industry. Again, OSHA used a minimum threshold level of annualized compliance costs equal to one percent of annual revenues—and, secondarily, annualized compliance 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.

Based on the results presented in Table IX–9, the annualized cost of compliance with the proposed rule for the average affected small entity is estimated to be \$8,108 in 2010 dollars. Based on the results presented in Table IX–10, the annualized cost of compliance with the proposed rule for the average affected very small entity is estimated to be \$1,955 in 2010 dollars. These tables also show that there are no industries in which the annualized costs of the proposed rule for small entities or very small entities exceed one percent of annual revenues. NAICS 331525b: Sand Copper Foundries (except die-casting) has the highest estimated cost

<sup>22</sup> By contrast, NAICS 332721b: Precision Turned Product Manufacturing of low content beryllium alloys has a cost to profit ratio of 6 percent.

impact as a percentage of revenues for small entities, 0.95 percent, and NAICS 336322b: Other motor vehicle electrical and electronic equipment has the highest estimated cost impact as a percentage of revenues for very small entities, 0.70 percent.

Small entities in four industries—NAICS 331525: Sand and non-sand foundries (except die-casting); NAICS 331524(a and b): Aluminum foundries (except die-casting); NAICS 811310: Commercial and Industrial Machinery and Equipment; and NAICS 331522: Nonferrous (except aluminum) die-casting foundries—have annualized costs in excess of 10 percent of annual profits (17.45 percent, 16.12 percent, 11.68 percent, and 10.64 percent, respectively). Very small entities in 7 industries are estimated to have annualized costs in excess of 10 percent of annual profit; NAICS 336322b: Other motor vehicle electrical and electronic equipment (38.49 percent);<sup>23</sup> NAICS 336322a: Other motor vehicle electrical and electronic equipment, (18.18 percent); NAICS 327113: Porcelain electrical Supply Manufacturing (13.82 percent); NAICS 811310: Commercial and Industrial Machinery and Equipment (Except Automotive and Electronic) Repair and Maintenance (12.76 percent); NAICS 332721a: Precision turned product manufacturing

<sup>23</sup> NAICS 336322 contains entities that fall into three separate application groups. NAICS 336322b is in the Beryllium Oxide Ceramics and Composites application group. NAICS 336322a (which follows in the text) is in the Fabrication of Beryllium Alloy Products application group.

(10.50 percent); NAICS 336214: Travel trailer and camper manufacturing (10.75 percent); and NAICS 336399: All other motor vehicle parts manufacturing (10.38 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 less 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—other than very small entities in NAICS 336322b: Other motor vehicle electrical and electronic equipment—generally fall within the range observed in other OSHA regulations and, as verified by OSHA's lookback reviews, have not been of such a magnitude to lead to the economic failure of regulated small businesses.

The ratio of annualized costs to annual profit is a sizable 38.49 percent in NAICS 336322b: Other motor vehicle electrical and electronic equipment. However, OSHA believes that the actual ratio is significantly lower. There are 386 very small entities in NAICS 336322, of which only 6, or 1.5 percent, are affected entities using beryllium. When OSHA calculated the cost-to-

profit ratio, it used the average profit per firm for the entire NAICS industry, not the average profit rate for firms working with beryllium. The profit rate for all establishments in NAICS 336322b was estimated at 1.83 percent. If, for example, the average profit rate for a very small entity in NAICS 336322b were equal to 5.95 percent, the average profit rate for its application group, Beryllium Oxide Ceramics and Composites, then the ratio of the very small entity's annualized cost of the proposed rule to its annual profit would actually be 11.77 percent. OSHA tentatively concludes the 6 establishments in the NAICS specializing in beryllium production will have a higher than average profit rate and will be able to pass much of the cost onto the consumer for three main reasons: (1) The absence of substitutes containing the rare performance characteristics of beryllium; (2) the relative price insensitivity of (other) motor vehicles containing the special performance characteristics of beryllium and beryllium alloys; and (3) the fact that electrical and electronic components made of beryllium or beryllium-containing alloys typically account for only a small portion of the overall cost of the finished (other) motor vehicles. The annualized compliance cost to annual revenue ratio for NAICS 336322b is 0.70 percent, 0.30 percent below the 1 percent threshold. Based on OSHA's experience, price increases of this magnitude have not historically been associated with the economic failure of small businesses.

NAICS Code	Industry	Total Small Entities	Total Affected Small Entities	Revenues		Profit		Compliance Costs		
				Total for SBA Entities (\$1,000)	Per Entity (\$s)	Rate	Per Entity (\$s)	Per Entity (\$s)	As a Percent of Revenues	As a Percent of Profits
<b>Beryllium Production</b>										
331419	Primary smelting and refining of nonferrous metals	--	--	--	--	--	--	--	--	--
<b>Beryllium Oxide Ceramics and Composites</b>										
327113a	Porcelain electrical supply manufacturing (primary)	85	1	\$326,127	--	--	--	--	--	--
327113b	Porcelain electrical supply manufacturing (secondary)	85	11	\$326,127	\$3,836,783	5.01%	\$192,368	\$12,979	0.34%	6.75%
334220	Cellular telephones manufacturing	724	9	\$35,475,343	\$48,999,093	6.08%	\$2,980,355	\$19,318	0.04%	0.65%
334310	Compact disc players manufacturing	460	5	\$3,975,351	\$8,642,068	4.39%	\$379,730	\$16,768	0.19%	4.42%
334411	Electron tube manufacturing	62	16	\$1,220,476	19,685,102	7.85%	1,544,859	\$21,598	0.11%	1.40%
334415	Electronic resistor manufacturing	46	9	\$385,781	8,386,547	7.85%	658,164	\$15,052	0.18%	2.29%
334419	Other electronic component manufacturing	990	8	\$4,796,313	4,844,761	7.85%	380,210	\$12,982	0.27%	3.41%
334510	Electromedical equipment manufacturing	494	7	\$3,752,243	7,595,634	6.75%	512,503	\$8,812	0.12%	1.72%
336322b	Other motor vehicle electrical and electronic equipment	585	9	\$12,152,053	20,772,740	1.83%	379,243	\$18,415	0.09%	4.86%
<b>Nonferrous Foundries</b>										
331521	Aluminum die-casting foundries	209	6	\$2,070,759	9,907,938	5.22%	517,103	\$38,396	0.39%	7.43%
331522	Nonferrous (except aluminum) die-casting foundries	129	35	\$813,444	6,305,771	5.22%	329,103	\$35,014	0.56%	10.64%
331524	Aluminum foundries (except die-casting)	351	6	\$1,690,008	4,814,839	5.22%	251,290	\$40,517	0.84%	16.12%
331525a	Copper foundries (except die-casting) (non-sand casting)	195	19	\$925,667	4,747,008	5.22%	247,750	\$41,295	0.87%	16.67%
331525b	Copper foundries (except die-casting) (sand casting)	195	23	\$925,667	4,747,008	5.22%	247,750	\$45,131	0.95%	18.22%
<b>Secondary Smelting, Refining, and Alloying</b>										
331314	Secondary smelting & alloying of aluminum	98	1	\$4,837,129	49,358,460	4.54%	2,243,316	\$33,757	0.07%	1.50%
331421b	Copper rolling, drawing, and extruding	70	1	\$12,513,425	178,763,215	4.79%	8,569,920	\$34,206	0.02%	0.40%
331423	Secondary smelting, refining, & alloying of copper	23	3	\$723,759	31,467,777	4.79%	1,508,567	\$35,101	0.11%	2.33%
331492	Secondary smelting, refining, & alloying of nonferrous metals	217	26	\$8,195,807	37,768,697	4.79%	1,810,634	\$22,183	0.06%	1.23%
<b>Precision Turned Products</b>										
332721a	Precision turned product manufacturing (high speed)	3,006	18	\$11,393,081	3,790,113	5.82%	220,539	\$19,481	0.51%	8.83%
332721b	Precision turned product manufacturing (low speed)	3,006	283	\$11,393,081	3,790,113	5.82%	220,539	\$14,207	0.37%	6.44%
<b>Copper Rolling, Drawing and Extruding</b>										
331421a	Copper rolling, drawing, and extruding	70	11	\$12,513,425	178,763,215	4.79%	8,569,920	\$119,129	0.07%	1.39%
331422	Copper wire (except mechanical) drawing	84	43	\$6,471,491	77,041,555	4.79%	3,693,377	\$105,463	0.14%	2.86%
<b>Fabrication of Beryllium Alloy Products</b>										
332612	Light gauge spring manufacturing	262	262	\$1,030,905	3,934,752	5.61%	220,868	\$7,277	0.18%	3.29%
332116	Metal stamping	1,367	68	\$7,693,541	5,628,048	5.12%	288,086	\$8,395	0.15%	2.91%
334417	Electronic connector manufacturing	176	35	\$1,556,871	8,845,860	7.85%	694,211	\$5,765	0.07%	0.83%
336322a	Other motor vehicle electrical & electronic equipment	585	146	\$12,152,053	20,772,740	1.83%	379,243	\$10,048	0.05%	2.65%

**Table IX-9, continued**  
**Screening Analysis for SBA-Defined Small Entities Affected by the Proposed Beryllium Standard**  
**With Costs Calculated Using a Three Percent Discount Rate**

NAICS Code	Industry	Total		Revenues		Profit		Compliance Costs		
		Establishments	Affected Establishments	Total (\$1,000)	Per Establishment (\$)	Per Establishment Rate	Per Establishment (\$)	As a Percent of Revenues	As a Percent of Profits	
<b>Arc and Gas Welding</b>										
331111	Iron and steel mills	461	5	\$92,726,004	201,141,005	5.41%	10,877,459	\$10,377	0.01%	0.10%
331221	Rolled steel shape manufacturing	134	1	\$8,376,271	62,509,488	5.41%	3,380,437	\$12,541	0.02%	0.37%
331513	Steel foundries (except investment)	188	1	\$2,739,158	14,569,989	5.22%	760,419	\$8,657	0.06%	1.14%
332117	Powder metallurgy part manufacturing	106	1	\$841,084	7,934,752	5.12%	406,161	\$8,278	0.10%	2.04%
332212	Hand and edge tool manufacturing	975	3	\$3,072,300	3,151,077	5.61%	176,878	\$7,037	0.22%	3.98%
332312	Fabricated structural metal manufacturing	3,001	49	\$15,405,728	5,133,531	4.74%	243,251	\$6,076	0.12%	2.50%
332313	Plate work manufacturing	1,220	20	\$4,900,364	4,016,692	4.74%	190,330	\$7,379	0.18%	3.88%
332322	Sheet metal work manufacturing	3,835	63	\$12,607,305	3,287,433	4.74%	155,774	\$7,010	0.21%	4.50%
332323	Ornamental and architectural metal work manu	2,287	38	\$4,118,512	1,800,836	4.74%	85,332	\$6,548	0.36%	7.67%
332439	Other metal container manufacturing	302	5	\$1,698,117	5,622,904	4.30%	242,034	\$5,858	0.10%	2.42%
332919	Other metal valve and pipe fitting manufactur	207	2	\$2,028,451	9,799,278	7.00%	686,061	\$6,301	0.06%	0.92%
332999	All other miscellaneous fabricated metal produ	3,111	32	\$10,202,505	3,279,494	7.00%	229,602	\$6,782	0.21%	2.95%
333111	Farm machinery and equipment manufacturing	941	18	\$5,132,720	5,454,538	6.36%	347,100	\$3,899	0.07%	1.12%
333414a	Heating equipment (except warm air furnaces)	410	5	\$2,583,472	6,301,151	4.68%	294,852	\$5,769	0.09%	1.96%
333911	Pump and pumping equipment manufacturing	399	5	\$3,348,262	8,391,635	5.36%	449,783	\$4,457	0.05%	0.99%
333922	Conveyor and conveying equipment manufact	707	8	\$4,768,668	6,744,933	5.36%	361,522	\$6,809	0.10%	1.88%
333924	Industrial truck, tractor, trailer, and stacker mac	347	4	\$7,444,451	21,453,748	5.36%	1,149,899	\$9,122	0.04%	0.79%
333999	All other miscellaneous general purpose machi	1,385	16	\$5,601,674	4,044,530	5.36%	216,783	\$5,282	0.13%	2.44%
336211	Motor vehicle body manufacturing	652	13	\$9,877,558	15,149,628	1.83%	276,583	\$9,055	0.06%	3.27%
336214	Travel trailer and camper manufacturing	585	12	\$2,513,608	4,296,766	1.83%	78,445	\$4,404	0.10%	5.61%
336399a	All other motor vehicle parts manufacturing	1,156	6	\$32,279,766	27,923,673	1.83%	509,796	\$9,445	0.03%	1.85%
336510	Railroad rolling stock	157	2	\$11,927,191	75,969,367	5.47%	4,156,603	\$12,983	0.02%	0.31%
336999	All other transportation equipment manufactur	349	3	\$941,637	2,698,100	6.56%	177,073	\$4,339	0.16%	2.45%
337215	Showcase, partition, shelving, and locker manu	1,120	3	\$3,688,129	3,292,972	4.26%	140,227	\$6,966	0.21%	4.97%
811310	Commercial and industrial machinery and equip	19,857	129	\$17,088,964	860,601	5.42%	46,622	\$5,445	0.63%	11.68%
<b>Resistance Welding</b>										
333411	Air purification equipment manufacturing	283	20	\$1,327,014	4,689,095	4.68%	219,418	\$8,363	0.18%	3.81%
333412	Industrial and commercial fan and blower manu	118	8	\$1,001,835	8,490,124	4.68%	397,281	\$11,780	0.14%	2.97%
333414b	Heating equipment (except warm air furnaces)	410	29	\$2,583,472	6,301,151	4.68%	294,852	\$10,186	0.16%	3.45%
333415	Air-conditioning, warm air heating, and industr	695	49	\$25,454,383	36,625,012	4.68%	1,713,806	\$18,247	0.05%	1.06%
335211	Electric housewares and household fan manuf	101	5	\$2,209,657	21,877,797	4.03%	881,709	\$15,789	0.07%	1.79%
335212	Household vacuum cleaner manufacturing	29	1	\$891,600	30,744,844	4.03%	1,239,064	\$17,638	0.06%	1.42%
335221	Household cooking appliance manufacturing	91	5	\$3,757,849	41,295,040	4.03%	1,664,253	\$15,870	0.04%	0.95%
335222	Household refrigerator and home freezer manu	16	1	\$4,489,845	280,615,299	4.03%	11,309,226	\$16,548	0.01%	0.15%
335224	Household laundry equipment manufacturing	9	1	\$3,720,514	413,390,395	4.03%	16,660,266	\$8,274	0.00%	0.05%
335228	Other major household appliance manufacturin	24	1	\$185,373	7,723,871	4.03%	311,284	\$1,740	0.02%	0.56%

NAICS Code	Industry	Total Establishments	Total Affected Establishments	Revenues		Profit		Compliance Costs		
				Total (\$1,000)	Per Establishment (\$)	Rate	Per Establishment (\$)	Per Establishment (\$)	As a Percent of Revenues	As a Percent of Profits
<b>Resistance Welding</b>										
336311	Carburetor, piston, piston ring, and valve manuf	89	4	\$499,977	5,617,722	1.83%	102,562	\$5,227	0.09%	5.10%
336312	Gasoline engine and engine parts manufactur	697	35	\$20,000,705	28,695,417	1.83%	523,886	\$16,015	0.06%	3.06%
336321	Vehicular lighting equipment manufacturing	75	4	\$671,947	8,959,292	1.83%	163,568	\$6,084	0.07%	3.72%
336322c	Other motor vehicle electrical and electronic eq	585	29	\$12,152,053	20,772,740	1.83%	379,243	\$16,355	0.08%	4.31%
336330	Motor vehicle steering and suspension compo	209	10	\$8,856,584	42,376,000	1.83%	773,649	\$17,707	0.04%	2.29%
336340	Motor vehicle brake system manufacturing	159	8	\$8,147,826	51,244,189	1.83%	935,554	\$18,828	0.04%	2.01%
336350	Motor vehicle transmission and power train pa	397	20	\$21,862,014	55,068,044	1.83%	1,005,365	\$18,037	0.03%	1.79%
336360	Motor vehicle seating and interior trim manufa	273	14	\$3,482,677	12,757,060	1.83%	232,903	\$6,586	0.05%	2.83%
336370	Motor vehicle metal stamping	540	27	\$7,262,381	13,448,854	1.83%	245,533	\$8,894	0.07%	3.62%
336391	Motor vehicle air-conditioning manufacturing	72	4	\$3,798,464	52,756,449	1.83%	963,163	\$16,715	0.03%	1.74%
336399b	All other motor vehicle parts manufacturing	1,156	58	\$32,279,766	27,923,673	1.83%	509,796	\$17,568	0.06%	3.45%
<b>Dental Laboratories</b>										
339116	Dental laboratories	6,703	1,676	\$3,156,130	470,853	10.55%	49,696	\$1,394	0.30%	2.81%
621210	Offices of dentists	123,077	225	\$94,120,777	764,731	8.47%	64,809	\$1,630	0.21%	2.51%
<b>Total/Average</b>		<b>193,274</b>	<b>3,741</b>	<b>\$687,134,666</b>	<b>7,300,515</b>	<b>7.55%</b>	<b>550,848</b>	<b>\$8,108</b>	<b>0.11%</b>	<b>1.47%</b>
"--" indicates areas where data are not available. (While the average revenues and implied profits for the Beryllium Production (NAICS 331419) and Beryllium Oxide (NAICS 327113a) industries can be calculated, they would in no way reflect the actual revenues and profits of the affected facilities)										
Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.										



Table IX-10

Screening Analysis for Very Small Entities (with fewer than 20 employees) Affected by the Proposed Beryllium Standard With Costs Calculated Using a Three Percent Discount Rate											
		Revenues				Profit		Compliance Costs			
NAICS Code	Industry	Total Small Entities	Total Affected Small Entities	Total for Very Small Entities (\$1,000)	Per Entity (\$)	Rate	Per Entity (\$)	Per Entity (\$)	As a Percent of Revenues	As a Percent of Profits	
<b>Beryllium Production</b>											
331419	Primary smelting and refining of nonferrous metals	--	--	--	--	--	--	--	--	--	--
<b>Beryllium Oxide Ceramics and Composites</b>											
327113a	Porcelain electrical supply manufacturing (primary)	53	0	52,358	--	--	--	--	--	--	--
327113b	Porcelain electrical supply manufacturing (secondary)	53	7	52,358	\$987,892	5.01%	\$192,368	\$6,346	0.69%	13.82%	
334220	Cellular telephones manufacturing	445	4	576,956	\$1,296,530	6.08%	\$2,980,355	\$6,273	0.48%	7.95%	
334310	Compact disc players manufacturing	373	4	1,128,513	\$3,025,503	4.39%	\$379,730	\$8,383	0.28%	6.31%	
334411	Electron tube manufacturing	38	10	45,454	\$1,196,149	7.85%	\$1,544,859	\$6,430	0.54%	6.85%	
334415	Electronic resistor manufacturing	17	3	25,647	\$1,508,662	7.85%	\$658,164	\$6,848	0.45%	5.78%	
334419	Other electronic component manufacturing	624	5	639,599	\$1,024,999	7.85%	\$380,210	\$6,962	0.68%	8.65%	
334510	Electromedical equipment manufacturing	324	3	420,245	\$1,297,053	6.75%	\$512,503	\$6,271	0.48%	7.17%	
336322b	Other motor vehicle electrical and electronic equipment manufa	386	6	349,811	\$906,246	1.83%	\$379,243	\$6,368	0.70%	38.49%	
<b>Nonferrous Foundries</b>											
331521	Aluminum die-casting foundries	107	0	153,274	--	5.22%	\$517,103	--	--	--	
331522	Nonferrous (except aluminum) die-casting foundries	84	0	92,703	--	5.22%	\$329,103	--	--	--	
331524	Aluminum foundries (except die-casting)	217	0	204,397	--	5.22%	\$251,290	--	--	--	
331525a	Copper foundries (except die-casting) (non-sand casting found	131	0	139,372	--	5.22%	\$247,750	--	--	--	
331525b	Copper foundries (except die-casting) (sand casting foundries)	131	0	139,372	--	5.22%	\$247,750	--	--	--	
<b>Secondary Smelting, Refining, and Alloying</b>											
331314	Secondary smelting & alloying of aluminum	45	0	306,390	--	4.54%	\$2,243,316	--	--	--	
331421b	Copper rolling, drawing, and extruding	26	0	48,421	--	4.79%	\$8,569,920	--	--	--	
331423	Secondary smelting, refining, & alloying of copper	11	1	85,353	\$7,759,405	4.79%	\$1,508,567	\$21,589	0.28%	5.80%	
331492	Secondary smelting, refining, & alloying of nonferrous metal (e	121	15	388,603	\$3,211,598	4.79%	\$1,810,634	\$11,055	0.34%	7.18%	
<b>Precision Turned Products</b>											
332721a	Precision turned product manufacturing (high beryllium conten	1,970	12	2,219,340	\$1,126,568	5.82%	\$220,539	\$6,881	0.61%	10.50%	
332721b	Precision turned product manufacturing (low beryllium content	1,970	185	2,219,340	\$1,126,568	5.82%	\$220,539	\$5,045	0.45%	7.70%	
<b>Copper Rolling, Drawing and Extruding</b>											
331421a	Copper rolling, drawing, and extruding	26	4	48,421	\$1,862,347	4.79%	\$8,569,920	\$5,684	0.31%	6.37%	
331422	Copper wire (except mechanical) drawing	35	18	254,426	\$7,269,304	4.79%	\$3,693,377	\$7,682	0.11%	2.20%	
<b>Fabrication of Beryllium Alloy Products</b>											
332612	Light gauge spring manufacturing	164	164	156,603	\$954,897	5.61%	\$220,868	\$3,310	0.35%	6.18%	
332116	Metal stamping	807	40	1,033,657	\$1,280,864	5.12%	\$288,086	\$3,543	0.28%	5.40%	
334417	Electronic connector manufacturing	106	11	129,405	\$1,220,804	7.85%	\$694,211	\$3,014	0.25%	3.15%	
336322a	Other motor vehicle electrical & electronic equipment	386	60	349,811	\$906,246	1.83%	\$379,243	\$3,007	0.33%	18.18%	

Table IX-10, continued											
Screening Analysis for Very Small Entities (with fewer than 20 employees) Affected by the Proposed Beryllium Standard With Costs Calculated Using a Three Percent Discount Rate											
					Revenues		Profit		Compliance Costs		
NAICS Code	Industry	Total Small Entities	Total Affected Small Entities	Total for Very Small Entities (\$1,000)	Per Entity (\$)	Rate	Per Entity (\$)	Per Entity (\$)	As a Percent of Revenues	As a Percent of Profits	
<b>Arc and Gas Welding</b>											
331111	Iron and steel mills	268	0	1,018,914	--	5.41%	\$10,877,459	--	--	--	--
331221	Rolled steel shape manufacturing	50	0	208,799	--	5.41%	\$3,380,437	--	--	--	--
331513	Steel foundries (except investment)	94	0	\$112,227	--	5.22%	760,419	--	--	--	--
332117	Powder metallurgy part manufacturing	55	0	\$100,643	--	5.12%	406,161	--	--	--	--
332212	Hand and edge tool manufacturing	751	2	\$681,375	907,290	5.61%	176,878	\$3,171	0.35%	6.23%	
332312	Fabricated structural metal manufacturing	2,159	35	\$3,182,459	1,474,043	4.74%	243,251	\$2,299	0.16%	3.29%	
332313	Plate work manufacturing	845	14	\$1,007,308	1,192,080	4.74%	190,330	\$2,891	0.24%	5.12%	
332322	Sheet metal work manufacturing	2,778	46	\$2,631,155	947,140	4.74%	155,774	\$2,620	0.28%	5.84%	
332323	Ornamental and architectural metal work manufacturing	1,957	32	\$1,342,443	685,970	4.74%	85,332	\$3,153	0.46%	9.70%	
332439	Other metal container manufacturing	203	2	\$187,607	924,174	4.30%	242,034	\$2,471	0.27%	6.21%	
332919	Other metal valve and pipe fitting manufacturing	115	1	\$181,192	1,575,580	7.00%	686,061	\$4,302	0.27%	3.90%	
332999	All other miscellaneous fabricated metal product manufacturing	2,353	24	\$2,117,303	899,831	7.00%	229,602	\$2,560	0.28%	4.06%	
333111	Farm machinery and equipment manufacturing	673	7	\$785,460	1,167,103	6.36%	347,100	\$2,299	0.20%	3.10%	
333414a	Heating equipment (except warm air furnaces) manufacturing	283	2	\$365,551	1,291,699	4.68%	294,852	\$2,536	0.20%	4.20%	
333911	Pump and pumping equipment manufacturing	251	1	\$497,397	1,981,660	5.36%	449,783	\$2,477	0.12%	2.33%	
333922	Conveyor and conveying equipment manufacturing	407	4	\$541,532	1,330,547	5.36%	361,522	\$2,335	0.18%	3.27%	
333924	Industrial truck, tractor, trailer, and stacker machinery manufacturing	195	1	\$213,335	1,094,026	5.36%	1,149,899	\$2,761	0.25%	4.71%	
333999	All other miscellaneous general purpose machinery manufacturing	975	10	\$1,151,152	1,180,669	5.36%	216,783	\$2,298	0.19%	3.63%	
336211	Motor vehicle body manufacturing	400	4	\$535,923	1,339,807	1.83%	276,583	\$2,298	0.17%	9.39%	
336214	Travel trailer and camper manufacturing	410	5	\$480,503	1,171,958	1.83%	78,445	\$2,300	0.20%	10.75%	
336399a	All other motor vehicle parts manufacturing	653	1	\$835,261	1,279,114	1.83%	509,796	\$2,424	0.19%	10.38%	
336510	Railroad rolling stock	83	0	\$189,164	--	5.47%	4,156,603	--	--	--	--
336999	All other transportation equipment manufacturing	307	2	\$253,916	827,087	6.56%	177,073	\$2,938	0.36%	5.41%	
337215	Showcase, partition, shelving, and locker manufacturing	814	2	\$582,654	715,791	4.26%	140,227	\$3,035	0.42%	9.96%	
811310	Commercial and industrial machinery and equipment repair	18,714	122	\$10,692,921	571,386	5.42%	46,622	\$3,949	0.69%	12.76%	
<b>Resistance Welding</b>											
333411	Air purification equipment manufacturing	189	13	\$283,628	1,500,678	4.68%	219,418	\$2,506	0.17%	3.57%	
333412	Industrial and commercial fan and blower manufacturing	60	4	\$78,644	1,310,729	4.68%	397,281	\$2,401	0.18%	3.92%	
333414b	Heating equipment (except warm air furnaces) manufacturing	283	20	\$365,551	1,291,699	4.68%	294,852	\$2,321	0.18%	3.84%	
333415	Air-conditioning, warm air heating, and industrial refrigeration equipment manufacturing	395	28	\$806,994	2,043,023	4.68%	1,713,806	\$1,094	0.05%	1.14%	
335211	Electric housewares and household fan manufacturing	70	4	\$99,219	1,417,419	4.03%	881,709	\$1,151	0.08%	2.01%	
335212	Household vacuum cleaner manufacturing	18	0	\$21,745	--	4.03%	1,239,064	--	--	--	--
335221	Household cooking appliance manufacturing	57	2	\$66,863	1,173,037	4.03%	1,664,253	\$1,056	0.09%	2.23%	
335222	Household refrigerator and home freezer manufacturing	6	0	\$8,833	--	4.03%	11,309,226	--	--	--	--
335224	Household laundry equipment manufacturing	4	0	\$1,837	--	4.03%	16,660,266	--	--	--	--
335228	Other major household appliance manufacturing	15	0	\$24,856	--	4.03%	311,284	--	--	--	--

Table IX-10, continued

**Screening Analysis for Very Small Entities (with fewer than 20 employees) Affected by the Proposed Beryllium Standard  
With Costs Calculated Using a Three Percent Discount Rate**

NAICS Code	Industry	Total Small Entities	Total Affected Small Entities	Revenues		Profit		Compliance Costs		
				Total for Very Small Entities (\$1,000)	Per Entity (\$)	Rate	Per Entity (\$)	Per Entity (\$)	As a Percent of Revenues	As a Percent of Profits
<b>Resistance Welding</b>										
336311	Carburetor, piston, piston ring, and valve manufacturing	59	3	\$54,436	922,644	1.83%	102,562	\$1,395	0.15%	8.28%
336312	Gasoline engine and engine parts manufacturing	545	27	\$883,783	1,621,620	1.83%	523,886	\$1,331	0.08%	4.49%
336321	Vehicular lighting equipment manufacturing	45	2	\$59,894	1,330,971	1.83%	163,568	\$1,056	0.08%	4.35%
336322c	Other motor vehicle electrical and electronic equipment manufa	386	19	\$349,811	906,246	1.83%	379,243	\$1,452	0.16%	8.78%
336330	Motor vehicle steering and suspension components (except sp	116	5	\$998,968	8,611,797	1.83%	773,649	\$1,056	0.01%	0.67%
336340	Motor vehicle brake system manufacturing	82	3	\$96,867	1,181,305	1.83%	935,554	\$1,056	0.09%	4.90%
336350	Motor vehicle transmission and power train parts manufacturin	240	9	\$304,951	1,270,628	1.83%	1,005,365	\$1,056	0.08%	4.55%
336360	Motor vehicle seating and interior trim manufacturing	167	7	\$310,566	1,859,677	1.83%	232,903	\$1,056	0.06%	3.11%
336370	Motor vehicle metal stamping	225	11	\$478,984	2,128,816	1.83%	245,533	\$1,329	0.06%	3.42%
336391	Motor vehicle air-conditioning manufacturing	34	1	\$80,741	2,374,734	1.83%	963,163	\$1,056	0.04%	2.44%
336399b	All other motor vehicle parts manufacturing	653	33	\$835,261	1,279,114	1.83%	509,796	\$1,267	0.10%	5.43%
<b>Dental Laboratories</b>										
339116	Dental laboratories	6,379	1,595	1,807,075	\$283,285	10.55%	\$49,696	\$922	0.33%	3.09%
621210	Offices of dentists	119,544	219	81,995,117	\$685,899	8.47%	\$64,809	\$1,464	0.21%	2.52%
	<b>Total/Average</b>	<b>172,628</b>	<b>2,875</b>	<b>128,347,342</b>	<b>\$679,421</b>	<b>8.27%</b>	<b>\$56,189</b>	<b>\$1,955</b>	<b>0.29%</b>	<b>3.48%</b>
*--* indicates areas where data are not available. (While the average revenues and implied profits for the Beryllium Production (NAICS 331419) and Beryllium Oxide (NAICS 327113a) industries can be calculated, they would in no way reflect the actual revenues and profits of the affected facilities)										
Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.										

### (c) Regulatory Flexibility Screening Analysis

To determine if the Assistant Secretary of Labor for OSHA can certify that the proposed beryllium standard 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 proposed 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 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.

Tables IX–9 and Table IX–10, presented above, show that the annualized costs of the proposed standard do not exceed one percent of annual revenues for affected small entities or affected very small entities in any affected industry. These tables also show that the annualized costs of the proposed standard exceed five percent of annual profits for affected small entities in 12 industries and for affected very small entities in 30 industries. OSHA is therefore unable to certify that the proposed standard will not have a significant economic impact on a substantial number of small entities and must prepare an Initial Regulatory Flexibility Analysis (IRFA). The IRFA is presented in Chapter IX of the PEA and is reproduced in Section IX.I of this preamble.

#### G. Benefits and Net Benefits

In this section, OSHA presents a summary of the estimated benefits and net benefits of the proposed beryllium rule. This section proceeds in five steps. The first step estimates the numbers of diseases and deaths prevented by comparing the current (baseline) situation to a world in which the proposed PEL is adopted in a final standard to a world in which employees are exposed at the level of the proposed PEL throughout their working lives. The second step also assumes that the proposed PEL is adopted, but uses the results from the first step to estimate what would happen under a more realistic scenario in which employees have been exposed for varying periods of time to the baseline situation and will thereafter be exposed to the new PEL.

The third step covers the monetization of benefits. Then, in the

fourth step, OSHA estimates the net benefits and incremental benefits of the proposed rule by comparing the monetized benefits to the costs presented in Chapter V of the PEA. The models underlying each step inevitably need to make a variety of assumptions based on limited data. In the fifth step, OSHA provides a sensitivity analysis to explore the robustness of the estimates of net benefits with respect to many of the assumptions made in developing and applying the underlying models. A full explanation of the derivation of the estimates presented here is provided in Chapter VII of the PEA for the proposed rule. OSHA invites comments on any aspect of the data and methods used to estimate the benefits and net benefits of this proposed rule. Because dental labs constitute a significant source of both costs and benefits to the rule (over 40 percent), OSHA is particularly interested in comments regarding the appropriateness of the model, assumptions, and data to estimating the benefits to workers in that industry.

OSHA has added to the docket the spreadsheets used to calculate the estimates of benefits outlined below (OSHA, 2015a). Those interested in exploring the details and methodology of OSHA's benefits analysis, such as how the life table referred to below was developed and applied, should consult those spreadsheets.

#### Step 1—Estimation of the Steady-State Number of Beryllium-Related Diseases Avoided

##### Methods of Estimation

The first step in OSHA's development of the benefits analysis compares the situation in which employees continue to be at baseline exposure levels for their entire working lives to the situation in which all employees have been exposed at a given PEL for their entire working lives. This is a comparison of two steady-state situations. To do this, OSHA must estimate both the risk associated with the baseline exposure levels and the risk following the promulgation of a new beryllium standard. OSHA's approach assumes for inputs such as the turnover rate and the exposure response function that they are similar across all workers exposed to beryllium, regardless of industry.

An exposure-response model, discussed below, is used to estimate a worker's risk of beryllium-related disease based on the worker's cumulative beryllium exposure. The Agency used a lifetime risk model to estimate the baseline risk and the associated number of cases for the

various disease endpoints. A lifetime risk model explicitly follows a worker each year, from work commencement onwards, accumulating the worker's beryllium exposure in the workplace and estimating outcomes each year for the competing risks that can occur. To go from exposure to number of cases, the Agency needs to estimate an exposure-response relationship, and this is discussed below. The possible outcomes are no change, or the various health endpoints OSHA has considered (beryllium sensitization, CBD, lung cancer, and the mortality associated with these endpoints). As part of the estimation discussion, OSHA will mention specific parameters used in some of the estimation methods, but will further discuss how these parameters were derived later in this section.

The baseline lifetime risk model is the most complicated part of the analysis. The Agency only needs to make relatively simple adjustments to this model to reflect changes in activities and conditions due to the standard, which, working through the model, then lead to changes in relevant health outcomes. There are three channels by which the standard generates benefits. First are estimated benefits due to the lowering of the PEL. Second are estimated benefits with further exposure reductions from the substitution of non-beryllium for beryllium-containing materials, ending workers' beryllium exposures entirely. This potential source of benefits is particularly significant with respect to OSHA's assumptions for how dental labs are likely to reduce exposures (see below). Finally, the model estimates benefits due to the ancillary programs that are required by the proposed standard. The last channel affects CBD and sensitization, endpoints which may be mitigated or prevented with the help of ancillary provisions such as dermal protection and medical surveillance for early detection, and for which the Agency has some information on the effects on risk of ancillary provisions. The benefits of ancillary provisions are not estimated for lung cancer because the benefits from reducing lung cancer are considered to be the result of reducing airborne exposure only and thus the ancillary provisions will have no separable effect on airborne exposures. The discussion here will concentrate on CBD as being the most important and complex endpoint, and most illustrative of other endpoints: The structure for other endpoints is the same; only the exposure response functions are different. Here OSHA will

discuss first the exposure-response model, then the structure of the year-to-year changes for a worker, then the estimated exposure distribution in the affected population and the risk model with the lowering of the PEL, and, last, the other adjustments for the ancillary benefits and the substitution benefits.

The exposure response model is designed to translate beryllium exposure to risk of adverse health endpoints. In the case of beryllium sensitization and CBD, the Agency uses the cumulative exposure data from a beryllium manufacturing facility. Specifically, OSHA uses the quartile data from the Cullman plant that is presented in Table VI-7 of the Preliminary Risk Assessment in the preamble. The raw data from this study show cases of CBD with cumulative exposures that would represent an average exposure level of less than 0.1  $\mu\text{g}/\text{m}^3$  if exposed for 10 years; show cases of CBD with exposures lasting less than one year; and show cases of CBD with actual average exposure of less than 0.1  $\mu\text{g}/\text{m}^3$ .

Prevalence is defined as the percentage of persons with a condition in a population at a given point in time. The quartile data in Table VI-7 of the Preliminary Risk Assessment are prevalence percentages (the number of cases of illness documented over several years in the 319 person cohort from the Cullman plant) at different cumulative exposure levels. The Cullman data do not cover persons who left the work force or what happened to persons who remained in the workforce after the study was completed. For the lifetime risk model, the prevalence percentages will be translated into incidence percentages—the estimated number of new cases predicted to occur each year. For this purpose OSHA assumed that the incidence for any given cumulative exposure level is constant from year to year and continues after exposure ceases.

To calculate incidence from prevalence, OSHA assumed a steady state in which both the size of the beryllium-exposed affected population, exposure concentrations during employment and prevalence are constant over time. If these conditions are met, and turnover among workers with a condition is equal to turnover for workers without a condition, then the incidence rate will be equal to the turnover rate multiplied by the prevalence rate. If the turnover rate among persons with a condition is higher than the turnover rate for workers without the condition, then this assumption will underestimate incidence. This might happen if, in

addition to other reasons for leaving work, persons with a condition leave a place of employment more frequently because their disabilities cause them to have difficulty continuing to do the work. If the turnover rate among persons with a condition is lower than the turnover rate for workers without the condition, then this assumption will overestimate incidence. This could happen if an employer provides special benefits to workers with the condition, and the employer would cease to provide these benefits if the employee left work.

To illustrate, if 10 percent of the work force (including 10 percent of those with the condition) leave each year and if the overall prevalence is at 20 percent, then a 2 percent (10 percent times 20 percent) incidence rate will be needed in order to keep a steady 20 percent group prevalence rate each year. OSHA's model assumes a constant 10 percent turnover rate (see later in this section for the rationale for this particular turnover rate). While turnover rates are not available for the specific set of employees in question, for manufacturing as a whole, the turnover rates are greater than 20 percent, and greater than 30 percent for the economy as a whole (BLS, 2013). For this analysis, OSHA assumed an effective turnover rate of 10 percent. Different turnover rates will result in different incidence rates. The lower the turnover rate the lower the estimated incidence rate. This is a conservative assumption for the industries where turnover rates may be higher. However, some occupations/industries, such as dental lab technicians, may have lower turnover rates than manufacturing workers. Additionally, the typical dental technician even if leaving one workplace, has significant likelihood of continuing to work as a dental technician and going to another workplace that uses beryllium. OSHA welcomes comments on its turnover estimates and on sectors, such as dental laboratories, where turnover may be lower than ten percent.

Using Table VI-7 of the Preliminary Risk Assessment, when a worker's cumulative exposure is below 0.147 ( $\mu\text{g}/\text{m}^3\text{-years}$ ), the prevalence of CBD is 2.5 percent and so the derived annual risk would be 0.25 percent (0.10  $\times$  2.5 percent). It will stay at this level until the worker has reached a cumulative exposure of 1.468, where it will rise to 0.80 percent.

The model assumes a maximum 45-year (250 days per year) working life (ages 20 through 65 or age of death or onset of CBD, whichever is earlier) and follows workers after retirement through

age 80. The 45-year working life is based on OSHA's legal requirements and is longer than the working lives of most exposed workers. A shorter working life will be examined later in this section. While employed, the worker accumulates beryllium exposure at a rate depending on where the worker is in the empirical exposure profile presented in Chapter IV of the PEA (*i.e.*, OSHA calculates a general risk model which depends on the exposure level and then plug in our empirical exposure distribution to estimate the final number of cases of various health outcomes). Following a worker's retirement, there is no increased exposure, just a constant annual risk resulting from the worker's final cumulative exposure.

OSHA's model follows the population of workers each year, keeping track of cumulative exposure and various health outcomes. Explicitly, each year the model calculates: The increased cumulative exposure level for each worker versus last year, the incidence at the new exposure level, the survival rate for this age bracket, and the percentage of workers who have not previously developed CBD in earlier years.

For any individual year, the equation for predicting new cases of CBD for workers at age  $t$  is:

New CBD cases rate( $t$ ) = modeled incidence rate( $t$ ) \* survival rate( $t$ ) \* (1 - currently have CBD rate( $t$ )), where the variables used are:

New CBD cases rate( $t$ ) is the output variable to be calculated;  
 cumulative exposure( $t$ ) = cumulative exposure( $t-1$ ) + current exposure;  
 modeled incidence rate( $t$ ) is a function of cumulative exposure; and  
 survival rate( $t$ ) is the background survival rate from mortality due to other causes in the national population.

Then for the next year the model updates the survival rate (due to an increase in the worker's age), incidence rate (due to any increased cumulative exposure), and the rate of those currently having CBD, which increases due to the new CBD case rate of the year before. This process then repeats for all 60 years.

It is important to note that this model is based on the assumption that prevalence is explained by an underlying constant incidence, and as a result, prevalence will be different depending on the average number of years of exposure in the population examined and (though a sensitivity analysis is provided later) on the assumption of a maximum of 45 years of exposure. OSHA also examined (OSHA 2015c) a model in which prevalence is constant at the levels shown in Table VI-7 of the preliminary

risk assessment, with a population age (and thus exposure) distribution estimated based on an assumed constant turnover rate. OSHA solicits comment on this and other alternative approaches to using the available prevalence data to develop an exposure-response function for this benefits analysis.

In the next step, OSHA uses its model to take into account the adoption of the lower proposed PEL. OSHA uses the exposure profile for workers as estimated in Chapter IV of the PEA for each of the various application groups. These exposure profiles estimate the number of workers at various exposure levels, specifically the ranges less than 0.1 µg/m<sup>3</sup>, 0.1 to 0.2, 0.2 to 0.5, 0.5 to 1.0, 1.0 to 2.0, and greater than 2.0 µg/m<sup>3</sup>. Translating these ranges into exposure levels for the risk model, the model assumes an average exposure equal to the midpoint of the range, except for the lower end, where it was assumed to be equal to 0.1 µg/m<sup>3</sup>, and the upper end, where it was assumed to be equal to 2.0 µg/m<sup>3</sup>.

The model increases the workers' cumulative exposure each year by these midpoints and then plugs these new values into the new case equation. This alters the incidence rate as cumulative exposure crosses a threshold of the quartile data. So then using the exposure profiles by application group from Chapter IV of the PEA, the baseline exposure flows through the life time risk model to give us a baseline number of cases. Next OSHA calculated the number of cases estimated to occur after the implementation of the proposed PEL of 0.2 µg/m<sup>3</sup>. Here OSHA simply takes the number of workers with current average exposure above 0.2 µg/m<sup>3</sup> and

set their exposure level at 0.2 µg/m<sup>3</sup>; all exposures for workers exposed below 0.2 µg/m<sup>3</sup> stay the same. After adjusting the worker exposure profile in this way, OSHA goes through all the same calculations and obtains a post-standard number of CBD cases. Subtracting estimated post-standard CBD cases from estimated pre-standard CBD cases gives us the number of CBD cases that would be averted due to the proposed change in the PEL.

Based on these methods, OSHA's estimate of benefits associated with the proposed rule does not include benefits associated with current compliance that have already been achieved with regard to the new requirements, or benefits obtained from future compliance with existing beryllium requirements. However, available exposure data indicate that few employees are currently exposed above the existing standard's PEL of 2.0 µg/m<sup>3</sup>. To achieve consistency with the cost estimation method in chapter V, all employees in the exposure profile that are above 2.0 µg/m<sup>3</sup> are assumed to be at the 2.0 µg/m<sup>3</sup> level.

There is also a component that applies only to dental labs. OSHA has preliminarily assumed, based on the estimates of higher costs for engineering controls than using substitutes presented in the cost chapter, that rather than incur the costs of compliance with the proposed standard, many dental labs are likely to stop using beryllium-containing materials after the promulgation of the proposed standard.<sup>24</sup> OSHA estimated earlier in this PEA that, for the baseline, only 25 percent of dental lab workers still work with beryllium. OSHA estimates that, if

OSHA adopts the proposed rule, 75 percent of the 25 percent still using beryllium will stop working with beryllium; their beryllium exposure level will therefore drop to zero. OSHA estimates that the 75 percent of workers will not be a random sample of the dental lab exposure profile but instead will concentrate among workers who are currently at the highest exposure levels because it would cost more to reduce those higher exposures into compliance with the proposed PEL. Under this judgment OSHA is estimating that the rule would eliminate all cases of CBD in the 75 percent of dental lab workers with the highest exposure levels. As discussed in the sensitivity analysis below, dental labs constitute a significant source of both costs and benefits to the rule (over 40 percent), and the extent to which dental laboratories substitute other materials for beryllium has significant effects on the benefits and costs of the rule. To derive its baseline estimate of cases of CBD in dental laboratories, OSHA (1) estimated baseline cases of CBD using the existing rate of beryllium use in dental labs without a projection of further substitution; (2) estimated cases of CBD with the proposed regulation using an estimate that 75 percent of the dental labs with higher exposure would switch to other materials and thus eliminate exposure to beryllium; and (3) estimated that the turnover rate in the industry is 10 percent. OSHA welcomes comments on all aspects of the analysis of substitution away from beryllium in the dental laboratories sector.

Estimation results for both dental labs and non-dental workplaces appear in the table below.

CBD CASE ESTIMATES, 45-YEAR TOTALS, BASELINE AND WITH PEL OF 0.2 µg/m<sup>3</sup>

		Current beryllium exposure (µg/m <sup>3</sup> )						Total
		< 0.1	0.1–0.2	0.2–0.5	0.5–1.0	1.0–2.0	> 2.0	
Baseline .....	Dental labs .....	827	636	432	608	155	466	3,124
	Non-dental .....	5,912	631	738	287	112	214	7,893
	Total .....	6,739	1,267	1,171	895	267	679	11,017
PEL = 0.2 µg/m <sup>3</sup> .....	Dental labs .....	679	0	0	0	0	0	679
	Non-dental .....	5,912	631	693	255	98	186	7,774
	Total .....	6,591	631	693	255	98	186	8,454
Prevented by PEL reduction.	Dental labs .....	148	636	432	608	155	466	2,444
	Non-dental .....	0	0	45	32	14	27	119
	Total .....	148	636	478	640	169	493	2,563

<sup>24</sup> In Chapter V (Costs) of the PEA, OSHA explored the cost of putting in LEV instead of substitution. The Agency costed an enclosure for 2 technicians: The Powder Safe Type A Enclosure, 32

inch wide with HEPA filter, AirClean Systems (2011), which including operating and maintenance, was annualized at \$411 per worker. This is significantly higher than the annual cost for

substitution of \$166 per worker, shown later in this section.

In contrast to this PEL component of the benefits, both the ancillary program benefits calculation and the substitution benefits calculation are relatively simple. Both are percentages of the lifetime-risk-model CBD cases that still occur in the post-standard world. OSHA notes that in the context of existing CBD prevention programs, some ancillary-provision programs similar to those included in OSHA's proposal have eliminated a significant percentage of the remaining CBD cases (discussed later in this chapter). If the ancillary provisions reduce remaining CBD cases by 90 percent for example, and if the estimated baseline contains 120 cases of CBD, and post-standard compliance with a lower PEL reduces the total to 100 cases of CBD, then 90 of those remaining 100 cases of CBD would be averted due to the ancillary programs.

OSHA assumed, based on the clinical experience discussed further below, that approximately 65 percent of CBD cases ultimately result in death. Later in this chapter, OSHA provides a sensitivity analysis of the effects of different values for assuming this percentage at 50 percent and 80 percent on the number of CBD deaths prevented. OSHA welcomes comment on this assumption. OSHA's exposure-response model for lung cancer is based on lung cancer mortality data. Thus, all of the estimated cases of lung cancer in the benefits analysis are cases of premature death from beryllium-related lung cancer.

Finally, in recognition of the uncertainty in this aspect of these models, OSHA presents a "high" estimate, a "low" estimate, and uses the midpoint of these two as our "primary" estimate. The low estimate is simply those CBD fatalities prevented due to everything except the ancillary provisions, *i.e.*, both the reduction in the PEL and the substitution by dental labs. The high estimate includes both of these factors plus all the ancillary benefits calculated at an effectiveness rate of 90 percent in preventing cases of CBD not averted by the reduction of the PEL. The midpoint is the combination of reductions attributed to adopting the proposed PEL, substitution by dental labs, and the ancillary provisions calculated at an effectiveness rate of only 45 percent.

#### a. Chronic Beryllium Disease

CBD is a respiratory disease in which the body's immune system reacts to the presence of beryllium in the lung, causing a progression of pathological changes including chronic inflammation and tissue scarring. Immunological sensitization to beryllium (BeS) is a precursor that occurs before early-stage

CBD. Only sensitized individuals can go on to develop CBD. In early, asymptomatic stages of CBD, small granulomatous lesions and mild inflammation occur in the lungs. As CBD progresses, the capacity and function of the lungs decrease, which eventually affects other organs and bodily functions as well. Over time the spread of lung fibrosis (scarring) and loss of pulmonary function cause symptoms such as: A persistent dry cough, shortness of breath, fatigue, night sweats, chest and joint pain, clubbing of fingers due to impaired oxygen exchange, and loss of appetite. In these later stages CBD can also impair the liver, spleen, and kidneys, and cause health effects such as granulomas of the skin and lymph nodes, and *cor pulmonale* (enlargement of the heart). The speed and extent of disease progression may be influenced by the level and duration of exposure, treatment with corticosteroids, and genetics, but these effects are not fully understood.

Corticosteroid therapy, in workers whose beryllium exposure has ceased, has been shown to control inflammation, ease symptoms, and in some cases prevent the development of fibrosis. However, corticosteroid use can have adverse effects, including increased risk of infections; accelerated bone loss or osteoporosis; psychiatric effects such as depression, sleep disturbances, and psychosis; adrenal suppression; ocular effects; glucose intolerance; excessive weight gain; increased risk of cardiovascular disease; and poor wound healing. The effects of CBD, and of common treatments for CBD, are discussed in detail in this preamble at Section V, Health Effects, and Section VIII, Significance of Risk.

OSHA's review of the literature on CBD suggests three broad types of CBD progression (see this preamble at Section V, Health Effects). In the first, individuals progress relatively directly toward death related to CBD. They suffer rapidly advancing disability and their death is significantly premature. Medical intervention is not applied, or if it is, does little to slow the progression of disease. In the second type, individuals live with CBD for an extended period of time. The progression of CBD in these individuals is naturally slow, or may be medically stabilized. They may suffer significant disability, in terms of loss of lung function—and quality of life—and require medical oversight their remaining years. They would be expected to lose some years of normal lifespan. As discussed previously, advanced CBD can involve organs and

systems beyond the respiratory system; thus, CBD can contribute to premature death from other causes. Finally, individuals with the third type of CBD progression do not die prematurely from causes related to CBD. The disease is stabilized and may never progress to a debilitating state. These individuals nevertheless may experience some disability or loss of lung function, as well as side effects from medical treatment, and may be affected by the disease in many areas of their lives: Work, recreation, family, etc.<sup>25</sup>

In the analysis that follows, OSHA assumes, based on the clinical experience discussed below, that 35 percent of workers who develop CBD experience the third type of progression and do not die prematurely from CBD. The remaining 65 percent were estimated to die prematurely, whether from rapid disease progression (type 1) or slow (type 2). Although the proportion of CBD patients who die prematurely as a result of the disease is not well understood or documented at this time, OSHA believes this assumption is consistent with the information submitted in response to the RFI. Newman et al. (2003) presented a scenario for what they considered to be the "typical" CBD patient:

We have included an example of a life care plan for a typical clinical case of CBD. In this example, the hypothetical case is diagnosed at age 40 and assumed to live an additional 33.7 years (approximately 5% reduced life expectancy in this model). In this hypothetical example, this individual would be considered to have moderate severity of chronic beryllium disease at the time of initial diagnosis. They require treatment with prednisone and treatment for early *cor pulmonale* secondary to CBD. They have experienced some, but not all, of the side effects of treatment and only the most common CBD-related health effects.

In short, *most* workers diagnosed with CBD are expected to have shortened life expectancy, even if they do not progress rapidly and directly to death. It should be emphasized that this represents the Agency's best estimate of the mortality related to CBD based upon the current available evidence. As described in Section V, Health Effects, there is a substantial degree of uncertainty as to the prognosis for those contracting CBD, particularly as the relatively less severe

<sup>25</sup> As indicated in the Health Effects section of this preamble: "It should be noted, however, that treatment with corticosteroids has side-effects of their own that need to be measured against the possibility of progression of disease (Gibson *et al.*, 1996; Zaki *et al.*, 1987). Alternative treatments such as azathiopurine and infliximab, while successful at treating symptoms of CBD, have been demonstrated to have side-effects as well (Pallavicino *et al.*, 2013; Freeman, 2012)".

cases are likely not to be studied closely for the remainder of their lives.

As mentioned previously, OSHA used the Cullman data set for empirical estimates of beryllium sensitization and CBD prevalence in its exposure response model, which translates beryllium exposure to risk of adverse health endpoints for the purpose of determining the benefits that could be achieved by preventing those adverse health endpoints.

OSHA chose the cumulative exposure quartile data as the basis for this benefits analysis. The choice of cumulative quartiles was based in part on the need to use the cumulative exposure forecast developed in the model, and in part on the fact that in statistically fitted models for CBD, the cumulative exposure tended to fit the CBD data better than other exposure variables. OSHA also chose the quartile model because the outside expert who examined the logistic and proportional hazards models believed statistical modeling of the data set to be unreliable due to its small size. In addition, the proportional hazards model with its dummy variables by year of detection is difficult to interpret for purposes of this section. Of course regression analyses are often useful in empirical analysis. They can be a useful compact representation of a set of data, allow investigations of various variable interactions and possible causal relationships, have added flexibility due to covariate transformations, and under certain conditions can be shown to be statistically "optimal." However, they are only useful when used in the proper setting. The possibility of misspecification of functional form, endogeneity, or incorrect distributional assumptions are just three reasons to be cautious about using regression analyses.

On the other hand, the use of results produced by a quartile analysis as inputs in a benefits assessment implies that the analytic results are being interpreted as evidence of an exposure-response causal relationship. Regression analysis is a more sophisticated approach to estimating causal relationships (or even correlations) than quartile or other quantile analysis, and any data limitations that may apply to a particular regression-based exposure-response estimation also apply to exposure-response estimation conducted with a quartile analysis using the same data set. In this case, OSHA adopted the quartile analysis because the logistic regression analysis yielded extremely high prevalence rates for higher level of exposure over long time periods that some might not find

credible. Use of the quartile analysis serves to show that there are significant benefits even without using an extremely high estimate of prevalence for long periods of exposure at high levels. As a check on the quartile model, the Agency performed the same benefits calculation using the logit model estimated by the Agency's outside expert, and these benefit results are presented in a separate OSHA background document (OSHA, 2015b). The difference in benefits between the two models is slight, and there is no qualitative change in final outcomes. The Agency solicits comment on these issues.

#### (1) Number of CBD Cases Prevented by the Proposed PEL

To examine the effect of simply changing the PEL, including the effect of the standard on some dental labs to discontinue their use of beryllium, OSHA compared the number of CBD-related deaths (mortality) and cases of non-fatal CBD (morbidity) that would occur if workers were exposed for a 45-year working life to PELs of 0.1, 0.2, or 0.5  $\mu\text{g}/\text{m}^3$  to the number of cases that would occur at levels of exposure at or below the current PEL. The number of avoided cases over a hypothetical working life of exposure for the current population at a lower PEL is then equal to the difference between the number of cases at levels of exposure at or below the current PEL for that population minus the number of cases at the lower PEL. This approach represents a steady-state comparison based on what would hypothetically happen to workers who received a specific average level of occupational exposure to beryllium during an entire working life. (Chapter VII in the PEA modifies this approach by introducing a model that takes into account the timing of benefits before steady state is reached.)

As indicated in Table IX-11, the Agency estimates that there would be 16,240 cases of beryllium sensitization, from which there would be 11,017, or about 70 percent, progressing to CBD. The Agency arrived at these estimates by using the CBD and BeS prevalence values from the Agency's preliminary risk analysis, the exposure profile at current exposure levels (under an assumption of full, or fixed, compliance with the existing beryllium PEL), and the model outlined in the previous methods of estimation section after a working lifetime of exposure. Applying the prior midpoint estimate, as explained above, that 65 percent of CBD cases cause or contribute to premature death, the Agency predicts a total of 7,161 cases of mortality and 3,856 cases

of morbidity from exposure at current levels; this translates, annually, to 165 cases of mortality and 86 cases of morbidity. At the proposed PEL, OSHA's base model estimates that, due to the airborne factor only, a total of 2,563 CBD cases would be avoided from exposure at current levels, including 1,666 cases of mortality and 897 cases of morbidity—or an average of 37 cases of mortality and 20 cases of morbidity annually. OSHA has not estimated the quantitative benefits of sensitization cases avoided.

OSHA requests comment on this analysis, including feedback on the data relied on and the approach and assumptions used. As discussed earlier, based on information submitted in response to the RFI, the Agency estimates that most of the workers with CBD will progress to an early death, even if it comes after retirement, and has quantified those cases prevented. However, given the evolving nature of science and medicine, the Agency invites public comment on the current state of CBD-related mortality.

The proposed standard also includes provisions for medical surveillance and removal. The Agency believes that to the extent the proposal provides medical surveillance sooner and to more workers than would have been the case in the absence of the proposed standard, workers will be more likely to receive appropriate treatment and, where necessary, removal from beryllium exposure. These interventions may lessen the severity of beryllium-related illnesses, and possibly prevent premature death. The Agency requests public comment on this issue.

#### (2) CBD Cases Prevented by the Ancillary Provisions of the Proposed Standard

The nature of the chronic beryllium disease process should be emphasized. As discussed in this preamble at Section V, Health Effects, the chronic beryllium disease process involves two steps. First, workers become sensitized to beryllium. In most epidemiological studies of CBD conducted to date, a large percentage of sensitized workers have progressed to CBD. A certain percentage of the population has an elevated risk of this occurring, even at very low exposure levels, and sensitization can occur from dermal as well as inhalation exposure to beryllium. For this reason, the threat of beryllium sensitization and CBD persist to a substantial degree, even at very low levels of airborne beryllium exposure. It is therefore desirable not only to significantly reduce airborne beryllium exposure, but to avoid nearly any source



of beryllium exposure, so as to prevent beryllium sensitization.

The analysis presented above accounted only for CBD-prevention benefits associated with the proposed reduction of the PEL, from 2 ug/m<sup>3</sup> to 0.2 ug/m<sup>3</sup>. However, the proposed standard also includes a variety of ancillary provisions—including requirements for respiratory protection, personal protective equipment (PPE), housekeeping procedures, hygiene areas, medical surveillance, medical removal, and training—that the Agency believes would further reduce workers' risk of disease from beryllium exposure. These provisions were described in Chapter I of the PEA and discussed extensively in Section XVIII of this preamble, Summary and Explanation of the Proposed Standard.

The leading manufacturer of beryllium in the U.S., Materion Corporation (Materion), has implemented programs including these types of provisions in several of its plants and has worked with NIOSH to publish peer-reviewed studies of their effectiveness in reducing workers' risk of sensitization and CBD. The Agency used the results of these studies to estimate the health benefits associated with a comprehensive standard for beryllium.

The best available evidence on comprehensive beryllium programs comes from studies of programs introduced at Materion plants in Reading, PA; Tucson, AZ; and Elmore, OH. These studies are discussed in detail in this preamble at Section VI, Preliminary Risk Assessment, and Section VIII, Significance of Risk. All three facilities were in compliance with the current PEL prior to instituting comprehensive programs, and had taken steps to reduce airborne levels of beryllium below the PEL, but their medical surveillance programs continued to identify cases of sensitization and CBD among their workers. Beginning around 2000, these facilities introduced comprehensive beryllium programs that used a combination of engineering controls, dermal and respiratory PPE, and stringent housekeeping measures to reduce workers' dermal exposures and airborne exposures. These comprehensive beryllium programs have substantially lowered the risk of sensitization among workers. At the times that studies of the programs were published, insufficient follow-up time had elapsed to report directly on the results for CBD. However, since only sensitized workers can develop CBD, reduction of sensitization risk necessarily reduces CBD risk as well.

In the Reading, PA copper beryllium plant, full-shift airborne exposures in all jobs were reduced to a median of 0.1 ug/m<sup>3</sup> or below, and dermal protection was required for production-area workers, beginning in 2000–2001 (Thomas et al., 2009). In 2002, the process with the highest exposures (with a median of 0.1 ug/m<sup>3</sup>) was enclosed, and workers involved in that process were required to use respiratory protection. Among 45 workers hired after the enclosure was built and respiratory protection instituted, one was found to be sensitized (2.2 percent). This is more than an 80 percent reduction in sensitization from a previous group of 43 workers hired after 1992, 11.5 percent of whom had been sensitized by the time of testing in 2000.

In the Tucson beryllium ceramics plant, respiratory and skin protection was instituted for all workers in production areas in 2000 (Cummings et al., 2007). BeLPT testing in 2000–2004 showed that only 1 (1 percent) of 97 workers hired during that time period was sensitized to beryllium. This is a 90 percent reduction from the prevalence of sensitization in a 1998 BeLPT screening, which found that 6 (9 percent) of 69 workers hired after 1992 were sensitized.

In the Elmore, OH beryllium production and processing facility, all new workers were required to wear loose-fitting powered air-purifying respirators (PAPRs) in manufacturing buildings, beginning in 1999 (Bailey et al., 2010). Skin protection became part of the protection program for new workers in 2000, and glove use was required in production areas and for handling work boots, beginning in 2001. Bailey et al. (2010) found that 23 (8.9 percent) of 258 workers hired between 1993 and 1999, before institution of respiratory and dermal protection, were sensitized to beryllium. The prevalence of sensitization among the 290 workers who were hired after the respiratory protection and PPE measures were put in place was about 2 percent, close to an 80 percent reduction in beryllium sensitization.

In a response to OSHA's 2002 Request for Information (RFI), Lee Newman et al. from National Jewish Medical and Research Center (NJMRC) summarized results of beryllium program effectiveness from several sources. Said Dr. Newman (in response to Question #33):

*Q. 33. What are the potential impacts of reducing occupational exposures to beryllium in terms of costs of controls, costs for training, benefits from reduction in the number or severity of illnesses, effects on revenue and profit, changes in worker*

*productivity, or any other impact measures than you can identify?*

A: From experience in [the Tucson, AZ facility discussed above], one can infer that approximately 90 percent of beryllium sensitization can be eliminated. Furthermore, the preliminary data would suggest that potentially 100 percent of CBD can be eliminated with appropriate workplace control measures.

In a study by Kelleher 2001, Martyny 2000, Newman, JOEM 2001) in a plant that previously had rates of sensitization as high as 9.7 percent, the data suggests that when lifetime weighted average exposures were below 0.02 ug per cu meter that the rate of sensitization fell to zero and the rate of CBD fell to zero as well.

In an unpublished study, we have been conducting serial surveillance including testing new hires in a precision machining shop that handles beryllium and beryllium alloys in the Southeast United States. At the time of the first screening with the blood BeLPT of people tested within the first year of hire, we had a rate of 6.7 percent (4/60) sensitization and with 50 percent of these individuals showing CBD at the time of initial clinical evaluation. At that time, the median exposures in the machining areas of the plant was 0.47 ug per cu meter. Subsequently, efforts were made to reduce exposures, further educate the workforce, and increase monitoring of exposure in the plant. Ongoing testing of newly hired workers within the first year of hire demonstrated an incremental decline in the rate of sensitization and in the rate of CBD. For example, at the time of most recent testing when the median airborne exposures in the machining shop were 0.13 ug per cu meter, the percentage of newly hired workers found to have beryllium sensitization or CBD was now 0 percent (0/55). Notably, we also saw an incremental decline in the percentage of longer term workers being detected with sensitization and disease across this time period of exposure reduction and improved hygiene practices.

Thus, in calculating the potential economic benefit, it's reasonable to work with the assumption that with appropriate efforts to control exposures in the work place, rates of sensitization can be reduced by over 90 percent. (NJMRC, RFI Ex. 6–20)

OSHA has reviewed these papers and is in agreement with Dr. Newman's testimony. OSHA judges Dr. Newman's estimate to be an upper bound of the effectiveness of ancillary programs and examined the results of using Dr. Newman's estimate that beryllium ancillary programs can reduce BeS by 90 percent, and potentially eliminate CBD where sensitization is reduced, because CBD can only occur where there is sensitization. OSHA applied this 90 percent reduction factor to all cases of CBD remaining after application of the reductions due to lowering the PEL alone. OSHA applied this reduction broadly because the proposed standard would require housekeeping and PPE related to skin exposure (18,000 of

28,000 employees will need PPE because of possible skin exposure) to apply to all or most employees likely to come in contact with beryllium and not just those with exposure above the action level. Table IX–11 shows that there are 11,017 baseline cases of CBD and that the proposed PEL of 0.2  $\mu\text{g}/\text{m}^3$  would prevent 2,563 cases through airborne prevention alone. The remaining number of cases of CBD is then 8,454 (11,017 minus 2,563). If OSHA applies the full ninety percent reduction factor to account for prevention of skin exposure (“non-airborne” protections), then 7,609 (90 percent of 8,454 cases) additional cases of CBD would be prevented.

The Agency recognizes that there are significant differences between the comprehensive programs discussed above and the proposed standard. While the proposed standard includes many of the same elements, it is generally less stringent. For example, the proposed standard’s requirements for respiratory protection and PPE are narrower, and many provisions of the standard apply only to workers exposed above the proposed TWA PEL or STEL. However, many provisions, such as housekeeping and beryllium work areas, apply to all employers covered by the proposed standard. To account for these differences, OSHA has provided a range of benefits estimates (shown in Table IX–11), first, assuming that there are no ancillary provisions to the standard, and, second, assuming that the comprehensive standard achieves the full 90-percent reduction in risk documented in existing programs. The Agency is taking the midpoint of these two numbers as its main estimate of the benefits of avoided CBD due to the ancillary provisions of the proposed standard. The results in Table IX–11 suggest that approximately 60 percent of the beryllium sensitization cases and the CBD cases avoided would be attributable to the ancillary provisions of the standard. OSHA solicits comment on all aspects of this approach to analyzing ancillary provisions and solicits additional data that might serve to make more accurate estimates of the effects of ancillary provisions. OSHA is interested in the extent of the effects of ancillary provisions and whether these apply to all exposed employees or only those exposed above or below a given exposure level.

### (3) Morbidity Only Cases

As previously indicated, the Agency does not believe that all CBD cases will ultimately result in premature death. While currently strong empirical data on this are lacking, the Agency

estimates that approximately 35 percent of cases would not ultimately be fatal, but would result in some pain and suffering related to having CBD, and possible side effects from steroid treatment, as well as the dread of not knowing whether the disease will ultimately lead to premature death. These would be described as “mild” cases of CBD relative to the others. These are the residual cases of CBD after cases with premature mortality have been counted. As indicated in Table IX–11, the Agency estimates the standard will prevent 2,228 such cases (midpoint) over 45 years, or an estimated 50 cases annually.

### b. Lung Cancer

In addition to the Agency’s determinations with respect to the risk of chronic beryllium disease, the Agency has preliminarily determined that chronic beryllium exposure at the current PEL can lead to a significantly elevated risk of (fatal) lung cancer. OSHA used the estimation methodology outlined at the beginning of this section. However, unlike with chronic beryllium disease, the underlying data were based on incidence of lung cancer and thus there was no need to address the possible limitations of prevalence data. The Agency also used lifetime excess risk estimates of lung cancer mortality, presented in Table VI–20 in Section VI of this preamble, Preliminary Risk Assessment, to estimate the benefits of avoided lung cancer mortality. The lung cancer risk estimates are derived from one of the best-fitting models in a recent, high-quality NIOSH lung cancer study, and are based on average exposure levels. The estimates of excess lifetime risk of lung cancer were taken from the line in Table VI–20 in the risk assessment labeled PWL (piecewise log-linear) not including professional and asbestos workers. This model avoids possible confounding from asbestos exposure and reduces the potential for confounding due to smoking, as smoking rates and beryllium exposures can be correlated via professional worker status. Of the three estimates in the NIOSH study that excluded professional workers and those with asbestos exposure, this model was chosen because it was at the midpoint of risk results.

Table IX–11 shows the number of avoided fatal lung cancers for PELs of 0.2  $\mu\text{g}/\text{m}^3$ , 0.1  $\mu\text{g}/\text{m}^3$ , and 0.5  $\mu\text{g}/\text{m}^3$ . At the proposed PEL of 0.2  $\mu\text{g}/\text{m}^3$ , an estimated 180 lung cancers would be prevented over the lifetime of the current worker population. This is the equivalent of 4.0 cases avoided

annually, given a 45-year working life of exposure.

Combining the two major fatal health endpoints—for lung cancer and CBD-related mortality—OSHA estimates that the proposed PEL would prevent between 1,846 and 6,791 premature fatalities over the lifetime of the current worker population, with a midpoint estimate of 4,318 fatalities prevented. This is the equivalent of between 41 and 151 premature fatalities avoided annually, with a midpoint estimate of 96 premature fatalities avoided annually, given a 45-year working life of exposure.

Note that the Agency based its estimates of reductions in the number of beryllium-related diseases over a working life of constant exposure for workers who are employed in a beryllium-exposed occupation for their entire working lives, from ages 20 to 65. In other words, workers are assumed not to enter or exit jobs with beryllium exposure mid-career or to switch to other exposure groups during their working lives. While the Agency is legally obligated to examine the effect of exposures from a working lifetime of exposure and set its standard accordingly,<sup>26</sup> in an alternative analysis purely for informational purposes, using the same underlying risk model for CBD, the Agency examined, in Chapter VII of the PEA, the effect of assuming that workers are exposed for a maximum of only 25 working years, as opposed to the 45 years assumed in the main analysis. While all workers are assumed to have less cumulative exposure under the 25-years-of-exposure assumption, the effective exposed population over time is proportionately increased.

A comparison of exposures over a maximum of 25 working years versus over a potentially 45-year working life shows variations in the number of estimated prevented cases by health outcome. For chronic beryllium disease, there is a substantial increase in the number of estimated baseline and prevented cases if one assumes that the typical maximum exposure period is 25 years, as opposed to 45. This reflects the

<sup>26</sup> 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 it is necessary for OSHA to reach a determination of significant risk over a working life, it is a logical extension to estimate what this translates into in terms of estimated benefits for the affected population over the same period.

relatively flat CBD risk function within the relevant exposure range, given varying levels of airborne beryllium exposure—shortening the average tenure and increasing the exposed population over time translates into larger total numbers of people sensitized to beryllium. This, in turn, results in larger populations of individuals contracting CBD. Since the lung cancer model itself is based on average, as opposed to cumulative, exposure, it is not adaptable to estimate exposures over a shorter period of time. As a practical matter, however, over 90 percent of

illness and mortality attributable to beryllium exposure in this analysis comes from CBD.

Overall, the 45-year-maximum-working-life assumption yields smaller estimates of the number of cases of avoided fatalities and illnesses than does the maximum-25-years-of-exposure assumption. For example, the midpoint estimates of the number of avoided fatalities and illnesses related to CBD under the proposed PEL of  $0.2 \mu\text{g}/\text{m}^3$  increases from 92 and 50, respectively, under the maximum-45-year-working-life assumption to 145 and 78,

respectively, under the maximum-25-year-working-life assumption—or approximately a 57 to 58 percent increase.<sup>27</sup>

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<sup>27</sup> Technically, this analysis assumes that workers receive 25 years' worth of beryllium exposure, but that they receive it over 45 working years, as is assumed by the risk models in the risk assessment. It also accounts for the turnover implied by 25, as opposed to 45, years of work. However, it is possible that an alternate analysis, which accounts for the larger number of post-exposure worker-years implied by workers departing their jobs before the end of their working lifetime, might find even larger health effects for workers receiving 25 years' worth of beryllium exposure.

<b>Airborne Factor Only</b>								
	Baseline	PEL Option ( $\mu\text{g}/\text{m}^3$ )			Baseline	PEL Option ( $\mu\text{g}/\text{m}^3$ )		
	Total Cases	Total	Number of AVOIDED Cases		Annual Cases	Annual Number of AVOIDED Cases		
		0.1	0.2	0.5		0.1	0.2	0.5
<b>Total Cases</b>								
Be S	16,240	3,826	3,594	3,503	361	85.0	79.9	77.9
CBD	11,017	2,763	2,563	2,463	245	61.4	56.9	54.7
<b>Mortality</b>								
Lung Cancer	279	192	180	163	6.2	4.3	4.0	3.6
CBD-Related	7,161	1,796	1,666	1,601	159	39.9	37.0	35.6
Total Mortality	7,440	1,988	1,846	1,764	165	44.2	41.0	39.2
<b>Morbidity</b>								
	3,856	967	897	862	86	21.5	19.9	19.2
<b>Non-Airborne Factor Included</b>								
	Baseline	PEL Option ( $\mu\text{g}/\text{m}^3$ )			Baseline	PEL Option ( $\mu\text{g}/\text{m}^3$ )		
	Total Cases	Total	Number of AVOIDED Cases		Annual Cases	Annual Number of AVOIDED Cases		
		0.1	0.2	0.5		0.1	0.2	0.5
<b>Total Cases</b>								
Be S	16,240	14,998	14,975	9,235	361	333.3	332.8	205.2
CBD	11,017	10,191	10,171	6,312	245	226.5	226.0	140.3
<b>Mortality</b>								
Lung Cancer	279	192	180	163	6	4.3	4.0	3.6
CBD-Related	7,161	6,624	6,611	4,103	159	147.2	146.9	91.2
Total Mortality	7,440	6,816	6,791	4,266	165	151.5	150.9	94.8
<b>Morbidity</b>								
	3,856	3,567	3,560	2,209	86	79.3	79.1	49.1
<b>Midpoint Estimates</b>								
	Baseline	PEL Option ( $\mu\text{g}/\text{m}^3$ )			Baseline	PEL Option ( $\mu\text{g}/\text{m}^3$ )		
	Total Cases	Total	Number of AVOIDED Cases		Annual Cases	Annual Number of AVOIDED Cases		
		0.1	0.2	0.5		0.1	0.2	0.5
<b>Total Cases</b>								
Be S - Total	16,240	9,412	9,284	6,369	361	209.2	206.3	141.5
CBD	11,017	6,477	6,367	4,387	245	143.9	141.5	97.5
<b>Mortality</b>								
Lung Cancer	279	192	180	163	6	4.3	4.0	3.6
CBD-Related	7,161	4,210	4,139	2,852	159	93.6	92.0	63.4
Total Mortality	7,440	4,402	4,318	3,015	165	97.8	96.0	67.0
<b>Morbidity</b>								
	3,856	2,267	2,228	1,536	86	50.4	49.5	34.1

Source: Office of Regulatory Analysis, Directorate of Standards and Guidance

## Step 2—Estimating the 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 demonstrated previously in this section, 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 proposed standard takes effect, creating a "steady state" estimate of benefits. However, in order to annualize the benefits for the period of time after the beryllium rule takes effect, it is necessary to create a timeline of benefits for an entire active workforce over that period.

While there are various approaches that could be taken for modeling the workforce, there seem to be two polar extremes. At one extreme, one could assume that none of the benefits occur until after the worker retires, or at least 45 years in the future. In the case of lung cancer, that period would effectively be at least 55 years, since the 45 years of exposure must be added to a 10-year latency period during which it is assumed that lung cancer does not develop.<sup>28</sup> At the other extreme, one could assume that the benefits occur immediately, or at least immediately after a designated lag. However, based on the various risk models discussed in this preamble at Section VI, Risk Assessment, 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.

At first glance, the simplest intermediate approach would be to 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. Thus, the older the person exposed to beryllium, the higher the odds that that person will have developed the disease.

However, while this is a good working model for an individual exposed over a working life, it is not very descriptive of the effect of lowering exposures for an entire working population. In the latter case, in order to estimate the benefits of the standard over time, one has to consider that workers currently being exposed to beryllium are going to vary considerably in age. Since the calculated health risks from beryllium

exposure depend on a worker's cumulative exposure over a working lifetime, the overall benefits of the proposed 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 beryllium-related illnesses reaches a new, significantly lowered "steady state."<sup>29</sup> That said, the near-term impact of the proposed rule estimated for those workers with similar current levels of cumulative exposure will be greater for workers who are now middle-aged or older. This conclusion follows in part from the structure of the relative risk model used for lung cancer in this analysis and the fact that the background mortality rates for lung cancer 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 beryllium-related disease would gradually decline as a result of the proposed rule, they would not reach the steady-state level until 45 years had passed. The reduction in cases estimated to occur 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. Expressed mathematically:

$$N_t = (C - S) \times (t/45),$$

Where  $N_t$  is the number of non-malignant beryllium-related diseases avoided in year  $t$ ;  $C$  is the current annual number of non-malignant beryllium-related diseases;  $S$  is the steady-state annual number of non-malignant beryllium-related diseases; and  $t$  represents the number of years after the proposed standard takes effect, with  $t \leq 45$ .

In the case of lung cancer, the function representing the decline in the number of beryllium-related cases as a result of the proposed rule is similar, but there would be a 10-year lag before any reduction in cancer cases would be achieved. Expressed mathematically, for lung cancer:

$$L_t = (C_m - S_m) \times ((t - 10)/45),$$

<sup>29</sup> Technically, the RA lung cancer model is based on average exposure. Nonetheless, as noted in the RA, the underlying studies found lung cancer to be significantly related to cumulative exposure. Particularly since the large majority of the benefits are related to CBD, the Agency considers this fairly descriptive of the overall phase-in of benefits from the standard.

Where  $10 \leq t \leq 55$  and  $L_t$  is the number of lung cancer cases avoided in year  $t$  as a result of the proposed rule;  $C_m$  is the current annual number of beryllium-related lung cancers; and  $S_m$  is the steady-state annual number of beryllium-related lung cancers.

This model was extended to 60 years for all the health effects previously discussed in order to incorporate the 10-year lag, in the case of lung cancer, and a maximum-45-year working life, as well as to capture some occupationally-related disease that manifests itself after retirement.<sup>30</sup> As a practical matter, however, there is no overriding reason for stopping the benefits analysis at 60 years. An internal analysis by OSHA indicated that, both in terms of cases prevented, and even with regard to monetized benefits, particularly when lower discount rates are used, the estimated benefits of the standard are larger on an annualized basis if the analysis extends further into the future. The Agency welcomes comment on the merit of extending the benefits analysis beyond the 60-years analyzed in the PEA.

In order to compare costs to benefits, OSHA assumes that economic conditions remain constant and that annualized costs—and the underlying costs—will repeat for the entire 60-year time horizon used for the benefits analysis (as discussed in Chapter V of the PEA). OSHA welcomes comments on the assumption for both the benefit and cost analysis that economic conditions remain constant for sixty years. OSHA is particularly interested in what assumptions and time horizon should be used instead and why.

## Separating the Timing of Mortality

In previous sections, OSHA modeled the timing and incidence of morbidity. OSHA's benefit estimates are based on an underlying CBD-related mortality rate of 65 percent. However, this mortality is not simultaneous with the onset of morbidity. Although mortality from CBD has not been well studied, OSHA believes, based on discussions with experienced clinicians, that the average lag for a larger population has a range of 10 to 30 years between morbidity and mortality. The Agency's review of Workers Compensation data related to beryllium exposure from the Office of Worker Compensation Programs (OWCP) Division of Energy Employees Occupational Illness Compensation is consistent with this range. Hence, for the purposes of this

<sup>28</sup> This assumption is consistent with the 10-year lag incorporated in the lung cancer risk models used in OSHA's preliminary risk assessment.

<sup>30</sup> The left-hand columns in the tables in Appendix VII-A of the PEA provide estimates using this model of the stream of prevented fatalities and illnesses due to the proposed beryllium rule.

proposal, OSHA estimates that mortality occurs on average 20 years after the onset of CBD morbidity. Thus, for example, the prevented deaths that would have occurred in year 21 after the promulgation of the rule are associated with the CBD morbidity cases prevented in year one. OSHA requests comment on this estimate and range.

The Agency invites comment on each of these elements of the analysis, particularly on the estimates of the expected life expectancy of a patient with CBD.

### Step 3—Monetizing the Benefits of the Proposed Rule

To estimate the monetary value of the reductions in the number of beryllium-related fatalities, OSHA relied, as OMB recommends, 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 immediate family—to pay to reduce that individual's risk of fatality.

For estimates using the willingness-to-pay concept, OSHA relied 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 accuracy, particularly that workers understand the risks to which they are exposed and that workers have legitimate choices between high- and low-risk jobs. These assumptions are far from obviously met in actual labor markets.<sup>31</sup> A number of academic studies, as summarized in Viscusi & Aldy (2003), 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.<sup>32</sup>

OSHA has used this approach in many recent proposed and final rules. Although this approach has been criticized for yielding results that are less than statistically robust (see, for example, Hintermann, Alberini and Markandya, 2010), a more recent WTP analysis, by Kniesner *et al.* (2012), of the trade-off between fatal job risks and wages, using panel data, seems to address many of the earlier econometric criticisms by controlling for measurement error, endogeneity, and heterogeneity. In conclusion, the Agency views the WTP approach as the best available and will rely on it to monetize benefits.<sup>33</sup> OSHA welcomes comments on the use of willingness-to-pay measures and estimates based on compensating wage differentials.

Viscusi & 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. Using the GDP Deflator (U.S. BEA, 2010), this \$7 million base number in 2000 dollars yields an estimate of \$8.7 million in 2010 dollars for each fatality avoided.<sup>34</sup>

In addition to the benefits that are based on the implicit value of fatalities avoided, workers also place an implicit 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. Chronic beryllium disease and lung cancer can adversely affect individuals for years, or even decades, in non-fatal cases, or before ultimately proving fatal. Because measures of the benefits of avoiding

<sup>32</sup> For example, if workers are willing to pay \$90 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 \$90 divided by 1/100,000, or \$9,000,000. 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 \$9,000,000.

<sup>33</sup> Note that, consistent with the economics literature, these estimates would be for reducing the risk of an acute (immediate) fatality. They do not include an individual's willingness to pay to avoid a higher risk of illness prior to fatality, which is separately estimated in the following section.

<sup>34</sup> 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) for discussion of VSLY theory and FDA (2003), pp. 41488–9, for an application of VSLY in rulemaking. OSHA has not investigated this approach, but welcomes comment on the issue.

these illnesses are rare and difficult to find, OSHA has included a range based on a variety of estimation methods.

For both CBD and lung cancer, there is typically some permanent loss of lung function and disability, on-going medical treatments, side effects of medicines, and major impacts on one's ability to work, marry, enjoy family life, and quality of life.

While diagnosis with CBD is evidence of 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. For that reason, for this preliminary analysis, the Agency 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 2010 dollars) that runs from approximately \$62,000 per case—which reflects estimates developed by Viscusi and Aldy (2003), based on a series of studies primarily describing simple accidents—to upwards of \$5 million per case—which reflects work developed by Magat, Viscusi, and Huber (1996) for non-fatal cancer. The latter number is based on an approach that places a willingness-to-pay value to avoid serious illness that is calibrated relative to the value of an avoided fatality. OSHA previously used this approach in the Preliminary Economic Analysis (PEA) supporting its respirable crystalline silica proposal (2013) and in the Final Economic Analysis (FEA) supporting its hexavalent chromium final rule (2006), and EPA (2003) used this approach in its Stage 2 Disinfection and Disinfection Byproducts Rule concerning regulation of primary drinking water. Based on Magat, Viscusi, and Huber (1996), EPA used studies 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 million for an avoided case of non-fatal cancer is based on this 58.3 percent figure.

The Agency believes this range of estimates, between \$62,000 and \$5 million, is descriptive of the value of preventing morbidity associated with moderate to severe CBD that ultimately results in premature death.<sup>35</sup>

<sup>35</sup> There are several benchmarks for valuation of health impairment due to beryllium exposure, using

<sup>31</sup> On the former assumption, see the discussion in Chapter II of the PEA on imperfect information. On the latter, see, for example, the discussion of wage compensation for risk for union versus nonunion workers in Dorman and Hagstrom (1998).

While the Agency has estimated that 65 percent of CBD cases will result in premature mortality, the Agency has also estimated that approximately 35 percent of CBD cases will not result in premature mortality. However, the Agency acknowledges that it is possible there have been new developments in medicine and industrial hygiene related to the benefits of early detection, medical intervention, and greater control of exposure achieved within the past decade. For that reason, as elsewhere, the Agency requests comment on these issues.

Also not clear are the negative effects of the illness in terms of lost productivity, medical costs, and potential side-effects of a lifetime of immunosuppressive medication. Nonetheless, the Agency is assigning a valuation of \$62,000 per case, to reflect the WTP value of a prevented injury not estimated to precede premature mortality. The Agency believes this is conservative, in part because, with any given case of CBD, the outcome is not known in advance, certainly not at the point of discovery; indeed much of the psychic value of preventing the cases may come from removing the threat of premature mortality. In addition, as previously noted, some of these cases could involve relatively severe forms of CBD where the worker died of other

a variety of techniques, which provide a number of mid-range estimates between OSHA's high and low estimates. For a fuller discussion of these benchmarks, see Chapter VII of the PEA.

causes; however, in those cases, the duration of the disease would be shortened. While beryllium sensitization is a critical precursor of CBD, this preliminary analysis does not attempt to assign a separate value to sensitization itself.

Particularly given the uncertainties in valuation on these questions, the Agency is interested in public input on the issue of valuing the cost to society of morbidity associated with CBD, both in cases preceding mortality, and those that may not result in premature mortality. The Agency is also interested in comments on whether it is appropriate to assign a separate valuation to prevented sensitization cases in their own right, and if so, how such cases should be valued.

#### a. Summary of Monetized Benefits

Table IX-12 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 uncertainty of the prevention factor (*i.e.*, the estimated range of prevented cases, depending on how large an impact the rule has on cases beyond an airborne-only effect), and the range of uncertainty regarding valuation of morbidity. (Mid-point estimates of the undiscounted benefits for each of the first 60 years are provided in the middle columns of Table VII-A-1 in Appendix VII-A at the end of Chapter VII in the PEA. The estimates by year

reach a peak of \$3.5 billion in the 60th year. Note that, by using a 60-year time-period, OSHA is not including any monetized fatality benefits associated with reduced worker CBD cases originating after year 40 because the 20-year lag takes these CBD fatalities beyond the 60-year time horizon. To this extent, OSHA will have underestimated benefits.)

As shown in Table IX-12, the full range of monetized benefits, undiscounted, for the proposed PEL of 0.2  $\mu\text{g}/\text{m}^3$  runs from \$291 million annually, in the case of the lowest estimate of prevented cases of CBD, and the lowest valuation for morbidity, up to \$2.1 billion annually, for the highest of both. Note that the value of total benefits is more sensitive to the prevention factor used (ranging from \$430 million to \$1.6 billion, given estimates at the midpoint of the morbidity valuation) than to the valuation of morbidity (ranging from \$666 million to \$1.3 billion, given estimates at the midpoint of prevention factor).

Also, the analysis illustrates that most of the morbidity benefits are related to CBD and lung cancer cases that are ultimately fatal. At the valuation and case frequency midpoint, \$663 million in benefits are related to mortality, \$226 million are related to morbidity preceding mortality, and \$4.3 million are related to morbidity not preceding mortality.

TABLE IX-12

Estimated Annualized Undiscounted Monetized Benefits of the Beryllium Proposal for Morbidity and Mortality

PEL	0.1 µg/m <sup>3</sup>			0.2 µg/m <sup>3</sup>			0.5 µg/m <sup>3</sup>		
	Valuation			Valuation			Valuation		
	Low	Midpoint	High	Low	Midpoint	High	Low	Midpoint	High
Cases									
Fatalities - Total									
Low	\$308,027,593	\$308,027,593	\$308,027,593	\$285,909,109	\$285,909,109	\$285,909,109	\$272,760,749	\$272,760,749	\$272,760,749
Midpoint	\$666,610,424	\$666,610,424	\$666,610,424	\$653,373,439	\$653,373,439	\$653,373,439	\$458,581,095	\$458,581,095	\$458,581,095
High	\$1,025,193,255	\$1,025,193,255	\$1,025,193,255	\$1,020,660,530	\$1,020,660,530	\$1,020,660,530	\$644,401,440	\$644,401,440	\$644,401,440
Morbidity Preceding Mortality - CBD and lung cancer deaths									
Low	\$3,765,360	\$153,711,707	\$303,658,053	\$3,495,142	\$142,680,735	\$281,866,327	\$3,343,232	\$136,479,355	\$269,615,478
Midpoint	\$8,431,448	\$344,193,474	\$679,955,500	\$8,274,496	\$337,786,267	\$667,298,039	\$5,761,234	\$235,188,453	\$464,615,672
High	\$13,097,537	\$534,675,242	\$1,056,252,947	\$13,053,849	\$532,891,800	\$1,052,729,751	\$8,179,237	\$333,897,551	\$659,615,865
Morbidity Not Preceding Mortality									
Low	\$1,869,166	\$1,869,166	\$1,869,166	\$1,733,636	\$1,733,636	\$1,733,636	\$1,665,847	\$1,665,847	\$1,665,847
Midpoint	\$4,381,675	\$4,381,675	\$4,381,675	\$4,307,133	\$4,307,133	\$4,307,133	\$2,967,849	\$2,967,849	\$2,967,849
High	\$7,320,735	\$7,320,735	\$7,320,735	\$7,306,343	\$7,306,343	\$7,306,343	\$4,321,800	\$4,321,800	\$4,321,800
TOTAL									
Low	\$313,662,119	\$463,608,465	\$613,554,812	\$291,137,887	\$430,323,479	\$569,509,072	\$277,769,829	\$410,905,952	\$544,042,075
Midpoint	\$679,423,547	\$1,015,185,573	\$1,350,947,599	\$665,955,068	\$995,466,840	\$1,324,978,612	\$467,310,178	\$696,737,396	\$926,164,615
High	\$1,045,611,526	\$1,567,189,232	\$2,088,766,937	\$1,041,020,722	\$1,560,858,673	\$2,080,696,625	\$656,902,477	\$982,620,791	\$1,308,339,106

Source: Office of Regulatory Analysis, Directorate of Standards & Guidance

b. Adjustment of WTP Estimates to Reflect Rising Real Income Over Time  
 OSHA's estimates of the monetized benefits of the proposed rule are based

on the imputed value of each avoided fatality and each avoided beryllium-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 \$8.7 million in 2010 dollars) and to avoid a beryllium-related disease (with an imputed value per disease avoided of between \$62,000



and \$5 million in 2010 dollars). To this point, these imputed values have been assumed to remain constant over time. However, two related factors suggest that these values will tend to increase over time.

First, economic theory indicates 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. 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 and in relatively fixed or limited supply. 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) is not subject to the same type of diminishing returns—implying that an effective way to increase lifetime utility is by extending one's life and maintaining one's good health (Hall and Jones, 2007).

Second, real per capita income has broadly been increasing throughout U.S. history, including recent periods. 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),<sup>36</sup> 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). More important is the fact that real U.S. per capita income is projected to grow significantly in future years. For example, the Annual Energy Outlook (AEO) projections, prepared by the Energy Information Administration (EIA) in the Department of Energy (DOE), show an average annual growth rate of per capita income in the United States of 2.7 percent for the period 2011–2035.<sup>37</sup> The U.S. Environmental Protection Agency prepared its economic analysis of the Clean Air Act using the AEO projections. OSHA believes that it is reasonable to use the same AEO projections employed by DOE and EPA, and correspondingly projects that per capita income in the

United States will increase by 2.7 percent a year.

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 proposed rule to reflect the anticipated increase in their value over time. This type of adjustment has been recognized by OMB (2003), supported by EPA's Science Advisory Board (EPA, 2000), and applied by EPA<sup>38</sup>. OSHA proposes to accomplish 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 proposed rule.

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 “ $\eta$ ” 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.

Other, more indirect evidence comes from estimates in the economics literature of “ $\eta$ ”, the income elasticity of the value of a statistical life. Viscusi and Aldy (2003) performed a meta-analysis on 0.2 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. 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), 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 proposed rule and the fact that the projected increase in real per capita income in the United States has flattened in recent years and could flatten in the long run, OSHA suggests a conservative value for “ $k$ ” of approximately two percent a year. The Agency invites comment on this estimate and on estimates of the income elasticity of the value of a statistical life.

The Agency believes 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 proposed rule. Table IX–13, in the following section on discounting benefits, shows estimates of the monetized benefits of the proposed rule (under alternative discount rates) with this estimated increase in monetized benefits over time. The Agency invites comment on this adjustment to monetized benefits.

#### c. The Discounting of Monetized Benefits

As previously noted, the estimated stream of benefits arising from the proposed beryllium 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 beryllium exposure over their entire working lives and because of, in the case of lung cancer, a 10-year latency period between reduced exposure and a reduction in the probability of disease. An appropriate discount rate<sup>39</sup> is needed to reflect the timing of benefits over the 60-year period after the rule takes effect and to allow conversion to an equivalent steady stream of annualized benefits.

##### 1. Alternative Discount Rates for Annualizing Benefits

Following OMB (2003) guidelines, OSHA has estimated the annualized benefits of the proposed rule using separate discount rates of 3 percent and 7 percent. Consistent with the Agency's own practices in recent rulemakings, OSHA has also estimated, for benchmarking purposes, undiscounted benefits—that is, benefits using a zero percent discount rate.

<sup>39</sup> 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.

<sup>36</sup> 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).

<sup>37</sup> The EIA used DOE's National Energy Modeling System (NEMS) to produce the Annual Energy Outlook (AEO) projections (EIA, 2011). Future per capita GDP was calculated by dividing the projected real gross domestic product each year by the projected U.S. population for that year.

<sup>38</sup> See, for example, EPA (2003, 2008).

The question remains, what is the “appropriate” or “preferred” discount rate to use to monetize health benefits? The choice of discount rate is a controversial topic, one that has been the source of scholarly economic debate for several decades. However, in simplest terms, the basic choices involve a social opportunity cost of capital approach or social rate of time preference approach.

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, 1982, pp. 24–32).

The rate of time preference approach is intended to measure the tradeoff between current consumption and future consumption, or in the context of the proposed 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).

The 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, p. 33). 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.

In accordance with OMB Circular A–4 (2003), 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 Agency is interested in any evidence, theoretical or applied, that would inform the application of discount rates to the costs and benefits of a regulation.

## 2. Summary of Annualized Benefits under Alternative Discount Rates

Table IX–13 presents OSHA’s estimates of the sum of the annualized

benefits of the proposed rule, using alternative discount rates of 0, 3, and 7 percent, with the suggested adjustment for increasing monetized benefits in response to annual increases in per capita income over time.

Given that the stream of benefits extends out 60 years, the value of future benefits is sensitive to the choice of discount rate. The undiscounted benefits in Table IX–13 range from \$291 million to \$2.1 billion annually. Using a 7 percent discount rate, the annualized benefits range from \$60 million to \$591 million. As can be seen, going from undiscounted benefits to a 7 percent discount rate has the effect of cutting the annualized benefits of the proposed rule by about 74 percent.

Taken as a whole, the Agency’s best preliminary estimate of the total annualized benefits of the proposed rule—using a 3 percent discount rate with an adjustment for the increasing value of health benefits over time—is between \$158 million and \$1.2 billion, with a mid-point value of \$576 million.

<b>Table IX-13</b>				
<b>Total Annualized Monetized Benefits - Midpoint Estimates (\$Millions)</b>				
<b>(Quartile Model)</b>				
<b>PEL Option (<math>\mu\text{g}/\text{m}^3</math>)</b>				
<b>Discount Rate</b>				
	<b>0.1</b>	<b>0.2</b>	<b>0.5</b>	
<b>Low Estimates</b>				
Undiscounted (0%)	\$313.7	\$291.1	\$277.8	
Discounted at 3%	\$170.3	\$158.0	\$150.7	
Discounted at 7%	\$64.9	\$60.2	\$57.4	
<b>High Estimates</b>				
Undiscounted (0%)	\$2,088.8	\$2,080.7	\$1,308.3	
Discounted at 3%	\$1,250.0	\$1,245.2	\$782.8	
Discounted at 7%	\$593.3	\$591.1	\$371.3	
<b>Midpoint Estimates</b>				
Undiscounted (0%)	\$1,015.2	\$995.5	\$696.7	
Discounted at 3%	\$587.3	\$575.8	\$403.1	
Discounted at 7%	\$260.4	\$255.3	\$178.8	

Source: Office of Regulatory Analysis, Directorate of Standards and Guidance

#### Step 4: Net Benefits of the Proposed Rule

OSHA has estimated, in Table IX-14, the monetized and annualized net benefits of the proposed rule (with a PEL of  $0.2 \mu\text{g}/\text{m}^3$ ), based on the benefits and costs previously presented. Table IX-14 also provides estimates of annualized net benefits for alternative PELs of  $0.1$  and  $0.5 \mu\text{g}/\text{m}^3$ . Both the proposed rule and the alternatives PEL options have the same ancillary provisions and an action level equal to half of the PEL in both cases.

Table IX-14 is being provided for informational purposes only. 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 net benefits has not been used by OSHA as the basis for its decision concerning the choice of a PEL or of other ancillary requirements for the proposed beryllium rule.

Table IX-14 shows net benefits using alternative discount rates of 0, 3, and 7 percent for benefits and costs, having previously included an adjustment to monetized benefits to reflect increases in real per capita income over time. OSHA has relied on a uniform discount rate applied to both costs and benefits. The Agency is interested in any evidence, theoretical or applied, that would support or refute the application of differential discount rates to the costs and benefits of a regulation.

As previously noted in this section, 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 3 percent discount rate, declining by over half under all scenarios. (Conversely, as noted in Chapter V of the PEA, the choice of discount rate for annualizing costs has a relatively minor effect on annualized costs.)

Based on the results presented in Table IX-14, OSHA finds:

- While the net benefits of the proposed rule vary considerably—depending on the choice of discount rate used to annualize benefits and on whether the benefits being used are in the high, midpoint, or low range—benefits exceed costs for the proposed  $0.2 \mu\text{g}/\text{m}^3$  PEL in all cases that OSHA considered.

• The Agency's best estimate of the net annualized benefits of the proposed rule—using a uniform discount rate for both benefits and costs of 3 percent—is

between \$120 million and \$1.2 billion, with a midpoint value of \$538 million.

• The alternative of a 0.5  $\mu\text{g}/\text{m}^3$  PEL has lower net benefits under all assumptions, whereas the effect on net

benefits of the 0.1  $\mu\text{g}/\text{m}^3$  PEL is mixed, relative to the proposed 0.2  $\mu\text{g}/\text{m}^3$  PEL. However, for these alternative PELs, benefits were also found to exceed costs in all cases that OSHA considered.

PEL		0.1	0.2	0.5
	<b>Discount Rate</b>			
	<b>Range</b>			
Undiscounted (0%)	Low	\$271.1	\$254.6	\$245.5
	Midpoint	\$972.6	\$958.9	\$664.4
	High	\$2,046.2	\$2,044.2	\$1,276.0
Discounted at 3%	Low	\$126.5	\$120.4	\$117.6
	Midpoint	\$543.5	\$538.2	\$370.0
	High	\$1,206.3	\$1,207.6	\$749.6
Discounted at 7%	Low	\$19.5	\$21.0	\$23.0
	Midpoint	\$214.9	\$216.2	\$144.4
	High	\$547.8	\$552.0	\$336.9

Source: Office of Regulatory Analysis, Directorate of Standards & Guidance

#### Incremental Benefits of the Proposed 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 proposed PEL and the alternative PELs. Again, OSHA has conducted these calculations for informational purposes only and has not used these results as the basis for selecting the PEL for the proposed rule.

OSHA provides, in Table IX-15, estimates of the net benefits of the alternative 0.1 and 0.5  $\mu\text{g}/\text{m}^3$  PELs. The incremental costs, benefits, and net benefits of meeting a 0.5  $\mu\text{g}/\text{m}^3$  PEL and then going to a 0.2  $\mu\text{g}/\text{m}^3$  PEL (as well as meeting a 0.2  $\mu\text{g}/\text{m}^3$  PEL and then going to a 0.1  $\mu\text{g}/\text{m}^3$  PEL—which the Agency has not yet determined is

feasible), for alternative discount rates of 3 and 7 percent, are presented in Table IX-15. Table IX-15 breaks out costs by provision and benefits by type of disease and by morbidity/mortality. As Table IX-15 shows, at a discount rate of 3 percent, a PEL of 0.2  $\mu\text{g}/\text{m}^3$ , relative to a PEL of 0.5  $\mu\text{g}/\text{m}^3$ , imposes additional costs of \$4.4 million per year; additional benefits of \$172.7 million per year; and additional net benefits of \$168.2 million per year. The proposed PEL of 0.2  $\mu\text{g}/\text{m}^3$  also has higher net benefits, relative to a PEL of 0.5  $\mu\text{g}/\text{m}^3$ , using a 7 percent discount rate.

Table IX-15 demonstrates that, regardless of discount rate, there are net benefits to be achieved by lowering exposures from the current PEL of 2.0  $\mu\text{g}/\text{m}^3$  to 0.5  $\mu\text{g}/\text{m}^3$  and then, in turn, lowering them further to 0.2  $\mu\text{g}/\text{m}^3$ . However, the majority of the benefits

and costs attributable to the proposed rule are from the initial effort to lower exposures to 0.5  $\mu\text{g}/\text{m}^3$ . Consistent with the previous analysis, net benefits decline across all increments as the discount rate for annualizing benefits increases. As also shown in Table IX-15, there is a slight positive net incremental benefit from going from a PEL of 0.2  $\mu\text{g}/\text{m}^3$  to 0.1  $\mu\text{g}/\text{m}^3$  for a discount rate of 3 percent, and a slight negative net increment for a discount rate of 7 percent. (Note that these results are for OSHA's midpoint estimate of benefits, although as indicated in Table IX-14, this is not universal across all estimation parameters.)

In addition to examining alternative PELs, OSHA also examined alternatives to other provisions of the standard. These regulatory alternatives are discussed Section IX.H of this preamble.

Table IX-15: Annualized Costs, Benefits and Incremental Benefits of OSHA's Proposed Beryllium Standard of of 0.1 µg/m3 and 0.5 µg/m3 PEL Alternative Millions (\$2010)

	Alternative 4 (PEL = 0.1 µg/m <sup>3</sup> , AL = 0.05 µg/m <sup>3</sup> )		Alternative 4 Incremental Costs/Benefits		Proposed PEL		Alternative 5 Incremental Costs/Benefits		Alternative 5 (PEL = 0.5 µg/m <sup>3</sup> , AL = 0.25 µg/m <sup>3</sup> )						
	3%	7%	3%	7%	3%	7%	3%	7%	3%	7%					
<b>Discount Rate</b>															
<b>Annualized Costs</b>															
Control Costs	\$12.9	\$13.9	\$3.3	\$3.5	\$9.5	\$10.3	\$3.6	\$3.9	\$6.0	\$6.5					
Respirators	\$0.7	\$0.7	\$0.4	\$0.5	\$0.2	\$0.3	\$0.1	\$0.1	\$0.1	\$0.1					
Exposure Assessment	\$3.8	\$3.9	\$1.6	\$1.5	\$2.2	\$2.4	\$0.3	\$0.3	\$1.9	\$2.1					
Regulated Areas	\$0.9	\$0.9	\$0.3	\$0.3	\$0.6	\$0.7	\$0.3	\$0.3	\$0.3	\$0.4					
Medical Surveillance	\$3.0	\$3.1	\$0.1	\$0.1	\$2.9	\$3.0	\$0.1	\$0.1	\$2.8	\$2.9					
Medical Removal	\$0.4	\$0.5	\$0.3	\$0.3	\$0.1	\$0.2	\$0.1	\$0.1	\$0.1	\$0.1					
Exposure Control Plan	\$1.8	\$1.8	\$0.0	\$0.0	\$1.8	\$1.8	\$0.0	\$0.0	\$1.8	\$1.8					
Protective Clothing and Equipment	\$1.4	\$1.4	\$0.0	\$0.0	\$1.4	\$1.4	\$0.0	\$0.0	\$1.4	\$1.4					
Hygiene Areas and Practices	\$0.6	\$0.6	\$0.2	\$0.2	\$0.4	\$0.4	\$0.0	\$0.0	\$0.4	\$0.4					
Housekeeping	\$12.6	\$12.9	\$0.0	\$0.0	\$12.6	\$12.9	\$0.0	\$0.0	\$12.6	\$12.9					
Training	\$5.8	\$5.8	\$0.0	\$0.0	\$5.8	\$5.8	\$0.0	\$0.0	\$5.8	\$5.8					
<b>Total Annualized Costs (point estimate)</b>	<b>\$43.7</b>	<b>\$45.5</b>	<b>\$6.1</b>	<b>\$6.3</b>	<b>\$37.6</b>	<b>\$39.1</b>	<b>\$4.4</b>	<b>\$4.8</b>	<b>\$33.2</b>	<b>\$34.4</b>					
<b>Annual Benefits: Number of Cases Prevented</b>	<b>Cases</b>		<b>Cases</b>		<b>Cases</b>		<b>Cases</b>		<b>Cases</b>						
Fatal Lung Cancers (midpoint estimate)	4		0		4		0		4						
Fatal Chronic Beryllium Disease	94		2		92		29		63						
Beryllium-Related Mortality	98	\$584.4	\$258.8	2	\$11.1	\$4.9	96	\$573.0	\$253.7	29	\$171.8	\$76.1	67	\$401.2	\$177.7
Beryllium Morbidity	50	\$2.9	\$1.6	1	\$0.0	\$0.0	50	\$2.8	\$1.6	15	\$0.9	\$0.5	34	\$2.0	\$1.1
<b>Monetized Annual Benefits (midpoint estimate)</b>	<b>\$587.3</b>	<b>\$260.4</b>	<b>\$11.2</b>	<b>\$5.1</b>	<b>\$575.8</b>	<b>\$255.3</b>	<b>\$172.7</b>	<b>\$76.6</b>	<b>\$403.1</b>	<b>\$178.8</b>					
<b>Net Benefits</b>	<b>\$543.5</b>	<b>\$214.9</b>	<b>\$5.3</b>	<b>-\$1.3</b>	<b>\$538.2</b>	<b>\$216.2</b>	<b>\$168.2</b>	<b>\$71.8</b>	<b>\$370.0</b>	<b>\$144.4</b>					

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

Step 5: Sensitivity Analysis  
 In this section, OSHA presents the results of two different types of sensitivity analysis to demonstrate how

robust the estimates of net benefits are to changes in various cost and benefit parameters. 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. For both types of sensitivity analyses, OSHA used the annualized costs and benefits obtained from a three-percent discount rate as the reference point.

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 proposed 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 in a particular input parameter. For example, if the estimated time that employees need to

travel to (and from) medical screenings were doubled, the corresponding labor costs would 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 proposed rule. The results of the individual sensitivity tests are summarized in Table IX–16 and are described in more detail below.

In the first of these sensitivity tests, where OSHA doubled the estimated

portion of employees in need of protective clothing and equipment (PPE), essentially doubling the estimated baseline non-compliance rate (e.g., from 10 to 20 percent), and estimates of other input parameters remained unchanged, Table IX–16 shows that the estimated total costs of compliance would increase by \$1.4 million annually, or by about 3.7 percent, while net benefits would also decline by \$1.4 million annually, from \$538.2 million to \$536.8 million annually.

In a second sensitivity test, OSHA increased the estimated unit cost of ventilation from \$13.18 per cfm for most sectors to \$25 per cfm for most sectors. As shown in Table IX–16, if OSHA’s estimates of other input parameters remained unchanged, the total estimated costs of compliance would increase by \$2.0 million annually, or by about 5.3 percent, while net benefits would also decline by \$2.0 million annually, from \$538.2 million to \$536.2 million annually.

Table IX-16 Sensitivity Tests

Uncertainty Scenarios	Change from OSHA's Primary Estimate	Difference From Primary Estimate	Percentage Impact on Costs or Benefits	Total Annualized Cost or Benefit	Net Benefit
<b>Cost Scenarios</b>					
Proposed Rule - OSHA's best estimate	NA	\$0	0.0%	\$37,597,325	\$538,229,309
Reduced PPE Compliance Rates	Double PPE non-compliance rates	\$1,385,575	3.7%	\$38,982,900	\$536,843,733
Increased CFM Unit Cost	Increase CFM Unit Cost to \$25 for most sectors	\$1,993,863	5.3%	\$39,591,188	\$536,235,445
Increased share of workers showing signs and symptoms	Increase share of workers showing signs and symptoms to 25%	\$1,545,310	4.1%	\$39,142,635	\$536,683,999
Increased housekeeping	Increase the estimated incremental time per worker for housekeeping by 50%	\$5,429,113	14.4%	\$43,026,437	\$532,800,196
Increased establishment-based costs	For establishment-based costs, increased the number of affected establishments by up to 100%	\$4,483,148	11.9%	\$42,080,472	\$533,746,161
<b>Benefit Scenarios</b>					
Proposed Rule - OSHA's best estimate	NA	\$0	0.0%	\$575,826,633	\$538,229,309
Low morbidity valuation	Benefits estimated using low morbidity value	-\$216,839,627	-37.7%	\$358,987,006	\$321,389,682
High morbidity valuation	Benefits estimated using high morbidity value	\$443,411,757	77.0%	\$1,019,238,390	\$981,641,066
Remove adjustment for future valuation of benefits (due to positive income elasticity of health benefits)	Set the growth in future benefits to 0.0%	-\$314,319,477	-54.6%	\$261,507,156	\$223,909,831

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

In a third sensitivity test, OSHA increased the estimated share of workers showing signs and symptoms of CBD from 15 to 25 percent, thereby adding these workers to the group eligible for medical surveillance and assuming that they would not be otherwise eligible for

another reason (working in a regulated area, exposed during an emergency, etc.). As shown in Table IX-16, if OSHA's estimates of other input parameters remained unchanged, the total estimated costs of compliance would increase by \$1.5 million

annually, or by about 4.1 percent, while net benefits would also decline by \$1.5 million annually, from \$538.2 million to \$536.7 million annually.

In a fourth sensitivity test, OSHA increased its estimated incremental time per workers for housekeeping by 50

percent. As shown in Table IX–16, if OSHA's estimates of other input parameters remained unchanged, the total estimated costs of compliance would increase by \$5.4 million annually, or by about 14.4 percent, while net benefits would also decline by \$5.4 million annually, from \$538.2 million to \$532.8 million annually.

In a fifth sensitivity test, OSHA increased the estimated number of establishments needing engineering controls. For this sensitivity test, if less than 50 percent of the establishments in an industry needed engineering controls, OSHA doubled the percentage of establishments needing engineering controls. If more than 50 percent of establishments in an industry needed engineering controls, then OSHA increased the percentage of establishment needing engineering control to 100 percent. The purpose of this sensitivity analysis was to check the importance of using a methodology that treated 50 percent of workers in a given occupation exposed above the PEL as equivalent to 50 percent of facilities lacking adequate exposure controls. As shown in Table IX–16, if OSHA's estimates of other input parameters remained unchanged, the total estimated costs of compliance would increase by \$4.5 million, or by about 11.9 percent, while net benefits would also decline by \$4.5 million, from \$538.2 million to \$533.7 million annually.

The Agency also performed sensitivity tests on several input parameters used to estimate the benefits of the proposed rule. In the first two tests, in an extension of results previously presented in Table IX–12, 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, specifically examining the effect on undiscounted benefits of varying the valuation of individual morbidity cases. Table IX–16 presents the effect on annualized net benefits of using the extreme values of these ranges: the high morbidity valuation case and the low morbidity valuation case. For the low estimate of valuation, the benefits decline by 37.7 percent, to \$359 million annually, yielding net benefits of \$321 million annually. As shown, using the high estimate of morbidity valuation, the benefits rise by 77.0 percent to \$1.0 billion annually, yielding net benefits of \$982 million annually.

In a third sensitivity test of benefits, the Agency examined the effect of removing the component for the estimated rising value of health and safety over time. This would reduce the

benefits by 54.6 percent, or \$314 million annually, lowering the net benefits to \$224 million annually.

In Chapter VII of the PEA the Agency examined the effect of raising the discount rate for costs and benefits to 7 percent. Raising the discount rate to 7 percent would increase costs by \$1.5 million annually and lower benefits by \$320.5 million annually, yielding annualized net benefits of \$216.2 million.

Also in Chapter VII of the PEA the Agency performed a sensitivity analysis of dental lab substitution. In the PEA, OSHA estimates that 75 percent of the dental laboratory industry will react to a new standard on beryllium by substituting away from using beryllium to the use of other materials. Substitution is not costless, and Chapter V of the PEA estimates the increased cost due to the higher costs of using non-beryllium alloys. These costs are smaller than the avoided costs of the ancillary provisions and engineering controls. Thus, as indicated in Table VII–8 of the PEA, the benefits of the proposal would be lower and the costs higher if there were less substitution out of beryllium in dental labs. The lowest net benefits would occur if labs were unable to substitute out beryllium-containing materials at all, and had to use ventilation to control exposures. In this case, the proposal would yield only \$420 million in net benefits. The highest net benefits, larger than assumed for OSHA's primary estimate, would be if all dental labs substituted out of beryllium-containing materials as a result of the proposal; as a result, the proposal would yield \$573 million in net benefits. Another possibility is a scenario in which technology and the market move along rapidly away from using beryllium-containing materials, independently of an OSHA rule, and the proposal itself would therefore produce neither costs nor benefits in this sector. If dental labs are removed from the PEA, the net benefits for the proposal—for the remaining industry sectors—decline to \$284 million. This analysis demonstrates, however, that regardless of any assumption regarding substitution in dental labs, the proposal would generate substantially more monetized benefits than costs.

Finally, the Agency examined in Chapter VII of the PEA the effects of changes in two important inputs to the benefits analysis: the factor that transforms CBD prevalence rates into incidence rates, needed for the equilibrium lifetime risk model, and the percentage of CBD cases that eventually lead to a fatality.

From the Cullman dataset, the Agency has estimated the prevalence of CBD cases at any point in time as a function of cumulative beryllium exposure. In order to utilize the lifetime risk model, which tracks workers over their working life in a job, OSHA has turned these prevalence rates into an incidence rate, which is the rate of contracting CBD at a point in time. OSHA's baseline estimate of the turnover rate in the model is 10 percent. In Table VII–10 in the PEA, OSHA also presented alternative turnover rates of 5 percent and 20 percent. A higher turnover rate translates into a higher incidence rate, and the table shows that, from a baseline midpoint estimate with 10 percent turnover the number of CBD cases prevented is 6,367, while raising the turnover rate to 20 percent causes this midpoint estimate to rise to 11,751. Conversely, a rate of 5 percent lowers the number of CBD cases prevented to 3,321. Translated into monetary benefits, the table shows that the baseline midpoint estimate of \$575.8 million now ranges from \$314.4 million to \$1,038 million.

Also in Table VII–10 of the PEA, the Agency looked at the effects of varying the percentage of CBD cases that eventuate in fatality. The Agency's baseline estimate of this outcome is 65 percent, with half of this occurring relatively soon, and the other half after an extended debilitating condition. The Agency judged that a reasonable range to investigate was a low of 50 percent and a high of 80 percent, while maintaining the shares of short-term and long-term endpoint fatality. At a baseline of 65 percent, the midpoint estimate of total CBD cases prevented is 4,139. At the low end of 50 percent mortality this estimate lowers to 3,183 while at the high end of 80 percent mortality this estimate rises to 5,094. Translated into monetary benefits, the table shows that the baseline midpoint estimate of \$575.8 million now ranges from \$500.1 million to \$651.5 million.

#### b. "Break-Even" Analysis

OSHA also performed sensitivity tests on several other parameters used to estimate the net costs and benefits of the proposed 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 IX–17.

In one break-even test on cost estimates, OSHA examined how much total costs would have to increase in order for costs to equal benefits. As shown in Table IX–17, this point would



be reached if costs increased by \$538.2 million, or by 1,431 percent.

In a second test, looking specifically at the estimated engineering control costs, the Agency found that these costs would need to increase by \$566.7 million, or 6,240 percent, for costs to equal 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 the estimated costs of \$38 million, 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.

The Agency, 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 IX-17, a 94 percent reduction in the monetized value of all avoided illnesses and fatalities would be necessary for costs to equal benefits, reducing the estimated value to \$733,303 per fatality prevented, and an equivalent percentage reduction to about \$4,048 per illness prevented.

In a fourth break-even sensitivity test, OSHA estimated how many fewer beryllium-related fatalities and illnesses would be required for benefits to equal costs. Paralleling the previous discussion, eliminating either the prevented mortality or morbidity cases alone would be insufficient to lower benefits to the break-even point. The Agency therefore examined them as a group. As shown in Table IX-17, a reduction of 96 percent, for both simultaneously, is required to reach the break-even point—90 fewer fatalities prevented annually, and 46 fewer beryllium-related illnesses-only cases prevented annually.

Taking into account both types of sensitivity analysis the Agency performed on its point estimates of the annualized costs and annualized benefits of the proposed rule, the results demonstrate that net benefits would be positive in all plausible cases tested. In particular, this finding would hold even with relatively large variations in individual input parameters. Alternately, one would have to imagine extremely large changes in costs or benefits for the rule to fail to produce net benefits. OSHA concludes that its finding of significant net benefits resulting from the proposed rule is a robust one.

OSHA welcomes input from the public regarding all aspects of this sensitivity analysis, including any data or information regarding the accuracy of the preliminary estimates of compliance costs and benefits and how the estimates of costs and benefits may be affected by varying assumptions and methodological approaches. OSHA also invites comment on the risk analysis and risk estimates from which the benefits estimates were derived.

**Table IX-17**  
**Break-Even Sensitivity Analysis**

	OSHA's Best Estimate of Annualized Cost or Benefit Factor	Factor Value at Which Benefits Equal Costs	Required Factor Dollar/Number Change	Percentage Factor Change
Total Costs	\$37,597,325	\$575,826,633	\$538,229,309	1431.6%
Engineering Control Costs	\$9,082,884	\$575,826,633	\$566,743,749	6239.7%
Benefits Valuation per Case Avoided				
Monetized Benefit per Fatality Avoided	\$11,231,000	\$733,303	-\$10,497,697	-93.5%
Monetized Benefit per Illness Avoided	\$62,000	\$4,048	-\$57,952	-93.5%
Cases Avoided				
Deaths Avoided	96	6	-90	-93.5%
Illnesses Avoided	50	3	-46	-93.5%

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

*H. Regulatory Alternatives*

This section discusses various regulatory alternatives to the proposed OSHA beryllium standard. Executive

Order 12866 instructs agencies to “select those approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages;

distributive impacts; and equity), unless a statute requires another regulatory approach.” The OSH Act, as interpreted by the courts, requires health regulations to reduce significant risk to

the extent feasible. Nevertheless OSHA has examined possible regulatory alternatives that may not meet its statutory requirements.

Each regulatory alternative presented here is described and analyzed relative to the proposed rule. Where appropriate, the Agency notes whether the regulatory alternative, to be a legitimate candidate for OSHA consideration, requires evidence contrary to the Agency's preliminary findings of significant risk and feasibility. To facilitate comment, OSHA has organized some two dozen specific regulatory alternatives into five categories: (1) Scope; (2) exposure limits; (3) methods of compliance; (4) ancillary provisions; and (5) timing.

### 1. Scope Alternatives

The first set of regulatory alternatives would alter scope of the proposed standard—that is, the groups of employees and employers covered by the proposed standard. The scope of the current beryllium proposal applies only to general industry work, and does not apply to employers when engaged in construction or maritime activities. In addition, the proposed rule provides an exemption for those working with materials that contain beryllium only as a trace contaminant (less than 0.1 percent composition by weight).<sup>40</sup>

As discussed in the explanation of paragraph (a) in Section XVIII of this preamble, Summary and Explanation of the Proposed Standard, OSHA is considering alternatives to the proposed scope that would increase the range of employers and employees covered by the standard. OSHA's review of several industries indicates that employees in some construction and maritime industries, as well as some employees who deal with materials containing less than 0.1 percent beryllium, may be at significant risk of CBD and lung cancer as a result of their occupational exposures. Regulatory Alternatives #1a, #1b, #2a, and #2b would increase the scope of the proposed standard to provide additional protection to these workers.

Regulatory Alternative #1a would expand the scope of the proposed standard to also include all operations in general industry where beryllium exists only as a trace contaminant; that is, where the materials used contain less than 0.1 percent beryllium by weight. Regulatory Alternative #1b is similar to Regulatory Alternative #1a, but exempts

operations where beryllium exists only as a trace contaminant and the employer can show that employees' exposures will not meet or exceed the action level or exceed the STEL. Where the employer has objective data demonstrating that a material containing beryllium or a specific process, operation, or activity involving beryllium cannot release beryllium in concentrations at or above the proposed action level or above the proposed STEL under any expected conditions of use, that employer would be exempt from the proposed standard except for recordkeeping requirements pertaining to the objective data. Alternative #1a and Alternative #1b, like the proposed rule, would not cover employers or employees in construction or shipyards.

OSHA has identified two industries with workers engaged in general industry work that would be excluded under the proposed rule but would fall within the scope of the standard under Regulatory Alternatives #1a and #1b: Primary aluminum production and coal-fired power generation. Beryllium exists as a trace contaminant in aluminum ore and may result in exposures above the proposed permissible exposure limits (PELs) during aluminum refining and production. Coal fly ash in coal-powered power plants is also known to contain trace amounts of beryllium, which may become airborne during furnace and baghouse operations and might also result in worker exposures. See Appendices VIII–A and VIII–B at the end of Chapter VIII in the PEA for a discussion of beryllium exposures and available controls in these two industries.

As discussed in Appendix IV–B of the PEA, beryllium exposures from fly ash high enough to exceed the proposed PEL would usually be coupled with arsenic exposures exceeding the arsenic PEL. Employers would in that case be required to implement all feasible engineering controls, work practices, and necessary PPE (including respirators) to comply with the OSHA Inorganic Arsenic standard (29 CFR 1910.1018)—which would be sufficient to comply with those aspects of the proposed beryllium standard as well. The degree of overlap between the applicability of the two standards and, hence, the increment of costs attributable to this alternative are difficult to gauge. To account for this uncertainty, the Agency at this time is presenting a range of costs for Regulatory Alternative #1a: From no costs being taken for ancillary provisions under Regulatory Alternative #1a to all such costs being included. At the low end, the only additional costs

under Regulatory Alternative #1a are due to the engineering control costs incurred by the aluminum smelters (see Appendix VIII–A).

Similarly, the proposed beryllium standard would not result in additional benefits from a reduction in the beryllium PEL or from ancillary provisions similar to those already in place for the arsenic standard, but OSHA does anticipate some benefits will flow from ancillary provisions unique to the proposed beryllium standard. To account for significant uncertainty in the benefits that would result from the proposed beryllium standard for workers in primary aluminum production and coal-fired power generation, OSHA estimated a range of benefits for Regulatory Alternative #1a. The Agency estimated that the proposed ancillary provisions would avert between 0 and 45 percent<sup>41</sup> of those baseline CBD cases not averted by the proposed PEL. Though the Agency is presenting a range for both costs and benefits for this alternative, the Agency judges the degree of overlap with the arsenic standard is likely to be substantial, so that the actual costs and benefits are more likely to be found at the low end of this range. The Agency invites comment on all these issues.

Table IX–18 presents, for informational purposes, the estimated costs, benefits, and net benefits of Regulatory Alternative #1a using alternative discount rates of 3 percent and 7 percent. In addition, this table presents the incremental costs, incremental benefits, and incremental net benefits of this alternative relative to the proposed rule. Table IX–18 also breaks out costs by provision, and benefits by type of disease and by morbidity/mortality.

As shown in Table IX–18, Regulatory Alternative #1a would increase the annualized cost of the rule from \$37.6 million to between \$39.6 and \$56.0 million using a 3 percent discount rate and from \$39.1 million to between \$41.3 and \$58.1 million using a 7 percent discount rate. OSHA estimates that regulatory Alternative #1a would prevent as few as an additional 0.3 (*i.e.*, almost one fatality every 3 years) or as many as an additional 31.8 beryllium-related fatalities annually, relative to the proposed rule. OSHA also estimates that Regulatory Alternative #1a would prevent as few as an additional 0.002 or as many as an additional 9 beryllium-related non-fatal illnesses annually, relative to the proposed rule. As a result, annualized benefits in monetized

<sup>40</sup> Employers engaged in general industry activities exempted from the proposed rule must still ensure that their employees are protected from beryllium exposure above the current PEL, as listed in 29 CFR 1910.1000 Table Z–2.

<sup>41</sup> As discussed in Chapter VII of the PEA, OSHA used 45 percent to develop its best estimate.

terms would increase from \$575.8 million to between \$578.0 and \$765.2 million, using a 3 percent discount rate, and from \$255.3 million to between \$256.3 and \$339.3 million using a 7 percent discount rate. Net benefits would increase from \$538.2 million to between \$538.4 and \$709.2 million using a 3 percent discount rate and from \$216.2 million to somewhere between \$215.1 to \$281.2 million using a 7 percent discount rate. As noted in Appendix VIII-B of Chapter VIII in the PEA, the Agency emphasizes that these estimates of benefits are subject to a significant degree of uncertainty, and the benefits associated with Regulatory Alternative #1a arguably could be a

small fraction of OSHA's best estimate presented here.

OSHA estimates that the costs and the benefits of Regulatory Alternative #1b will be somewhat lower than the costs of Regulatory Alternative #1a, because most—but not all—of the provisions of the proposed standard are triggered by exposures at the action level, 8-hour time-weighted average (TWA) PEL, or STEL. For example, where exposures exist but are below the action level and at or below the STEL, Alternative #1a would require employers to establish work areas; develop, maintain, and implement a written exposure control plan; provide medical surveillance to employees who show signs or

symptoms of CBD; and provide PPE in some instances. Regulatory Alternative #1b would not require employers to take these measures in operations where they can produce objective data demonstrating that exposures are below the action level and at or below the STEL. OSHA only analyzed costs, not benefits, for this alternative, consistent with the Agency's treatment of Regulatory Alternatives in the past. Total costs for Regulatory Alternative #1b versus #1a, assuming full ancillary costs, drop from to \$56.0 million to \$49.9 million using a 3 percent discount rate, and from \$58.1 million to \$51.8 million using a 7 percent discount rate.

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Table IX-18: Annualized Costs, Benefits and Incremental Benefits of OSHA's Proposed Beryllium Standard of Alternative Scope  
Millions (\$2010)

Discount Rate	Alternative 1a (Include trace contaminants)		Alternative 1a Incremental Costs/Benefits		Proposed PEL (PEL = 0.2 µg/m <sup>3</sup> , AL = 0.10 µg/m <sup>3</sup> )	
	3%	7%	3%	7%	3%	7%
<b>Annualized Costs</b>						
Control Costs	\$10.8 - \$10.8	\$11.7 - \$11.7	\$1.3 - \$1.3	\$1.3 - \$1.3	\$9.5	\$10.3
Respirators	\$0.3 - \$0.3	\$0.3 - \$0.3	\$0.0 - \$0.0	\$0.0 - \$0.0	\$0.2	\$0.3
Exposure Assessment	\$2.3 - \$3.8	\$2.5 - \$4.1	\$0.1 - \$1.5	\$0.1 - \$2.1	\$2.2	\$2.4
Regulated Areas and Beryllium Work Areas	\$0.7 - \$0.7	\$0.7 - \$0.7	\$0.0 - \$0.1	\$0.0 - \$0.1	\$0.6	\$0.7
Medical Surveillance	\$3.0 - \$4.3	\$3.1 - \$4.5	\$0.1 - \$1.5	\$0.7 - \$2.7	\$2.9	\$3.0
Medical Removal	\$0.2 - \$0.3	\$0.2 - \$0.3	\$0.0 - \$0.1	\$0.0 - \$0.1	\$0.1	\$0.2
Exposure Control Plan	\$1.8 - \$2.8	\$1.8 - \$2.8	\$0.0 - \$1.0	\$0.0 - \$1.3	\$1.8	\$1.8
Protective Clothing and Equipment	\$1.4 - \$1.4	\$0.0 - \$0.0	\$0.0 - \$0.0	\$0.2 - \$0.2	\$1.4	\$1.4
Hygiene Areas and Practices	\$0.4 - \$0.4	\$0.4 - \$0.4	\$0.0 - \$0.0	\$0.0 - \$0.0	\$0.4	\$0.4
Housekeeping	\$12.9 - \$21.4	\$13.3 - \$22.0	\$0.4 - \$6.8	\$0.4 - \$10.9	\$12.6	\$12.9
Training	\$6.0 - \$9.9	\$6.0 - \$9.9	\$0.2 - \$4.1	\$0.2 - \$4.9	\$5.8	\$5.8
<b>Total Annualized Costs (point estimate)</b>	<b>\$39.6 - \$56.0</b>	<b>\$41.3 - \$58.1</b>	<b>\$2.0 - \$18.4</b>	<b>\$0.1 - \$17.9</b>	<b>\$37.6</b>	<b>\$39.1</b>
<b>Annual Benefits: Number of Cases Prevented</b>	<b>Cases</b>		<b>Cases</b>		<b>Cases</b>	
Fatal Lung Cancers (midpoint estimate)	4.1 - 4.1		0.1 - 0.1		4	
Fatal Chronic Beryllium Disease	92.1 - 123.7		0.2 - 31.7		92	
Beryllium-Related Mortality	96.3 - 127.8	\$575.0 - \$761.4	0.3 - 31.8	\$2.0 - \$188.4	96	\$573.0 - \$253.7
Beryllium Morbidity	49.5 - 58.5	\$3.0 - \$3.8	0.0 - 9.0	\$0.2 - \$1.0	50	\$2.8 - \$1.6
<b>Monetized Annual Benefits (midpoint estimate)</b>	<b>\$578.0 - \$765.2</b>	<b>\$256.3 - \$339.3</b>	<b>\$2.2 - \$189.4</b>	<b>\$1.0 - \$84.0</b>	<b>\$575.8</b>	<b>\$255.3</b>
<b>Net Benefits</b>	<b>\$538.4 - \$709.2</b>	<b>\$215.1 - \$281.2</b>	<b>\$0.2 - \$171.0</b>	<b>\$-1.1 - \$85.0</b>	<b>\$538.2</b>	<b>\$216.2</b>

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.

Regulatory Alternative #2a would expand the scope of the proposed

standard to include employers in construction and maritime. For

example, this alternative would cover abrasive blasters, pot tenders, and

cleanup staff working in construction and shipyards who have the potential for airborne beryllium exposure during blasting operations and during cleanup of spent media. Regulatory Alternative #2b would update 29 CFR 1910.1000 Tables Z-1 and Z-2, 1915.1000 Table Z, and 1926.55 Appendix A so that the proposed TWA PEL and STEL would apply to all employers and employees in general industry, shipyards, and construction, including occupations where beryllium exists only as a trace contaminant. For example, this alternative would cover abrasive blasters, pot tenders, and cleanup staff working in construction and shipyards who have the potential for significant airborne exposure during blasting operations and during cleanup of spent media. The changes to the Z tables would also apply to workers exposed to beryllium during aluminum refining and production, and workers engaged in maintenance operations at coal-powered utility facilities. All provisions of the standard other than the PELs, such as exposure monitoring, medical removal, and PPE, would be in effect only for employers and employees that fall within the scope of the proposed rule.<sup>42</sup> Alternative #2b would not be as protective as Alternative #1a or Alternative #1b for employees in aluminum refining and production or coal-powered utility facilities because the other provisions of the proposed standard would not apply.

As discussed in the explanation of proposed paragraph (a) in this preamble at Section XVIII, Summary and Explanation of the Proposed Standard, abrasive blasting is the primary application group in construction and maritime industries where workers may be exposed to beryllium. OSHA has judged that abrasive blasters and their helpers in construction and maritime industries have the potential for significant airborne exposure during blasting operations and during cleanup of spent media. Airborne concentrations of beryllium have been measured above the current TWA PEL of 2 µg/m<sup>3</sup> when blast media containing beryllium are used as intended (see Appendix IV-C in the PEA for details).

To address high concentrations of various hazardous chemicals in abrasive blasting material, employers must

already be using engineering and work practice controls to limit workers' exposures and must be supplementing these controls with respiratory protection when necessary. For example, abrasive blasters in the construction industry fall under the protection of the Ventilation standard (29 CFR 1926.57). The Ventilation standard includes an abrasive blasting subsection (29 CFR 1926.57(f)), which requires that abrasive blasting respirators be worn by all abrasive blasting operators when working inside blast-cleaning rooms (29 CFR 1926.57(f)(5)(ii)(A)), or when using silica sand in manual blasting operations where the nozzle and blast are not physically separated from the operator in an exhaust-ventilated enclosure (29 CFR 1926.57(f)(5)(ii)(B)), or when needed to protect workers from exposures to hazardous substances in excess of the limits set in § 1926.55 (29 CFR 1926.57(f)(5)(ii)(C); ACGIH, 1971). For maritime, standard 29 CFR 1915.34(c) covers similar requirements for respiratory protection needed in blasting operations. Due to these requirements, OSHA believes that abrasive blasters already have controls in place and wear respiratory protection during blasting operations. Thus, in estimating costs for Regulatory Alternatives #2a and #2b, OSHA judged that the reduction of the TWA PEL would not impose costs for additional engineering controls or respiratory protection in abrasive blasting (see Appendix VIII-C of Chapter VIII in the PEA for details). OSHA requests comment on this issue—in particular, whether abrasive blasters using blast material that may contain beryllium as a trace contaminant are already using all feasible engineering and work practice controls, respiratory protection, and PPE that would be required by Regulatory Alternatives #2a and #2b.

In the estimation of benefits for Regulatory Alternative #2a, OSHA has estimated a range to account for significant uncertainty in the benefits to this population from some of the ancillary provisions of the proposed beryllium standard. It is unclear how many of the workers associated with abrasive blasting work would benefit from dermal protection, as comprehensive dermal protection may already be used by most blasting operators. It is also unclear whether the housekeeping requirements of the proposed standard would be feasible to implement in the context of abrasive blasting work, and to what extent they would benefit blasting helpers, who are themselves exposed while performing

cleanup activities. OSHA estimated that the proposed ancillary provisions would avert between 0 and 45 percent of those baseline CBD cases not averted by the proposed PEL.

These considerations also lead the Agency to present a range for the costs of this alternative: From no costs being estimated for ancillary provisions under Regulatory Alternative #2a to including all such costs. Based on the considerations discussed above, the Agency judges that costs and benefits at the low end of this range are more likely to be correct. The Agency invites comment on these issues.

In addition, OSHA believes that a small number of welders in the maritime industry may be exposed to beryllium via arc and gas welding (and none through resistance welding). The number of maritime welders was estimated using the same methodology as was used to estimate the number of general industry welders. Brush Wellman's customer survey estimated 2,000 total welders on beryllium-containing products (Kolanz, 2001). Based on ERG's assumption of 4 welders per establishment, ERG estimated that a total of 500 establishments would be affected. These affected establishments were then distributed among the 26 NAICS industries with the highest number of IMIS samples for welders that were positive for beryllium. To do this, ERG first consulted the BLS OES survey to determine what share of establishments in each of the 26 NAICS employed welders and estimated the total number of establishments that perform welding regardless of beryllium exposure (BLS, 2010a). Then ERG distributed the 500 affected beryllium welding facilities among the 26 NAICS based on the relative share of the total number of establishments performing welding. Finally, to estimate the number of welders, ERG used the assumption of four welders per establishment. Based on the information from ERG, OSHA estimated that 30 welders would be covered in the maritime industry under this regulatory alternative. For these welders, OSHA used the same controls and exposure profile that were used to estimate costs for arc and gas welders in Chapter V of the PEA. ERG judged there to be no construction welders exposed to beryllium due to a lack of any evidence that the construction sector uses beryllium-containing products or electrodes in resistance welding. OSHA solicits comment and any relevant data on beryllium exposures for welders in construction and maritime employment.

Estimated costs and benefits for Regulatory Alternative #2a are shown in Table IX-18a. Regulatory Alternative

<sup>42</sup> However, many of the occupations excluded from the scope of the proposed beryllium standard receive some ancillary provision protections from other rules, such as Personal Protective Equipment (29 CFR 1910 subpart I, 1915 subpart I, 1926.28, also 1926 subpart E), Ventilation (including abrasive blasting) (§§ 1926.57 and 1915.34), Hazard Communication (§ 1910.1200), and specific provisions for welding (parts 1910 subpart Q, 1915 subpart D, and 1926 subpart J).

#2a would increase costs from \$37.6 million to between \$37.7 and \$55.3 million, using a 3 percent discount rate, and from \$39.1 million to between \$39.2 and \$57.3 million using a 7 percent discount rate. Annualized benefits would increase from \$575.8 million to between \$575.9 and \$675.3 million using a 3 percent discount rate, and from \$255.3 million to between \$255.4 and \$299.4 million using a 7 percent discount rate. Net benefits would change from \$538.2 million to between \$538.2 and \$620.0 million using a 3 percent discount rate, and from \$216.2 million to between \$216.1 and \$242.1 million using a 7 percent discount rate.

Table IX–18b presents, for informational purposes, the estimated costs, benefits, and net benefits, of Regulatory Alternative #2b using alternative discount rates of 3 percent and 7 percent. In addition, this table presents the incremental costs, incremental benefits, and incremental net benefits of this alternative relative to the proposed rule. Table IX–18b also breaks out costs by provision and benefits by type of disease and by morbidity/mortality.

As shown in Table IX–18b, this regulatory alternative would increase the annualized cost of the rule from \$37.6 million to \$39.6 million, using a 3 percent discount rate, and from \$39.1

million to \$41.1 million using a 7 percent discount rate. Regulatory Alternative #2b would prevent less than one additional beryllium-related fatalities and less than one beryllium-related illness annually relative to the proposed rule. As a result, annualized benefits would increase from \$575.8 million to \$578.1 million, using a 3 percent discount rate, and from \$255.3 million to \$256.3 million using a 7 percent discount rate. Net benefits would increase from \$538.2 million to \$538.5 million using a 3 percent discount rate and slightly decrease from \$216.2 million to \$215.2 million using a 7 percent discount rate.

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Table IX-18a: Annualized Costs, Benefits and Incremental Benefits of OSHA's Proposed Beryllium Standard of Alternative Scope Including Maritime and Construction  
Millions (\$2010)

Discount Rate	Alternative 2a Include Maritime and Construction Sectors		Alternative 2a Include Maritime and Construction Sectors (Incremental costs and benefits)		Proposed PEL (PEL = 0.2 µg/m <sup>3</sup> , AL = 0.10 µg/m <sup>3</sup> )				
	3%	7%	3%	7%	3%	7%			
<b>Annualized Costs</b>									
Control Costs	\$9.8 - \$9.8	\$10.4 - \$10.4	\$0.0 - \$0.0	\$0.0 - \$0.0	\$9.5	\$10.3			
Respirators	\$0.3 - \$0.3	\$0.3 - \$0.3	\$0.0 - \$0.0	\$0.0 - \$0.0	\$0.2	\$0.3			
Exposure Assessment	\$2.2 - \$3.8	\$2.4 - \$4.0	\$0.0 - \$1.5	\$0.0 - \$1.6	\$2.2	\$2.4			
Regulated areas and Beryllium Work Areas	\$0.8 - \$1.4	\$0.7 - \$1.4	\$0.0 - \$0.7	\$0.0 - \$0.7	\$0.6	\$0.7			
Medical Surveillance	\$2.9 - \$6.2	\$3.0 - \$6.4	\$0.0 - \$3.3	\$0.0 - \$3.3	\$2.9	\$3.0			
Medical Removal	\$0.1 - \$0.5	\$0.2 - \$0.6	\$0.0 - \$0.4	\$0.0 - \$0.4	\$0.1	\$0.2			
Exposure Control Plan	\$1.8 - \$2.7	\$1.8 - \$2.8	\$0.0 - \$1.0	\$0.0 - \$1.0	\$1.8	\$1.8			
Protective Clothing and Equipment	\$1.4 - \$1.4	\$1.4 - \$1.4	\$0.0 - \$0.0	\$0.0 - \$0.0	\$1.4	\$1.4			
Hygiene Areas and Practices	\$0.4 - \$1.6	\$0.4 - \$1.6	\$0.0 - \$1.2	\$0.0 - \$1.1	\$0.4	\$0.4			
Housekeeping	\$12.8 - \$19.1	\$12.9 - \$19.6	\$0.0 - \$6.6	\$0.0 - \$6.7	\$12.6	\$12.9			
Training	\$5.8 - \$8.8	\$5.8 - \$8.9	\$0.0 - \$3.0	\$0.0 - \$3.0	\$5.8	\$5.8			
<b>Total Annualized Costs (point estimate)</b>	<b>\$37.7 - \$55.3</b>	<b>\$39.2 - \$57.3</b>	<b>\$0.1 - \$17.7</b>	<b>\$0.1 - \$17.9</b>	<b>\$37.6</b>	<b>\$39.1</b>			
<b>Annual Benefits: Number of Cases Prevented</b>	<b>Cases</b>		<b>Cases</b>		<b>Cases</b>				
Fatal Lung Cancers (midpoint estimate)	4.0 - 4.0		0.0 - 0.0		4				
Fatal Chronic Beryllium Disease	92.0 - 108.7		0.0 - 16.7		92				
Beryllium-Related Mortality	96.0 - 112.7	\$573.0 - \$671.9	\$253.8 - \$297.6	0.0 - 16.7	\$0.0 - \$99.0	\$0.0 - \$43.8	96	\$573.0	\$253.7
Beryllium Morbidity	49.5 - 58.5	\$2.8 - \$3.4	\$1.6 - \$1.9	0.0 - 9.0	\$0.0 - \$0.5	\$0.0 - \$0.3	50	\$2.8	\$1.6
<b>Monetized Annual Benefits (midpoint estimate)</b>	<b>\$575.9 - \$675.3</b>	<b>\$255.4 - \$299.4</b>	<b>\$0.0 - \$99.0</b>	<b>\$0.0 - \$44.1</b>	<b>\$575.8</b>	<b>\$255.3</b>			
<b>Net Benefits</b>	<b>\$538.2 - \$620.0</b>	<b>\$216.1 - \$242.1</b>	<b>\$0.0 - \$81.8</b>	<b>\$0.0 - \$25.9</b>	<b>\$538.2</b>	<b>\$216.2</b>			

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.



Discount Rate	Alternative 2b Update Z Tables 1910.1000, 1915.1000, and 1926.55 and Require Control Costs for Industries with Trace Contaminants		Alternative 2b Update Z Tables 1910.1000, 1915.1000, and 1926.55 and Require Control Costs for Industries with Trace Contaminants (Incremental costs and benefits)		Proposed PEL (PEL = 0.2 µg/m <sup>3</sup> , AL = 0.10 µg/m <sup>3</sup> )	
	3%	7%	3%	7%	3%	7%
<b>Annualized Costs</b>						
Control Costs	\$11.5	\$12.3	\$2.0	\$2.0	\$9.5	\$10.3
Respirators	\$0.2	\$0.3	\$0.0	\$0.0	\$0.2	\$0.3
Exposure Assessment	\$2.2	\$2.4	\$0.0	\$0.0	\$2.2	\$2.4
Regulated areas and Beryllium Work Areas	\$0.6	\$0.7	\$0.0	\$0.0	\$0.6	\$0.7
Medical Surveillance	\$2.9	\$3.0	\$0.0	\$0.0	\$2.9	\$3.0
Medical Removal	\$0.1	\$0.2	\$0.0	\$0.0	\$0.1	\$0.2
Exposure Control Plan	\$1.8	\$1.8	\$0.0	\$0.0	\$1.8	\$1.8
Protective Clothing and Equipment	\$1.4	\$1.4	\$0.0	\$0.0	\$1.4	\$1.4
Hygiene Areas and Practices	\$0.4	\$0.4	\$0.0	\$0.0	\$0.4	\$0.4
Housekeeping	\$12.6	\$12.9	\$0.0	\$0.0	\$12.6	\$12.9
Training	\$5.8	\$5.8	\$0.0	\$0.0	\$5.8	\$5.8
<b>Total Annualized Costs (point estimate)</b>	<b>\$39.6</b>	<b>\$41.1</b>	<b>\$2.0</b>	<b>\$2.0</b>	<b>\$37.6</b>	<b>\$39.1</b>
<b>Annual Benefits: Number of Cases Prevented</b>	<b>Cases</b>		<b>Cases</b>		<b>Cases</b>	
Fatal Lung Cancers (midpoint estimate)	4.1		0.1		4.0	
Fatal Chronic Beryllium Disease	92.1		0.2		92.0	
Beryllium-Related Mortality	96.3	\$575.0	\$254.6	0.3	\$2.02	\$0.90
Beryllium Morbidity	49.6	\$3.0	\$1.7	0.1	\$0.20	\$0.11
<b>Monetized Annual Benefits (midpoint estimate)</b>	<b>\$578.1</b>	<b>\$256.3</b>	<b>\$2.2</b>	<b>\$1.0</b>	<b>\$575.8</b>	<b>\$255.3</b>
<b>Net Benefits</b>	<b>\$538.5</b>	<b>\$215.2</b>	<b>\$0.3</b>	<b>-\$1.0</b>	<b>\$538.2</b>	<b>\$216.2</b>

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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2. Exposure Limit (TWA PEL, STEL, and ACTION LEVEL) Alternatives

OSHA is proposing a new TWA PEL for beryllium of 0.2 µg/m<sup>3</sup> and a STEL

of 2.0 µg/m<sup>3</sup> for all application groups covered by the rule. OSHA's proposal 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 of this preamble, Pertinent Legal Authority, for a full discussion of OSHA legal requirements.

Paragraph (c) of the proposed standard establishes two PELs for beryllium in all forms, compounds, and mixtures: An 8-hour TWA PEL of 0.2  $\mu\text{g}/\text{m}^3$  (proposed paragraph (c)(1)), and a 15-minute short-term exposure limit (STEL) of 2.0  $\mu\text{g}/\text{m}^3$  (proposed paragraph (c)(2)). OSHA has defined the action level for the proposed standard as an airborne concentration of beryllium of 0.1  $\mu\text{g}/\text{m}^3$  calculated as an eight-hour TWA (proposed paragraph (b)). In this proposal, as in other standards, the action level has been set at one-half of the TWA PEL.

As discussed in this preamble explanation of paragraph (c) in Section XVIII, Summary and Explanation of the Proposed Standard, OSHA is considering three regulatory alternatives that would modify the PELs for the proposed standard.

Regulatory Alternative #3 would modify the proposed STEL to be five times the TWA PEL, as is typical for OSHA standards that have STELs. A STEL five times the TWA PEL has more

practical effect because a STEL ten times the TWA PEL will rarely be exceeded without also driving exposures above the TWA PEL. For example, assuming a background exposure level of 0.1  $\mu\text{g}/\text{m}^3$ , a STEL ten times the TWA PEL could only be exceeded once in a work shift for 15 minutes without driving exposures above the TWA PEL, whereas a STEL five times the TWA PEL could be exceeded three times before driving exposures above the TWA PEL. OSHA's standards for methylene chloride (29 CFR 1910.1052), acrylonitrile (29 CFR 1910.1045), benzene (29 CFR 1910.1028), ethylene oxide (29 CFR 1910.1047), and 1,3-Butadiene (29 CFR 1910.1051) all set STELs at five times the TWA PEL. Thus, if OSHA promulgates the proposed TWA PEL of 0.2  $\mu\text{g}/\text{m}^3$ , the accompanying STEL under this regulatory alternative would be set at 1  $\mu\text{g}/\text{m}^3$ .

As discussed in this preamble at Section V, Health Effects, immunological sensitization can be triggered by short-term exposures. OSHA believes a STEL for beryllium will help reduce the risk of sensitization and CBD in beryllium-exposed employees. For instance, without a STEL, workers' exposures could be as high as 6.4  $\mu\text{g}/\text{m}^3$  ( $32 \times 0.2 \mu\text{g}/\text{m}^3$ ) for 15 minutes under the proposed TWA PEL, if exposures during the remainder

of the 8-hour work shift are non-detectable. A STEL serves to minimize high task-based exposures by requiring feasible controls in these situations, and has the added effect of further reducing the TWA exposure.

OSHA requests comment on the range of short-term exposures in covered industries, the types of operations where these are occurring, and on the proposed and alternative STELs, including any data or information that may help OSHA choose between them.

OSHA identified two job categories where workers would be expected to have short-term exposures in the range between the proposed STEL and the STEL under Regulatory Alternative #3 (that is, between 2.0 and 1.0  $\mu\text{g}/\text{m}^3$ ): Furnace operators in nonferrous foundries and material preparation operators in the beryllium oxide ceramics application group. To estimate the costs for this alternative, OSHA judged, conservatively, that all workers in these job categories would need to wear respirators to meet a STEL of 1.0. OSHA also estimated costs for additional regulated areas and medical surveillance for workers in these two job categories. The costs for this alternative are presented in Table IX-19. Total costs rise from \$37.6 million to \$37.7 million using a 3 percent discount rate and from \$39.1 million to \$39.3 million using a 7 percent discount rate.

**Table IX-19: Cost of Regulatory Alternatives, Alternative 3  
(Proposed PEL=0.2, STEL=2.0, AL=0.1)**

<b>3% Discount Rate</b>	<b>Total Cost</b>	<b>Incremental Cost Relative to Proposal</b>
<b>Proposed Rule</b>	\$37,597,325	—
<b>Alternative 3: STEL=1.0, all else the same</b>	\$37,742,714	\$145,389

<b>7% Discount Rate</b>	<b>Total Cost</b>	<b>Incremental Cost Relative to Proposal</b>
<b>Proposed Rule</b>	\$39,147,434	—
<b>Alternative 3: STEL=1.0, all else the same</b>	\$39,294,987	\$147,553

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

Under Regulatory Alternative #4, the TWA PEL would be 0.1  $\mu\text{g}/\text{m}^3$  with an action level of 0.05  $\mu\text{g}/\text{m}^3$ . The Agency's

preliminary risk assessment indicates that the risks remaining at the proposed TWA PEL of 0.2  $\mu\text{g}/\text{m}^3$ —while lower

than risks at the current TWA PEL—are still significant (see this preamble at Section VIII, Significance of Risk). A

TWA PEL of 0.1  $\mu\text{g}/\text{m}^3$  would reduce some of the remaining risks to workers at the proposed PEL. The OSH Act requires the Agency to set its standards to address significant risks of harm to the extent economically and technologically feasible, so OSHA would have very limited flexibility to adopt a higher PEL if a lower PEL is technologically and economically feasible.

While OSHA's preliminary analysis indicates that the proposed TWA PEL of 0.2  $\mu\text{g}/\text{m}^3$  is economically and technologically feasible, OSHA has less confidence in the feasibility of a TWA PEL of 0.1  $\mu\text{g}/\text{m}^3$ . In some industry sectors it is difficult to determine whether a TWA PEL of 0.1  $\mu\text{g}/\text{m}^3$  could be achieved in most operations most of the time (see Section IX.D of this preamble, Technological Feasibility). OSHA believes that one way this uncertainty could be resolved would be with additional information on exposure control technologies and the exposure levels that are currently being achieved in these industry sectors. OSHA requests additional data and information to inform its final determinations on feasibility (see Section IX.D of this preamble, Technological Feasibility) and the alternative PELs under consideration.

Regulatory Alternative #5, which would set a TWA PEL at 0.5  $\mu\text{g}/\text{m}^3$  and an action level at 0.25  $\mu\text{g}/\text{m}^3$ , both higher than in the proposal, responds to an issue raised during the Small Business Advocacy Review (SBAR) process conducted in 2007 to consider a draft OSHA beryllium proposed rule that culminated in an SBAR Panel report (SBAR, 2008). That report included a recommendation that OSHA consider both the economic impact of a low TWA PEL and regulatory alternatives that would ease cost burden for small entities. OSHA has provided a full analysis of the economic impact of its proposed PELs (see Chapter VI of the PEA), and Regulatory Alternative #5 addresses the second half of that recommendation. However, the higher 0.5  $\mu\text{g}/\text{m}^3$  TWA PEL does not appear to

be consistent with the Agency's mandate under the OSH Act to promulgate a lower PEL if it is feasible and could prevent additional fatalities and non-fatal illnesses. The data presented in Table IX-20 below indicate that the lower TWA PEL would prevent additional fatalities and non-fatal illnesses, but nevertheless the Agency solicits comments on this alternative and OSHA's analysis of the costs and benefits associated with it.

Table IX-20 below presents, for informational purposes, the estimated costs, benefits, and net benefits of the proposed rule under the proposed TWA PEL of 0.2  $\mu\text{g}/\text{m}^3$  and for the regulatory alternatives of a TWA PEL of 0.1  $\mu\text{g}/\text{m}^3$  and a TWA PEL of 0.5  $\mu\text{g}/\text{m}^3$  (Regulatory Alternatives #4 and #5, respectively), using alternative discount rates of 3 percent and 7 percent. In addition, the table presents the incremental costs, the incremental benefits, and the incremental net benefits, of going from a TWA PEL of 0.5  $\mu\text{g}/\text{m}^3$  to the proposed TWA PEL of 0.2  $\mu\text{g}/\text{m}^3$  and then of going from the proposed TWA PEL of 0.2  $\mu\text{g}/\text{m}^3$  to a TWA PEL of 0.1  $\mu\text{g}/\text{m}^3$ . Table IX-20 also breaks out costs by provision and benefits by type of disease and by morbidity/mortality.

OSHA has not made a determination that a TWA PEL of 0.1  $\mu\text{g}/\text{m}^3$  would be feasible for all application groups (that is, engineering and work practices would be sufficient to reduce and maintain beryllium exposures to a TWA PEL of 0.1  $\mu\text{g}/\text{m}^3$  or below in most operations most of the time in the affected industries). For Regulatory Alternative #4, the Agency attempted to identify engineering controls and their costs for those affected application groups where the technology feasibility analysis in Chapter IV of the PEA indicated that a TWA PEL of 0.1  $\mu\text{g}/\text{m}^3$  could be achieved. For those application groups, OSHA costed out the set of feasible controls necessary to meet this alternative PEL. For the rest of the affected application groups, OSHA assumed that all workers exposed between 0.2  $\mu\text{g}/\text{m}^3$  and 0.1  $\mu\text{g}/\text{m}^3$  would

have to wear respirators to achieve compliance with the 0.1  $\mu\text{g}/\text{m}^3$  TWA PEL and estimated the associated additional costs for respiratory protection. For all affected industries, OSHA also estimated the costs to satisfy the ancillary requirements specified in the proposed rule for all affected workers under the alternative TWA PEL of 0.1  $\mu\text{g}/\text{m}^3$ . For both controls and respirators, the unit costs were the same as presented in Chapter V of the PEA.

The estimated benefits for Regulatory Alternative #4 were calculated based on the number of workers identified with exposures between 0.1 and 0.2  $\mu\text{g}/\text{m}^3$ , using the methods and unit benefit values developed in Chapter VII of the PEA.

As Table IX-20 shows, going from a TWA PEL of 0.5  $\mu\text{g}/\text{m}^3$  to a TWA PEL of 0.2  $\mu\text{g}/\text{m}^3$  would prevent, annually, an additional 29 beryllium-related fatalities and an additional 15 non-fatal illnesses. This is consistent with OSHA's preliminary risk assessment, which indicates significant risk to workers exposed at a TWA PEL of 0.5  $\mu\text{g}/\text{m}^3$ ; furthermore, OSHA's preliminary feasibility analysis indicates that a lower TWA PEL than 0.5  $\mu\text{g}/\text{m}^3$  is feasible. Net benefits of this regulatory alternative versus the proposed TWA PEL of 0.2  $\mu\text{g}/\text{m}^3$  would decrease from \$538.2 million to \$370.0 million using a 3 percent discount rate and from \$216.2 million to \$144.4 million using 7 percent discount rate.

Table IX-20 also shows the costs and benefits of going from the proposed TWA PEL of 0.2  $\mu\text{g}/\text{m}^3$  to a TWA PEL of 0.1  $\mu\text{g}/\text{m}^3$ . As shown there, going from a TWA PEL of 0.2  $\mu\text{g}/\text{m}^3$  to a TWA PEL of 0.1  $\mu\text{g}/\text{m}^3$  would prevent an additional 2 beryllium-related fatalities and 1 additional non-fatal illness. Net benefits of this regulatory alternative versus the proposed TWA PEL of 0.2  $\mu\text{g}/\text{m}^3$  would increase from \$538.2 million to \$543.5 million using a 3 percent discount rate and decrease from \$216.2 million to \$214.9 million using a 7 percent discount rate.

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Table IX-20: Annualized Costs, Benefits and Incremental Benefits of OSHA's Proposed Beryllium Standard of 0.1 µg/m<sup>3</sup> and 0.5 µg/m<sup>3</sup> PEL Alternative Millions (\$2010)

	Alternative 4 (PEL = 0.1 µg/m <sup>3</sup> , AL = 0.05 µg/m <sup>3</sup> )		Alternative 4 Incremental Costs/Benefits		Proposed PEL (PEL = 0.2 µg/m <sup>3</sup> , AL = 0.10 µg/m <sup>3</sup> )		Alternative 5 Incremental Costs/Benefits		Alternative 5 (PEL = 0.5 µg/m <sup>3</sup> , AL = 0.25 µg/m <sup>3</sup> )			
	3%	7%	3%	7%	3%	7%	3%	7%	3%	7%		
<b>Discount Rate</b>												
<b>Annualized Costs</b>												
Control Costs	\$12.9	\$13.9	\$3.3	\$3.5	\$9.5	\$10.3	\$3.6	\$3.9	\$6.0	\$6.5		
Respirators	\$0.7	\$0.7	\$0.4	\$0.5	\$0.2	\$0.3	\$0.1	\$0.1	\$0.1	\$0.1		
Exposure Assessment	\$3.8	\$3.9	\$1.6	\$1.5	\$2.2	\$2.4	\$0.3	\$0.3	\$1.9	\$2.1		
Regulated areas and Beryllium Work Areas	\$0.9	\$0.9	\$0.3	\$0.3	\$0.6	\$0.7	\$0.3	\$0.3	\$0.3	\$0.4		
Medical Surveillance	\$3.0	\$3.1	\$0.1	\$0.1	\$2.9	\$3.0	\$0.1	\$0.1	\$2.8	\$2.9		
Medical Removal	\$0.4	\$0.5	\$0.3	\$0.3	\$0.1	\$0.2	\$0.1	\$0.1	\$0.1	\$0.1		
Exposure Control Plan	\$1.8	\$1.8	\$0.0	\$0.0	\$1.8	\$1.8	\$0.0	\$0.0	\$1.8	\$1.8		
Protective Clothing and Equipment	\$1.4	\$1.4	\$0.0	\$0.0	\$1.4	\$1.4	\$0.0	\$0.0	\$1.4	\$1.4		
Hygiene Areas and Practices	\$0.6	\$0.6	\$0.2	\$0.2	\$0.4	\$0.4	\$0.0	\$0.0	\$0.4	\$0.4		
Housekeeping	\$12.6	\$12.9	\$0.0	\$0.0	\$12.6	\$12.9	\$0.0	\$0.0	\$12.6	\$12.9		
Training	\$5.8	\$5.8	\$0.0	\$0.0	\$5.8	\$5.8	\$0.0	\$0.0	\$5.8	\$5.8		
<b>Total Annualized Costs (point estimate)</b>	<b>\$43.7</b>	<b>\$45.5</b>	<b>\$6.1</b>	<b>\$6.3</b>	<b>\$37.6</b>	<b>\$39.1</b>	<b>\$4.4</b>	<b>\$4.8</b>	<b>\$33.2</b>	<b>\$34.4</b>		
<b>Annual Benefits: Number of Cases Prevented</b>	<u>Cases</u>		<u>Cases</u>		<u>Cases</u>		<u>Cases</u>		<u>Cases</u>			
Fatal Lung Cancers (midpoint estimate)	4		0		4		0		4			
Fatal Chronic Beryllium Disease	94		2		92		29		63			
Beryllium-Related Mortality	98	\$584.4	\$258.8	2	\$11.4	\$5.0	96	\$573.0	\$253.7	67	\$401.2	\$177.7
Beryllium Morbidity	50	\$2.9	\$1.6	1	\$0.0	\$0.0	50	\$2.8	\$1.6	34	\$2.0	\$1.1
<b>Monetized Annual Benefits (midpoint estimate)</b>	<b>\$587.3</b>	<b>\$260.4</b>	<b>\$11.4</b>	<b>\$5.1</b>	<b>\$575.8</b>	<b>\$255.3</b>	<b>\$172.7</b>	<b>\$76.6</b>	<b>\$403.1</b>	<b>\$178.8</b>		
<b>Net Benefits</b>	<b>\$543.5</b>	<b>\$214.9</b>	<b>\$5.3</b>	<b>-\$1.3</b>	<b>\$538.2</b>	<b>\$216.2</b>	<b>\$168.2</b>	<b>\$71.9</b>	<b>\$370.0</b>	<b>\$144.4</b>		

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.

### Informational Alternative Featuring Unchanged PEL but Full Ancillary Provisions

An Informational Analysis: This proposed regulation has the somewhat unusual feature for an OSHA substance-specific health standard that most of the quantified benefits would come from the ancillary provisions rather than from meeting the PEL with engineering controls. OSHA decided to analyze for informational purposes the effect of retaining the existing PEL but applying all of the ancillary provisions, including respiratory protection. Under this approach, the TWA PEL would remain at 2.0 micrograms per cubic meter, but all of the other proposed provisions (including respiratory protection, which OSHA does not consider an ancillary provision) would be required with their triggers remaining the same as in the proposed rule—either the presence of airborne beryllium at any level (*e.g.*, initial monitoring, written exposure control plan), at certain kinds of dermal exposure (PPE), at the action level of 0.1  $\mu\text{g}/\text{m}^3$  (*e.g.*, periodic monitoring, medical removal), or at 0.2  $\mu\text{g}/\text{m}^3$  (*e.g.*, regulated areas, respiratory protection, medical surveillance).

Given the record regarding beryllium exposures, this approach is not one OSHA could legally adopt because the absence of a more protective requirement for engineering controls would not be consistent with section 6(b)(5) of the OSH Act, which requires OSHA 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.” For that reason, this additional analysis is provided strictly for informational purposes. E.O. 12866 and E.O. 13563 direct agencies to identify approaches that maximize net benefits, and this analysis is purely for the purpose of exploring whether this approach would hold any real promise to maximize net benefits if it was permissible under the OSH Act. It does not appear to hold such promise because an ancillary-provisions-only approach would not be as protective and thus offers fewer benefits than one that includes a lower PEL and engineering controls, and OSHA estimates the costs would be about the same (or slightly lower, depending on certain assumptions) under that approach as under the traditional proposed approach.

On an industry by industry basis, OSHA found that some industries would have lower costs if they could adopt the ancillary-provisions-only approach. Some employers would use engineering controls where they are cheaper, even if they are not mandatory. OSHA does not have sufficient information to do an analysis of the employer-by-employer situations in which there exist some employers for whom the ancillary-provisions-only approach might be cheaper. In the majority of affected industries, the Agency estimates there are no costs saving to the ancillary-provisions-only approach. However, OSHA estimates a total of \$2,675,828 per year in costs saving for entire industries where the ancillary-provisions-only approach would be less expensive.

The above discussion does not account for the possibility that the lack of engineering controls would result in higher beryllium exposures for workers in adjacent (non-production) work areas due to the increased level of beryllium in the air. Because of a lack of data, and because the issue did not arise in the other regulatory alternatives OSHA considered (all of which have a PEL of less than 2.0  $\mu\text{g}/\text{m}^3$ ), OSHA did not carefully examine exposure levels in non-production areas for either cost or benefit purposes. To the extent such exposure levels would be above the action level, there would be additional costs for respiratory protection.

The ancillary-provisions-only approach adds uncertainty to the benefits analysis such that the benefits of the rule as proposed may exceed, and perhaps greatly exceed, the benefits of this ancillary-provisions-only approach:

(1) Most exposed individuals would be in respirators, which OSHA considers less effective than engineering controls in preventing employee exposure to beryllium. OSHA last did an extensive review of the evidence on effectiveness of respirators for its APFs rulemaking in 2006 (71 FR 50128–45, August 24, 2006). OSHA has not in the past tried to quantify the size of this effect, but it could partially negate the estimated benefits of 92 CBD deaths prevented per year and 4 lung cancer cases prevented per year by the proposed standard.

(2) As noted above, in the proposal OSHA did not consider benefits caused by reductions in exposure in non-production areas. Unless employers act to reduce exposures in the production areas, the absence of a requirement for such controls would largely negate such benefits from reductions in exposure in the non-productions areas.

(3) OSHA believes that there is a strong possibility that the benefits of the ancillary provisions (a midpoint estimate of eliminating 45 percent of all remaining cases of CBD) would be partially or wholly negated in the absence of engineering controls that would reduce both airborne and surface dust levels. The measured reduction in benefits from ancillary provision was in a facility with average exposure levels of less than 0.2  $\mu\text{g}/\text{m}^3$ .

Based on these considerations, OSHA believes that the ancillary-provisions-only approach is not one that is likely to maximize net benefits. The costs saving, if any, are estimated to be small, and the difficult-to-measure declines in benefits could be substantial.

### 3. A Method-of-Compliance Alternative

Paragraph (f)(2) of the proposed rule contains requirements for the implementation of engineering and work practice controls to minimize beryllium exposures in beryllium work areas. For each operation in a beryllium work area, employers must ensure that at least one of the following engineering and work practice controls is in place to minimize employee exposure: Material and/or process substitution; ventilated enclosures; local exhaust ventilation; or process controls, such as wet methods and automation. Employers are exempt from using engineering and work practice controls only when they can show that such controls are not feasible or where exposures are below the action level based on two exposure samples taken seven days apart.

These requirements, which are based on the stakeholders' recommended beryllium standard that beryllium industry and union stakeholders submitted to OSHA in 2012 (Materion and United Steelworkers, 2012), address a concern associated with the proposed TWA PEL. OSHA expects that day-to-day changes in workplace conditions, such as workers' positioning or patterns of airflow, may cause frequent exposures above the TWA PEL in workplaces where periodic sampling indicates exposures are between the action level and the TWA PEL. As a result, the default under the standard is that the controls are required until the employer can demonstrate that exposures have not exceeded the action level from at least two separate measurements taken seven days apart.

OSHA believes that substitution or engineering controls such as those outlined in paragraph (f)(2)(i) provide the most reliable means to control variability in exposure levels. However, OSHA also recognizes that the requirements of paragraph (f)(2)(i) are

not typical of OSHA standards, which usually require engineering controls only where exposures exceed the TWA PEL or STEL. The Agency is therefore considering Regulatory Alternative #6, which would drop the provisions of (f)(2)(i) from the proposed standard and make conforming edits to paragraphs (f)(2)(ii) and (iii). This regulatory

alternative does not eliminate the need for engineering controls to comply with the proposed TWA PEL and STEL, but does eliminate the requirement to use one or more of the specified engineering or work practice controls where exposures equal or exceed the action level. As shown in Table IX-21, Regulatory Alternative #6 would

decrease the annualized cost of the proposed rule by about \$457,000 using a discount rate of 3 percent and by about \$480,000 using a discount rate of 7 percent. OSHA has not been able to estimate the change in benefits resulting from Regulatory Alternative #6 at this time and invites public comment on this issue.

**Table IX-21: Cost of Regulatory Alternatives, Alternative 6  
(Proposed PEL=0.2, STEL=2.0, AL=0.1)**

<u>3% Discount Rate</u>	<u>Total Cost</u>	<u>Incremental Cost Relative to Proposal</u>
<b>Proposed Rule</b>	\$37,597,325	—
<b>Alternative 6: Eliminate (f)(2) controls</b>	\$37,140,020	-\$457,304

<u>7% Discount Rate</u>	<u>Total Cost</u>	<u>Incremental Cost Relative to Proposal</u>
<b>Proposed Rule</b>	\$39,147,434	—
<b>Alternative 6: Eliminate (f)(2) controls</b>	\$38,667,896	-\$479,538

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

#### 4. Regulatory Alternatives That Affect Ancillary Provisions

The proposed standard contains several ancillary provisions (provisions other than the exposure limits), including requirements for exposure assessment, medical surveillance, medical removal, training, and regulated areas or access control. As reported in Chapter V of the PEA, these ancillary provisions account for \$27.8 million (about 72 percent) of the total annualized costs of the rule (\$37.6 million) using a 3 percent discount rate, or \$28.6 million (about 73 percent) of the total annualized costs of the rule (\$39.1 million) using a 7 percent discount rate. The most expensive of the ancillary provisions are the requirements for housekeeping and training, with annualized costs of \$12.6 million and \$5.8 million, respectively, at a 3 percent discount rate (\$12.9 million and \$5.8 million, respectively, at a 7 percent discount rate).

OSHA's reasons for including each of the proposed ancillary provisions are explained in Section XVIII of this preamble, Summary and Explanation of the Standards.

In particular, OSHA is proposing the requirements for exposure assessment to provide a basis for ensuring that appropriate measures are in place to limit worker exposures. Medical surveillance is especially important because workers exposed above the proposed TWA PEL, as well as many workers exposed below the proposed TWA PEL, are at significant risk of death and illness. Medical surveillance would allow for identification of beryllium-related adverse health effects at an early stage so that appropriate intervention measures can be taken. OSHA is proposing regulated areas and access control because they serve to limit exposure to beryllium to as few employees as possible. OSHA is proposing worker training to ensure that employers inform employees of the hazards to which they are exposed, along with associated protective measures, so that employees understand how they can minimize their exposure to beryllium. Worker training on beryllium-related work practices is particularly important in controlling beryllium exposures because engineering controls frequently require

action on the part of workers to function effectively.

OSHA has examined a variety of regulatory alternatives involving changes to one or more of the proposed ancillary provisions. The incremental cost of each of these regulatory alternatives and its impact on the total costs of the proposed rule is summarized in Table IX-22 at the end of this section. OSHA has preliminarily determined that several of these ancillary provisions will increase the benefits of the proposed rule, for example, by helping to ensure the TWA PEL is not exceeded or by lowering the risks to workers given the significant risk remaining at the proposed TWA PEL. However, except for Regulatory Alternative #7 (involving the elimination of all ancillary provisions), OSHA did not estimate changes in monetized benefits for the regulatory alternatives that affect ancillary provisions. Two regulatory alternatives that involve all ancillary provisions are presented below (#7 and #8), followed by regulatory alternatives for exposure monitoring (#9, #10, and #11), for regulated areas (#12), for personal

protective clothing and equipment (#13), for medical surveillance (#14 through #21), and for medical removal (#22).

#### a. All Ancillary Provisions

The SBAR Panel recommended that OSHA analyze a PEL-only standard as a regulatory alternative. The Panel also recommended that OSHA consider not applying ancillary provisions of the standard where exposure levels are low so as to minimize costs for small businesses (SBAR, 2008). In response to these recommendations, OSHA analyzed Regulatory Alternative #7, a PEL-only standard, and Regulatory Alternative #8, which would apply ancillary provisions of the beryllium standard only where exposures exceed the proposed TWA PEL of 0.2 µg/m<sup>3</sup> or the proposed STEL of 2 µg/m<sup>3</sup>.

Regulatory Alternative #7 would solely update 1910.1000 Tables Z-1 and Z-2, so that the proposed TWA PEL and STEL would apply to all workers in general industry. This alternative would eliminate all of the ancillary provisions of the proposed rule, including exposure assessment, medical surveillance, medical removal, PPE, housekeeping, training, and regulated areas or access control. Under this regulatory alternative, OSHA estimates that the costs for the proposed ancillary provisions of the rule (estimated at \$27.8 million annually at a 3 percent discount rate) would be eliminated. In order to meet the PELs, employers would still commonly need to do monitoring, train workers on the use of controls, and set up some kind of regulated areas to indicate where respirator use would be required. It is also likely that, under this alternative, many employers would follow the recommendations of Materion and the United Steelworkers to provide medical surveillance, PPE, and other protective measures for their workers (Materion and USW, 2012). OSHA has not attempted to estimate the extent to which these ancillary-provision costs would be incurred if they were not formally required or whether any of these costs under Regulatory Alternative #7 would reasonably be attributable to the proposed rule. OSHA welcomes comment on the issue.

OSHA has also estimated the effect of this regulatory alternative on the benefits of the rule. As a result of eliminating all of the ancillary provisions, annualized benefits are estimated to decrease 57 percent, relative to the proposed rule, from \$575.8 million to \$249.1 million, using a 3 percent discount rate, and from \$255.3 million to \$110.4 million using

a 7 percent discount rate. This estimate follows from OSHA's analysis of benefits in Chapter VII of the PEA, which found that about 57 percent of the benefits of the proposed rule, evaluated at their mid-point value, were attributable to the combination of the ancillary provisions. As these estimates show, OSHA expects that the benefits estimated under the proposed rule will not be fully achieved if employers do not implement the ancillary provisions of the proposed rule.

Both industry and worker groups have recognized that a comprehensive standard is needed to protect workers exposed to beryllium. The stakeholders' recommended standard that representatives of the primary beryllium manufacturing industry and the United Steelworkers union provided to OSHA confirms the importance of ancillary provisions in protecting workers from the harmful effects of beryllium exposure (Materion and USW, 2012). Ancillary provisions such as personal protective clothing and equipment, regulated areas, medical surveillance, hygiene areas, housekeeping requirements, and hazard communication all serve to reduce the risks to beryllium-exposed workers beyond that which the proposed TWA PEL alone could achieve.

Moreover, where there is continuing significant risk at the TWA PEL, the decision in the *Asbestos case (Bldg. and Constr. Trades Dep't, AFL-CIO v. Brock, 838 F.2d 1258, 1274 (D.C. Cir. 1988))* indicated that OSHA should use its legal authority to impose additional requirements on employers to further reduce risk when those requirements will result in a greater than *de minimis* incremental benefit to workers' health. Nevertheless, OSHA requests comment on this alternative.

Under Regulatory Alternative #8, several ancillary provisions that the current proposal would require under a variety of exposure conditions (*e.g.*, dermal contact, any airborne exposure, exposure at or above the action level) would instead only apply where exposure levels exceed the TWA PEL or STEL. Regulatory Alternative #8 affects the following provisions of the proposed standard:

- Exposure monitoring: Whereas the proposed standard requires annual monitoring when exposure levels are at or above the action level and at or below the TWA PEL, Regulatory Alternative #8 would require annual exposure monitoring only where exposure levels exceed the TWA PEL or STEL;
- Written exposure control plan: Whereas the proposed standard

- requires written exposure control plans to be maintained in any facility covered by the standard, Regulatory Alternative #8 would require only facilities with exposures above the TWA PEL or STEL to maintain a plan;
- Housekeeping: Whereas the proposed standard's housekeeping requirements apply across a wide variety of beryllium exposure conditions, Alternative #8 would limit housekeeping requirements to areas and employees with exposures above the TWA PEL or STEL;
- PPE: Whereas the proposed standard requires PPE for employees under a variety of conditions, such as exposure to soluble beryllium or visible contamination with beryllium, Alternative #8 would require PPE only for employees exposed above the TWA PEL or STEL;
- Medical Surveillance: Whereas the proposed standard's medical surveillance provisions require employers to offer medical surveillance to employees with signs or symptoms of beryllium-related health effects regardless of their exposure level, Alternative #8 would require surveillance only for those employees exposed above the TWA PEL or STEL.

To estimate the cost savings for this alternative, OSHA re-estimated the group of workers that would fall under the above provisions and the changes to their scope. Combining these various adjustments along with associated unit costs, OSHA estimates that, under this regulatory alternative, the costs for the proposed rule would decline from \$37.6 million to \$18.9 million using a 3 percent discount rate and from \$39.1 million to \$20.0 million using a 7 percent discount rate.

The Agency has not quantified the impact of this alternative on the benefits of the rule. However, ancillary provisions that offer protective measures to workers exposed below the proposed TWA PEL, such as personal protective clothing and equipment, beryllium work areas, hygiene areas, housekeeping requirements, and hazard communication, all serve to reduce the risks to beryllium-exposed workers beyond that which the proposed TWA PEL and STEL could achieve. OSHA's preliminary conclusion is that the requirements triggered by the action level and other exposures below the proposed PELs will result in very real and necessary, but difficult to quantify, further reduction in risk beyond that provided by the PELs alone.

The remainder of this section discusses additional regulatory alternatives that apply to individual

ancillary provisions. At this time, OSHA is not able to quantify the effects of these regulatory alternatives on benefits. The Agency solicits comment on the effects of these regulatory alternatives on the benefits of the proposed rule.

#### b. Exposure Monitoring

Paragraph (d) of the proposed standard, Exposure Monitoring, requires annual monitoring where exposures are at or above the action level and at or below the TWA PEL. It does not require periodic monitoring where exposure levels have been determined to be below the action level, or above the TWA PEL. The rationale for this provision is provided in this preamble discussion of paragraph (a) in Section XVIII, Summary and Explanation of the Proposed Standard. Below is a brief summary, followed by a discussion of three alternatives.

Because of the variable nature of employee exposures to airborne concentrations of beryllium, maintaining exposures below the action level provides reasonable assurance that employees will not be exposed to beryllium at levels above the TWA PEL on days when no exposure measurements are made. Even when all measurements on a given day fall at or below the TWA PEL, if those measurements are still at or above the action level, there is a smaller safety margin and a greater chance that on another day, when exposures are not measured, the employee's exposure may exceed the TWA PEL. When exposure measurements are at or above the action level, the employer cannot be reasonably confident that employees have not been exposed to beryllium concentrations in excess of the TWA PEL during at least some part of the work week. Therefore, requiring periodic exposure measurements when the action level is met or exceeded provides the employer with a reasonable degree of confidence in the results of the exposure monitoring. The proposed action level that would trigger the exposure monitoring is one-half of the TWA PEL, which reflects the Agency's typical approach to setting action levels (see, e.g., Inorganic arsenic (29 CFR 1910.1018), Ethylene oxide (29 CFR 1910.1047), Benzene (29 CFR 1910.1028), and Methylene Chloride (29 CFR 1910.1052)).

Certain other aspects of the proposed periodic monitoring requirements, which the Agency based on the stakeholders' recommended standard submitted by Materion and the United Steelworkers (Materion and USW, 2012), depart significantly from OSHA's usual exposure monitoring

requirements. The proposed standard only requires annual monitoring, and does not require periodic monitoring when exposures are recorded above the TWA PEL, whereas most OSHA standards require monitoring at least every 6 months when exposure levels exceed the action level, and every 3 months when exposures are above the TWA PEL. For example, the standards for vinyl chloride (29 CFR 1910.1017), inorganic arsenic (29 CFR 1910.1018), lead (29 CFR 1910.1025), cadmium (29 CFR 1910.1027), methylene chloride (29 CFR 1910.1052), acrylonitrile (29 CFR 1910.1045), ethylene oxide (29 CFR 1910.1047), and formaldehyde (29 CFR 1910.1048), all specify periodic monitoring at least every six months when exposures are at, or above, the action level. Monitoring is required every three months when exposures exceed the TWA PEL in the standards for methylene chloride, ethylene oxide, acrylonitrile, inorganic arsenic, lead, and vinyl chloride. In the standards for cadmium, 1,3-Butadiene, formaldehyde, benzene and asbestos (29 CFR 1910.1001), monitoring is required every six months when exposures exceed the TWA PEL. In these standards, monitoring workers exposed above the TWA PEL ensures that employers know workers' exposure levels in order to select appropriate respirators and other PPE, and that records of their exposures are available if needed for medical, legal, or epidemiological purposes.

OSHA has examined three regulatory alternatives that would modify the requirements of paragraph (d) to be more similar to OSHA's typical periodic monitoring requirements. Under Regulatory Alternative #9, employers would be required to perform periodic exposure monitoring every 180 days when exposures are at or above the action level or above the STEL, but at or below the TWA PEL. As shown in Table IX-22, Regulatory Alternative #9 would increase the annualized cost of the proposed rule by about \$773,000 using either a 3 percent or 7 percent discount rate.

Under Regulatory Alternative #10, employers would be required to perform periodic exposure monitoring every 180 days when exposures are at or above the action level or above the STEL, including where exposures exceed the TWA PEL. As shown in Table IX-22, Regulatory Alternative #10 would increase the annualized cost of the proposed rule by about \$929,000 using either a 3 percent or 7 percent discount rate.

Under Regulatory Alternative #11, employers would be required to perform

periodic exposure monitoring every 180 days when exposures are at or above the action level, and every 90 days where exposures exceed the TWA PEL or STEL. This alternative is similar to the periodic monitoring requirements in the draft proposed rule presented to the SERs during the 2007 OSHA beryllium SBAR Panel process. Of the exposure monitoring alternatives, it is also the most similar to the exposure monitoring provisions of most other 6(b)(5) standards. As shown in Table IX-22, Regulatory Alternative #11 would increase the annualized cost of the proposed rule by about \$1.07 million using either a 3 percent or 7 percent discount rate.

#### c. Regulated Areas

Proposed paragraph (e) requires employers to establish and maintain beryllium work areas wherever employees are exposed to airborne beryllium, regardless of the level of exposure, and regulated areas wherever airborne concentrations of beryllium exceed the TWA PEL or STEL. Employers are required to demarcate beryllium work areas and regulated areas and limit access to regulated areas to authorized persons.

The SBAR Panel report recommended that OSHA consider dropping or limiting the provision for regulated areas (SBAR, 2008). In response to this recommendation, OSHA examined Regulatory Alternative #12, which would eliminate the requirement that employers establish regulated areas. This alternative is meant only to eliminate the requirement to set up and demarcate specific physical areas: All ancillary provisions would be triggered by the same conditions as under the standard's definition of a "regulated area." For example, under the current proposal, employees who work in regulated areas for at least 30 days annually are eligible for medical surveillance. If OSHA were to remove the requirement to establish regulated areas, the medical surveillance provisions would be altered so that employees who work more than 30 days annually in jobs or areas with exposures that exceed the TWA PEL or STEL are eligible for medical surveillance. This alternative would not eliminate the proposed requirement to establish beryllium work areas. As shown in Table IX-22, Regulatory Alternative #12 would decrease the annualized cost of the proposed rule by about \$522,000 using a 3 percent discount rate, and by about \$523,000 using a 7 percent discount rate.



#### d. Personal Protective Clothing and Equipment

Regulatory Alternative #13 would modify the requirements for personal protective equipment (PPE) by requiring appropriate PPE whenever there is potential for skin contact with beryllium or beryllium-contaminated surfaces. This alternative would be broader, and thus more protective, than the PPE requirement in the proposed standard, which requires PPE to be used in three circumstances: (1) Where exposure exceeds the TWA PEL or STEL; (2) where employees' clothing or skin may become visibly contaminated with beryllium; and (3) where employees may have skin contact with soluble beryllium compounds. These PPE requirements were based on the stakeholders' recommended standard that Materion and the United Steelworkers submitted to the Agency (Materion and USW, 2012).

The proposed rule's requirement to use PPE where work clothing or skin may become "visibly contaminated" with beryllium differs from prior standards, which do not require contamination to be visible in order for PPE to be required. While OSHA's language regarding PPE requirements varies somewhat from standard to standard, previous standards tend to emphasize potential for contact with a substance that can trigger health effects via dermal exposure, rather than "visible contamination" with the substance. For example, the standard for chromium (VI) requires the employer to provide appropriate PPE where a hazard is present or is likely to be present from skin or eye contact with chromium (VI) (29 CFR 1910.1026). The lead and cadmium standards require PPE where employees are exposed above the PEL or where there is potential for skin or eye irritation, regardless of airborne exposure level. Under the Methylenedianiline (MDA) standard (29 CFR 1910.1050), PPE must be provided where employees are subject to dermal exposure to MDA, where liquids containing MDA can be splashed into the eyes, or where airborne concentrations of MDA are in excess of the PEL.

OSHA requests comment on the proposed PPE requirements in Regulatory Alternative #13, which would modify the proposed PPE requirements to be similar to the chromium (VI), lead, cadmium, and MDA standards. Because small beryllium particles can pass through intact or broken skin and cause sensitization, limiting the requirements for PPE based on surfaces that are

"visibly contaminated" may not adequately protect workers from beryllium exposure. Submicron particles (less than 1  $\mu\text{g}$  in diameter) are not visible to the naked eye and yet may pass through the skin and cause beryllium sensitization. Although solubility may play a role in the level of sensitization risk, the available evidence suggests that contact with insoluble, as well as soluble, beryllium can cause sensitization via dermal contact (see this preamble at Section V, Health Effects). Sensitized workers are at significant risk of developing CBD (see this preamble at Section V, Health Effects, and Section VIII, Significance of Risk).

To estimate the cost of Regulatory Alternative #13, OSHA assumed that all at-risk workers, except administrative occupations, would require protective clothing and a pair of work gloves that would need to be replaced annually. The economic analysis of the proposed standard already contained costs for protective clothing for all employees whose clothing might be contaminated by beryllium (the analysis assumed that all clothing contamination would be visible, or the clothing is already provided even if not required by this standard) and gloves for many jobs where workers were expected to be exposed to visible contamination or soluble beryllium; thus OSHA estimated the cost of this alternative as the cost of providing gloves for the remainder of the jobs where workers have potential for skin exposure even in the absence of visible contamination. As shown in Table IX-22, Regulatory Alternative #13 would increase the annualized cost of the proposed rule by about \$138,000 using either a 3 percent or 7 percent discount rate.

#### e. Medical Surveillance

The proposed requirements for medical surveillance include: (1) Medical examinations, including a test for beryllium sensitization, for employees who are exposed to beryllium in a regulated area (*i.e.*, above the proposed TWA PEL or STEL) for 30 days or more per year, who are exposed to beryllium in an emergency, or who show signs or symptoms of CBD; and (2) CT scans for employees who were exposed above the proposed TWA PEL or STEL for more than 30 days in a 12-month period for 5 years or more. The proposed standard would require annual medical exams to be provided for employees exposed in a regulated area for 30 days or more per year and for employees showing signs or symptoms of CBD, while tests for beryllium sensitization and CT scans

would be provided to eligible employees biennially.

OSHA estimated in Chapter V of the PEA that the medical surveillance requirements would apply to 4,528 workers in general industry, of whom 387 already receive that surveillance.<sup>43</sup> In Chapter V, OSHA estimated the costs of medical surveillance for the remaining 4,141 workers who would now have such protection due to the proposed standard. The Agency's preliminary analysis indicates that 4 workers with beryllium sensitization and 6 workers with CBD will be referred to pulmonary specialists annually as a result of this medical surveillance. Medical surveillance is particularly important for this rule because beryllium-exposed workers, including many workers exposed below the proposed PELs, are at significant risk of illness. OSHA did not estimate, and the benefits analysis does not include, monetized benefits resulting from early discovery of illness.

OSHA has examined eight regulatory alternatives (#14 through #21) that would modify the proposed rule's requirements for employee eligibility, the tests that must be offered, and the frequency of periodic exams. Medical surveillance was a subject of special concern to SERs during the SBAR Panel process, and the SBAR Panel offered many comments and recommendations related to medical surveillance for OSHA's consideration. Some of the Panel's concerns have been partially addressed in this proposal, which was modified since the SBAR Panel was convened (see this preamble at Section XVIII, Summary and Explanation of the Proposed Standard, for more detailed discussion). Several of the regulatory alternatives presented here (#16, #18, and #20) also respond to recommendations by the SBAR Panel to reduce burdens on small businesses by dropping or reducing the frequency of medical surveillance requirements. OSHA is also considering several additional regulatory alternatives that would increase the frequency of surveillance or the range of employees covered by medical surveillance (#14, #15, #17, #19, and #21).

OSHA has preliminarily determined that a significant risk of beryllium sensitization, CBD, and lung cancer exists at exposure levels below the proposed TWA PEL and that there is evidence that beryllium sensitization can occur even from short-term exposures (see this preamble at Section V, Health Effects, and Section VIII,

<sup>43</sup> See current compliance rates for medical surveillance in Chapter V of the PEA, Table V-15.

Significance of Risk). The Agency therefore anticipates that more employees would develop adverse health effects without receiving the benefits of early intervention in the disease process because they are not eligible for medical surveillance (see this preamble at Section V, Health Effects).

OSHA is considering three regulatory alternatives that would expand eligibility for medical surveillance to a broader group of employees than those eligible under the proposed standard. Under Regulatory Alternative #14, medical surveillance would be available to employees who are exposed to beryllium above the proposed TWA PEL or STEL, including employees exposed for fewer than 30 days per year. Regulatory Alternative #15 would expand eligibility for medical surveillance to employees who are exposed to beryllium above the proposed action level, including employees exposed for fewer than 30 days per year. Regulatory Alternative #21 would extend eligibility for medical surveillance as set forth in proposed paragraph (k) to all employees in shipyards, construction, and general industry who meet the criteria of proposed paragraph (k)(1). However, all other provisions of the standard would be in effect only for employers and employees that fall within the scope of the proposed rule. Each of these alternatives would provide surveillance to fewer workers (and cost less to employers) than the draft proposed rule presented to SERs during the SBAR Panel process, which included skin contact as a trigger and would therefore cover most beryllium-exposed workers in general industry, construction, and maritime. These alternatives would provide more surveillance (and cost more to employers) than the medical surveillance requirements in the current proposal.

To estimate the cost of Regulatory Alternative #14, OSHA assumed that 1 person would enter regulated areas for less than 30 days a year for every 4 people working in regulated areas on a regular basis. Thus, this alternative includes costs for an incremental number of annual medical exams equal to 25 percent of the number of workers estimated to be working in regulated areas after the standard is promulgated. As shown in Table IX-22, Regulatory Alternative #14 would increase the annualized cost of the proposed rule by about \$38,000 using either a 3 percent or 7 percent discount rate.

To estimate the cost of Regulatory Alternative #15, OSHA assumed that all workers exposed above the action level

before the standard would continue to be exposed after the standard is promulgated. OSHA also assumed that 1 person would enter areas exceeding the action level for fewer than 30 days a year for every 4 people working in an area exceeding the action level on a regular basis. Thus, this alternative includes costs for medical exams for the number of workers exposed between the action level and the TWA PEL as well as an incremental 25 percent of all workers exposed above the action level. As shown in Table IX-22, Regulatory Alternative #15 would increase the annualized cost of the proposed rule by about \$3.9 million using a discount rate of 3 percent, and by about \$4.0 million using a discount rate of 7 percent.

For Alternative #21, OSHA is considering two different scenarios to estimate costs: One where the TWA PEL for the groups outside the scope of the proposed standard changes from  $2 \mu\text{g}/\text{m}^3$  to  $0.2 \mu\text{g}/\text{m}^3$ , as in Regulatory Alternative #2; and one where the TWA PEL remains at the current level of  $2.0 \mu\text{g}/\text{m}^3$ . For costing purposes, these have been designated as Regulatory Alternative #21a and Regulatory Alternative #21b, respectively.

For Regulatory Alternative #21a, medical surveillance above the proposed TWA PEL of 0.2, OSHA estimated the cost of extending medical surveillance to workers in aluminum production, abrasive blasting in construction, maritime abrasive blasting, maritime welding, and coal fired power plants, assuming that all feasible controls are in place to reduce exposures to the proposed TWA PEL of  $0.2 \mu\text{g}/\text{m}^3$  or lower. OSHA did not include control costs to achieve compliance with a TWA PEL of  $0.2 \mu\text{g}/\text{m}^3$ , as these costs were addressed in Regulatory Alternative #2. (For a summary of the estimates of affected workers and the exposure profile, see the discussion accompanying Regulatory Alternative #2.) As shown in Table IX-22, Regulatory Alternative #21a would increase the annualized cost of the proposed rule by about \$4.4 million using a 3-percent discount rate and \$4.5 million using a 7-percent discount rate.

For Alternative #21b, medical surveillance above the current TWA PEL of  $2.0 \mu\text{g}/\text{m}^3$ , OSHA estimated that all abrasive blasters in construction and shipyards who are currently above the current TWA PEL of  $2.0 \mu\text{g}/\text{m}^3$  would be eligible for medical surveillance. As discussed under alternative #2, outside of abrasive blasting, OSHA has identified a small group of maritime welders who may be exposed to beryllium above the current TWA PEL

in their work. Of these workers, 90 percent would be below the current TWA PEL if their employers instituted all feasible engineering and work practice controls to meet the existing standard. If they came into compliance with the current PELs, they would not be required to offer employees medical surveillance under Alternative #21b. OSHA estimated that the other 10 percent of these maritime welders, and 10 percent of workers in primary aluminum production and coal-fired power generation, with all feasible engineering controls and work practices in place, would still be exposed above the current TWA PEL and would be eligible for medical surveillance under Alternative #21b. OSHA's customary method in preparing an economic analysis of a new standard is to cost out the incremental cost of the new standard assuming full compliance with existing standards. Finally, OSHA estimated that 15 percent of the workers excluded from the scope of the proposed standard absent the alternative would show signs and symptoms of CBD or be exposed in emergencies, and so would be eligible for medical surveillance. As shown in Table IX-22, under these assumptions Regulatory Alternative #21b would increase the annualized cost of the proposed rule by about \$3.0 million using a 3-percent discount rate and \$3.1 million using a 7-percent discount rate. The Agency notes that, as abrasive blasters are the primary application group with beryllium exposure in construction and shipyards, it is unlikely that as many as 15 percent of other workers would show signs and symptoms of beryllium exposure or be exposed to beryllium in an emergency. Thus, OSHA believes the stated cost of about \$3.0 million may overestimate the true costs for this alternative and invites comment on this issue.

In response to concerns raised during the SBAR Panel process about testing requirements, OSHA is considering two regulatory alternatives that would provide greater flexibility in the program of tests provided as part of an employer's medical surveillance program. Under Regulatory Alternative #16, employers would not be required to offer employees testing for beryllium sensitization. As shown in Table IX-22, this alternative would decrease the annualized cost of the proposed rule by about \$710,000 using a discount rate of 3 percent, and by about \$724,000 using a discount rate of 7 percent.

Regulatory Alternative #18 would eliminate the CT scan requirement from the proposed rule. This alternative would decrease the annualized cost of

the proposed rule by about \$472,000 using a discount rate of 3 percent, and by about \$481,000 using a discount rate of 7 percent.

OSHA is considering several alternatives to the proposed frequency of sensitization testing, CT scans, and general medical examinations. The frequency of periodic medical surveillance is an important factor in the efficacy of the surveillance in protecting worker health. Regular, appropriately frequent medical surveillance promotes awareness of beryllium-related health effects and early intervention in disease processes among workers. In addition, the longer the time interval between when a worker becomes sensitized and when the worker's case is identified in the surveillance program, the more difficult it will be to identify and address the exposure conditions that led to sensitization. Therefore, reducing the frequency of sensitization testing would reduce the usefulness of the surveillance information in identifying problem areas and reducing risks to other workers. These concerns must be weighed against the costs and other burdens of surveillance.

Regulatory alternative #17 would require employers to offer annual testing for beryllium sensitization to eligible employees, as in the draft proposal presented to the SBAR Panel. As shown in Table IX-22, this alternative would increase the annualized cost of the proposed rule by about \$392,000 using a discount rate of 3 percent, and by about \$381,000 using a discount rate of 7 percent.

Regulatory Alternative #19 would similarly increase the frequency of periodic CT scans from biennial to annual scans, increasing the annualized cost of the proposed rule by about \$459,000 using a discount rate of 3 percent, and by about \$450,000 using a discount rate of 7 percent.

Finally, under Regulatory Alternative #20, employers would only have to provide all periodic components of the medical surveillance exams biennially to eligible employees. This alternative would decrease the annualized cost of the proposed rule by about \$446,000 using a discount rate of 3 percent and by about \$433,000 using a discount rate of 7 percent.

#### f. Medical Removal

Under paragraph (l) of the proposed standard, Medical Removal, employees in jobs with exposure at or above the action level become eligible for medical removal when they are diagnosed with CBD or confirmed positive for beryllium sensitization. When an employee chooses removal, the employer is required to remove the employee to comparable work in an environment where beryllium exposure is below the action level if such work is available and the employee is either already qualified or can be trained within one month. If comparable work is not available, paragraph (l) would require the employer to place the employee on paid leave for six months or until comparable work becomes available (whichever comes first). Or, rather than choosing removal, an eligible employee could choose to remain in a job with exposure at or above the action level and wear a respirator. The proposed medical removal protection (MRP) requirements are based on the stakeholders' recommended beryllium standard that representatives of the beryllium production industry and the United Steelworkers union submitted to OSHA in 2012 (Materion and USW, 2012).

The scientific information on effects of exposure cessation is limited at this time, but the available evidence suggests that removal from exposure can be beneficial for individuals who are sensitized or have early-stage CBD (see

this preamble at Section VIII, Significance of Risk). As CBD progresses, symptoms become serious and debilitating. Steroid treatment is less effective at later stages, once fibrosis has developed (see this preamble at Section VIII, Significance of Risk). Given the progressive nature of the disease, OSHA believes it is reasonable to conclude that removal from exposure to beryllium will benefit sensitized employees and those with CBD. Physicians at National Jewish Health, one of the main CBD research and treatment sites in the US, "consider it important and prudent for individuals with beryllium sensitization and CBD to minimize their exposure to airborne beryllium," and "recommend individuals diagnosed with beryllium sensitization and CBD who continue to work in a beryllium industry to have exposure of no more than 0.01 micrograms per cubic meter of beryllium as an 8-hour time-weighted average" (NJMRC, 2013). However, OSHA is aware that MRP may prove costly and burdensome for some employers and that the scientific literature on the effects of exposure cessation on the development of CBD among sensitized individuals and the progression from early-stage to late-stage CBD is limited.

The SBAR Panel report included a recommendation that OSHA give careful consideration to the impacts that an MRP requirement could have on small businesses (SBAR, 2008). In response to this recommendation, OSHA analyzed Regulatory Alternative #22, which would remove the proposed requirement that employers offer MRP. As shown in Table IX-22, this alternative would decrease the annualized cost of the proposed rule by about \$149,000 using a discount rate of 3 percent, and by about \$166,000 using a discount rate of 7 percent.

Table IX-22: Cost of Regulatory Alternatives Affecting Ancillary Provisions  
(Proposed PEL=0.2, STEL=2.0, AL=0.1)

3% Discount Rate	Total Cost	Incremental Cost Relative to Proposal	Benefits	Incremental Benefits Relative to the Proposal
Proposed Rule	\$37,597,325	—	\$575,826,633	—
Alternative 1b: Include Trace Contaminants; Offer Opt Out for Trace Contaminant Industries with Objective Data	\$49,863,812	\$12,266,488		
Alternative 7: Update Z table 1910.1000 only, (No ancillary provisions)	\$9,789,873	-\$27,807,451	\$249,099,326	-\$326,727,308
Alternative 8: Ancillary provisions apply only when exposure above PEL/STEL	\$18,917,028	-\$18,680,297		
Alternative 9: semiannual monitoring when exposure between AL/STEL and PEL	\$38,370,615	\$773,291		
Alternative 10: semiannual monitoring when exposure above AL/STEL	\$38,526,658	\$929,333		
Alternative 11: semiannual monitoring when exposure above AL/STE, quarterly monitoring when exposure above PEL	\$38,670,043	\$1,072,719		
Alternative 12: No regulated areas, ancillary provisions triggered by PEL or STEL	\$37,075,072	-\$522,252		
Alternative 13: PPE wherever there is contact with beryllium or beryllium contaminated surfaces	\$37,735,352	\$138,027		
Alternative 14: No 30 day minimum for medical surveillance in regulated areas	\$37,635,572	\$38,248		
Alternative 15: No 30 day minimum for medical surveillance and triggered by AL	\$41,466,339	\$3,869,014		
Alternative 16: No BeLPTs in medical surveillance	\$36,887,307	-\$710,018		
Alternative 17: BeLPTs part of annual exam, rather than biannually.	\$37,989,639	\$392,314		
Alternative 18: No CT Scans	\$37,124,958	-\$472,367		
Alternative 19: Annual CT scans rather than biannual	\$38,056,056	\$458,732		
Alternative 20: All periodic components of medical surveillance are biannual	\$37,150,975	-\$446,349		
Alternative 21a: Medical Surveillance (PEL 0.2)	\$42,042,633	\$4,445,308		
Alternative 21b: Medical Surveillance (PEL 2.0)	\$40,573,150	\$2,975,826		
Alternative 22: No medical removal protection	\$37,448,499	-\$148,826		

Table IX-22: Cost of Regulatory Alternatives Affecting Ancillary Provisions, Continued  
(Proposed PEL=0.2, STEL=2.0, AL=0.1)

7% Discount Rate	Total Cost	Incremental Cost Relative to Proposal	Benefits	Incremental Benefits Relative to the Proposal
Proposed Rule	\$39,147,434	—	\$255,334,295	—
Alternative 1b: Include Trace Contaminants, Offer Opt Out for Trace Contaminant Industries with Objective Data	\$51,781,738	\$12,634,305		
Alternative 7: Update Z table 1910.1000 only, (No ancillary provisions)	\$10,586,317	-\$28,561,116	\$110,383,499	-\$144,950,796
Alternative 8: Ancillary provisions apply only when exposure above PEL/STEL	\$19,986,867	-\$19,160,567		
Alternative 9: semiannual monitoring when exposure between AL/STEL and PEL	\$39,920,724	\$773,291		
Alternative 10: semiannual monitoring when exposure above AL/STEL	\$40,076,767	\$929,333		
Alternative 11: semiannual monitoring when exposure above AL/STE, quarterly monitoring when exposure above PEL	\$40,220,152	\$1,072,719		
Alternative 12: No regulated areas, ancillary provisions triggered by PEL or STEL	\$38,624,295	-\$523,139		
Alternative 13: PPE wherever there is contact with beryllium or beryllium contaminated surfaces	\$39,285,461	\$138,027		
Alternative 14: No 30 day minimum for medical surveillance in regulated areas	\$39,185,910	\$38,477		
Alternative 15: No 30 day minimum for medical surveillance and triggered by AL	\$43,162,902	\$4,015,468		
Alternative 16: No BeLPTs in medical surveillance	\$38,423,316	-\$724,117		
Alternative 17: BeLPTs part of annual exam, rather than biannually.	\$39,528,226	\$380,793		
Alternative 18: No CT Scans	\$38,666,205	-\$481,229		
Alternative 19: Annual CT scans rather than biannual	\$39,597,303	\$449,870		
Alternative 20: All periodic components of medical surveillance are biannual	\$38,714,200	-\$433,233		
Alternative 21a: Medical Surveillance (PEL 0.2)	\$43,708,041	\$4,560,608		
Alternative 21b: Medical Surveillance (PEL 2.0)	\$42,198,735	\$3,051,301		
Alternative 22: No medical removal protection	\$38,981,379	-\$166,054		

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

5. Timing

As proposed, the new standard would become effective 60 days following publication in the **Federal Register**. The majority of employer duties in the standard would become enforceable 90 days following the effective date. Change rooms, however, would not be required until one year after the effective date, and the deadline for engineering controls would be no later than two years after the effective date.

OSHA invites suggestions for alternative phase-in schedules for engineering controls, medical surveillance, and other provisions of the standard. Although OSHA did not explicitly develop or quantitatively analyze any other regulatory alternatives

involving longer-term or more complex phase-ins of the standard (possibly involving more delayed implementation dates for small businesses), some general outcomes are likely. For example, a longer phase-in time would have several advantages, such as reducing initial costs of the standard or allowing employers to coordinate their environmental and occupational safety and health control strategies to minimize potential costs. However, a longer phase-in would also postpone and reduce the benefits of the standard. Suggestions for alternatives may apply to specific industries (e.g., industries where first-year or annualized cost impacts are highest), specific size-classes of employers (e.g., employers with fewer than 20 employees),

combinations of these factors, or all firms covered by the rule.

OSHA requests comments on all these regulatory alternatives, including the Agency's regulatory alternatives presented above, the Agency's analysis of these alternatives, and whether there are other regulatory alternatives the Agency should consider.

*I. Initial Regulatory Flexibility Analysis*

The Regulatory Flexibility Act, as amended in 1996, requires the preparation of an Initial Regulatory Flexibility Analysis (IRFA) for proposed rules where there would be a significant economic impact on a substantial number of small entities. (5 U.S.C. 601–612). Under the provisions of the law, each such analysis shall contain:

1. A description of the impact of the proposed rule on small entities;

2. A description of the reasons why action by the agency is being considered;

3. A succinct statement of the objectives of, and legal basis for, the proposed rule;

4. A description of and, where feasible, an estimate of the number of small entities to which the proposed rule will apply;

5. A description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities which will be subject to the requirements and the type of professional skills necessary for preparation of the report or record;

6. An identification, to the extent practicable, of all relevant Federal rules which may duplicate, overlap, or conflict with the proposed rule;

7. A description and discussion of any significant alternatives to the proposed rule which accomplish the stated objectives of applicable statutes and which minimize any significant economic impact of the proposed rule on small entities, such as:

(a) The establishment of differing compliance or reporting requirements or timetables that take into account the resources available to small entities;

(b) The clarification, consolidation, or simplification of compliance and reporting requirements under the rule for such small entities;

(c) The use of performance rather than design standards; and

(d) An exemption from coverage of the rule, or any part thereof, for such small entities.

5 U.S.C. 603, 607. The Regulatory Flexibility Act further states that the required elements of the IRFA 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 IRFA. 5 U.S.C. 605.

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 PEA and its supporting materials, the IRFA summarizes the key aspects of OSHA's analysis as they affect small entities.

#### 1. A Description of the Impact of the Proposed Rule on Small Entities

Section IX.F of this preamble summarized the impacts of the proposed rule on small entities. Table IX-9 showed costs as a percentage of profits and revenues for small entities, classified as small by the Small

Business Administration, and Tables IX-10 showed costs as a percentage of revenues and profits for business entities with fewer than 20 employees. (The costs in these tables were annualized using a discount rate of 3 percent.)

#### 2. A Description of the Reasons Why Action by the Agency Is Being Considered

Chronic beryllium disease (CBD) is a hypersensitivity, or allergic reaction, to beryllium that leads to a chronic inflammatory disease of the lungs. It takes months to years after initial beryllium exposure before signs and symptoms of CBD occur. Removing an employee with CBD from the beryllium source does not always lead to recovery. In some cases CBD continues to progress following removal from beryllium exposure. CBD is not a chemical pneumonitis but an immune-mediated granulomatous lung disease. OSHA's preliminary risk assessment, presented in Section VI of this preamble, indicates that there is significant risk of beryllium sensitization and chronic beryllium disease from a 45-year (working life) exposure to beryllium at the current TWA PEL of 2  $\mu\text{g}/\text{m}^3$ . The risk assessment further indicates that there is significant risk of lung cancer to workers exposed to beryllium at the current TWA PEL of 2  $\mu\text{g}/\text{m}^3$ . The proposed standard, with a lower PEL of .2  $\mu\text{g}/\text{m}^3$ , will help to address these health concerns.

For CBD to occur, an employee must first become sensitized (*i.e.*, allergic) to beryllium. Once an employee is sensitized, inhaled beryllium that deposits and persists in the lung may trigger a cell-mediated immune response (*i.e.*, hypersensitivity reaction) that results in the formation of a type of lung scarring known as a granuloma. The granuloma consists of a localized mass of immune and inflammatory cells that have formed around a beryllium particle lodged in the interstitium, which is tissue between the air sacs that can be affected by fibrosis or scarring. With time, the granulomas spread and can lead to chronic cough, shortness of breath (especially upon exertion), fatigue, abnormal pulmonary function, and lung fibrosis.

While CBD primarily affects the lungs, it can also involve other organs such as the liver, skin, spleen, and kidneys. As discussed in more detail in this preamble, some studies demonstrate that sensitization and CBD cases have occurred in workplaces that use a wide range of beryllium compounds, including several beryllium salts, refined beryllium metal, beryllium

oxide, and the beryllium alloys. While water-soluble and insoluble beryllium compounds have the potential to cause sensitization, it has been suggested that CBD is the result of occupational exposure to beryllium oxide and other water-insoluble berylliums rather than exposure to water-soluble beryllium or beryllium ores. However, there are inadequate data, at this time, on employees selectively exposed to specific beryllium compounds to eliminate a potential CBD concern for any particular form of this metal. Regardless of the type of beryllium compound, in order to cause respiratory disease the inhaled beryllium must contain particulates that are small enough to reach the bronchoalveolar region of the lung where the disease takes place (OSHA, 2007).

Some research suggests that skin exposure to small beryllium particles or beryllium-containing solutions may also lead to sensitization (Tinkle *et al.*, 2003). These additional risk factors may explain why some individuals with seemingly brief, low level exposure to airborne beryllium become sensitized while others with long-term high exposures do not. Other studies indicate that even though employees sensitized to beryllium do not exhibit clinical symptoms, their immune function is altered such that inhalation to previously safe levels of beryllium can now trigger serious lung disease (Kreiss *et al.*, 1996; Kreiss *et al.*, 1997; Kelleher *et al.*, 2001 and Rossman, 2001).

In the 1980s, the laboratory blood test known as the BeLPT was developed. The test substantially improved identification of beryllium-sensitized individuals and provides an opportunity to diagnose CBD at an early stage. The BeLPT measures the ability of immune cells (*i.e.*, peripheral blood lymphocytes) to react with beryllium. It has been reported that the BeLPT can identify 70 to 90 percent of those sensitized with a high specificity (approximately 1 to 3 percent false positives) (Newman *et al.*, 2001; Stange *et al.*, 2004).

An employee with an abnormal BeLPT (*i.e.*, the individual is sensitized) can undergo fiber-optic bronchoscopy to obtain a lung biopsy sample from which granulomatous lung inflammation can be pathologically observed prior to the onset of symptoms. The combination of a confirmed abnormal BeLPT (that is, a second abnormal result from the BeLPT) and microscopic evidence of granuloma formation is considered diagnostic for CBD. The BeLPT assists in differentiating CBD from other granulomatous lung diseases (*e.g.*, sarcoidosis) with similar lung

pathology. This pre-clinical diagnostic tool provides opportunities for early intervention that did not exist when diagnosis relied on clinical symptoms, chest x-rays, and abnormal pulmonary function (OSHA, 2007).

The BeLPT/lung biopsy diagnostic approach has been utilized in several occupational surveys and surveillance programs over the last fifteen years. The findings have expanded scientific awareness of sensitization and CBD prevalence among beryllium employees and provided a better understanding of its work-related risk factors. Some of the more informative studies come from nuclear weapons facilities operated by the Department of Energy (Viet *et al.*, 2000; Stange *et al.*, 2001; DOE/HSS Report, 2006), a beryllium ceramics plant in Arizona (Kreiss *et al.*, 1996; Henneberger *et al.*, 2001; Cummings *et al.*, 2007), a beryllium production plant in Ohio (Kreiss *et al.*, 1997; Kent *et al.*, 2001), a beryllium machining facility in Alabama (Kelleher *et al.*, 2001; Madl *et al.*, 2007), and a beryllium alloy plant (Shuler *et al.*, 2005) and another beryllium processing plant (Rosenman *et al.*, 2005), both in Pennsylvania. The prevalence of beryllium sensitization from these surveyed workforces generally ranged from 1 to 10 percent with a prevalence of CBD from 0.6 to 8 percent.

In most of the surveys discussed above, 36–100 percent of those workers who initially tested positive with the BeLPT were diagnosed with CBD upon pathological evaluation. Most of these workers diagnosed with CBD had worked four to 10 years on the job, although some were diagnosed within several months of employment. Surveys that found a high proportion (*e.g.*, larger than 50 percent) of CBD among the sensitized employees were from facilities with a large number of employees who had been exposed to respirable beryllium for many years. It has been estimated from ongoing surveillance of sensitized individuals, with an average follow-up time of 4.5 years, that 37 percent of beryllium-exposed employees were estimated to progress to CBD (Newman *et al.*, 2005). Another study of nuclear weapons facility employees enrolled in an ongoing medical surveillance program found that only about 20 percent of sensitized individuals employed less than five years eventually were diagnosed with CBD while 40 percent of sensitized employees employed ten years or more developed CBD (Stange *et al.*, 2001). This observation, along with the study findings that CBD prevalence increases with cumulative exposure (described below), suggests that

sensitized employees who acquire a higher lung burden of beryllium may be at greater risk of developing CBD than sensitized employees who have lesser amounts of beryllium in their lungs.

The greatest prevalence of sensitization and CBD were reported for production processes that involve heating beryllium metal (*e.g.*, furnace operations, hot wire pickling, and annealing) or generating and handling beryllium powder (*e.g.*, machining, forming, firing). For example, nearly 15 percent of machinists at the Arizona beryllium ceramics plant were sensitized, compared to just 1 percent of workers who never worked in machining (Kreiss *et al.*, 1996). A low prevalence of sensitization and CBD was reported among current employees at the Department of Energy (DOE) clean-up sites where beryllium was once used in the production of nuclear weapons (DOE/OSS, 2006). These sites have been subject to the DOE CBD-prevention programs since 1999. While the prevalence of sensitization and CBD in non-production jobs was less, cases of CBD were found among secretaries, office employees, and security guards. CBD cases have also been reported in downstream uses of beryllium such as dental laboratories and metal recycling (OSHA, 2007).

The potential importance of respirable and ultrafine beryllium particulates in the onset of CBD is illustrated in studies of employees at a large beryllium metal, alloy, and oxide production plant in Ohio. An initial cross-sectional survey reported that the highest prevalence of sensitization and CBD occurred among workers employed in beryllium metal production, even though the highest airborne total mass concentrations of beryllium were generally among employees operating the beryllium alloy furnaces in a different area of the plant (Kreiss *et al.*, 1997). Preliminary follow-up investigations of particle size-specific sampling at five furnace sites within the plant determined that the highest respirable (*e.g.*, particles less than 10  $\mu\text{m}$  in diameter) and alveolar-deposited (*e.g.*, particles less than 1  $\mu\text{m}$  in diameter) beryllium mass and particle number concentrations, as collected by a general area impactor device, were measured at the beryllium metal production furnaces rather than the beryllium alloy furnaces (Kent *et al.*, 2001; McCawley *et al.*, 2001). A statistically significant linear trend was reported between the above alveolar-deposited particle mass concentration and prevalence of CBD and sensitization in the furnace production areas. On the other hand, a linear trend was not found for CBD and sensitization prevalence

and total beryllium mass concentration. The authors concluded that these findings suggest that alveolar-deposited particles may be a more relevant exposure metric for predicting the incidence of CBD or sensitization than the total mass concentration of airborne beryllium (OSHA, 2007).

Several epidemiological cohort studies have reported excess lung cancer mortality among workers employed in U.S. beryllium production and processing plants during the 1930s to 1960s. The largest and most comprehensive study investigated the mortality experience of over 9,000 workers employed in seven different beryllium processing plants over a 30 year period (Ward *et al.*, 1992). The employees at the two oldest facilities (*i.e.*, Lorain, OH and Reading, PA) were found to have significant excess lung cancer mortality relative to the U.S. population. These two plants were believed to have the highest exposure levels to beryllium. A different analysis of the lung cancer mortality in this cohort using various local reference populations and alternate adjustments for smoking generally found smaller, non-significant, excess mortality among the beryllium employees (Levy *et al.*, 2002). All the cohort studies are limited by a lack of job history and air monitoring data that would allow investigation of mortality trends with beryllium exposure.

The weight of evidence indicates that beryllium compounds should be regarded as potential occupational lung carcinogens, and OSHA has regulated it since 1974. Other organizations, such as the International Agency for Research on Cancer (IARC), the National Toxicology Program (NTP), the U.S. Environmental Protection Agency (EPA), the National Institute for Occupational Safety and Health (NIOSH), and the American Conference of Governmental Industrial Hygienists (ACGIH) have reached similar conclusions with respect to the carcinogenicity of beryllium.

### 3. A Statement of the Objectives of, and Legal Basis for, the Proposed Rule

The objective of the proposed beryllium standard is to reduce the number of fatalities and illnesses occurring among employees exposed to beryllium. This objective will be achieved by requiring employers to install engineering controls where appropriate and to provide employees with the equipment, respirators, training, medical surveillance, and other protective measures to perform their jobs safely. The legal basis for the rule is the responsibility given 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 of this preamble for a more detailed discussion.

#### 4. A Description of, and an Estimate of, the Number of Small Entities to Which the Proposed Rule Will Apply

OSHA has completed a preliminary analysis of the impacts associated with this proposed rule, including an analysis of the type and number of small entities to which the proposed rule would 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.

The proposed standard would impact occupational exposures to beryllium in all forms, compounds, and mixtures in general industry. Based on the definitions of small entities developed by SBA for each industry, the proposal is estimated to potentially affect a total of 3,741 small entities as shown in Table IX–1 in Chapter IX of the PEA.

The Agency also estimated costs and conducted a screening analysis for very small employers (those with fewer than 20 employees). OSHA estimates that approximately 2,875 very small entities would be affected by the proposed standard, as shown in Table III–13 in Chapter III of the PEA.

#### 5. A Description of the Projected Reporting, Recordkeeping, and Other Compliance Requirements of the Proposed Rule

Tables IX–23 and IX–24 show the average costs of the proposed standard

by NAICS code and by compliance requirement (PEL/STEL or ancillary provisions) for, respectively, small entities (classified as small by SBA) and very small entities (those with fewer than 20 employees). Total costs are reported as N/A for NAICS codes with no affected entities in the relevant size classification. The weighted average cost per small entity for the proposed rule would be about \$8,638 annually, with PEL/STEL compliance accounting for about 23 percent of the costs and ancillary provisions accounting for about 77 percent of the costs.

The weighted average cost per very small entity for the proposed rule would be about \$2,212 annually, with PEL/STEL compliance accounting for about 39 percent of the costs and ancillary provisions accounting for about 61 percent of the costs.



Table IX-23  
Average Costs for Small Entities Affected by the Proposed Beryllium Standard (2010 dollars)

Application Group	NAICS	Industry	PEL		Total
			Compliance (Includes Respirators)	Ancillary Provisions	
Beryllium Production	331419	Primary Smelting and Refining of Nonferrous Metals and Composites	N/A	N/A	N/A
	327113a	Porcelain electrical supply manufacturing (primary)	\$85,376	\$10,438	\$95,814
	327113b	Porcelain electrical supply manufacturing (secondary)	\$5,478	\$7,502	\$12,979
	334220	Cellular telephones manufacturing	\$5,901	\$13,417	\$19,319
	334310	Compact disc players manufacturing	\$5,331	\$11,438	\$16,769
	334411	Electron Tube Manufacturing BeO traveling wave tubes	\$6,721	\$14,878	\$21,599
	334415	Electronic resistor manufacturing	\$5,812	\$9,241	\$15,052
	334419	Other electronic component manufacturing	\$5,357	\$7,625	\$12,982
	334510	Electromedical equipment manufacturing	\$5,268	\$3,545	\$8,812
	336322b	Other motor vehicle electrical & electronic equipment	\$5,735	\$12,681	\$18,416
Nonferrous Foundries	331521	Aluminum die-casting foundries	\$24,256	\$14,141	\$38,397
	331522	Nonferrous (except aluminum) die-casting foundries	\$23,001	\$12,013	\$35,015
	331524	Aluminum foundries (except die-casting)	\$25,338	\$15,180	\$40,518
	331525a	Copper foundries (except die-casting) (non-sand casting foundries)	\$25,540	\$15,755	\$41,295
	331525b	Copper foundries (except die-casting) (sand casting foundries)	\$27,012	\$18,120	\$45,132
Secondary Smelting, Refining, and Alloying	331314	Secondary smelting & alloying of aluminum	\$22,432	\$11,325	\$33,757
	331421b	Copper rolling, drawing, and extruding	\$22,432	\$11,775	\$34,206
	331423	Secondary smelting, refining, & alloying of copper	\$23,335	\$11,767	\$35,102
	331492	Secondary Smelting, Refining, and Alloying of Nonferrous Metal (Except Copper and Aluminum)	\$11,155	\$11,029	\$22,183
Precision Machining	332721a	Precision turned product manufacturing (high beryllium content)	\$8,643	\$10,839	\$19,482
	332721b	Precision turned product manufacturing (low beryllium content)	\$2,904	\$11,304	\$14,208
Copper Rolling, Drawing and Extruding	331421a	Copper rolling, drawing, and extruding	\$2,316	\$116,815	\$119,132
	331422	Copper wire (except mechanical) drawing	\$2,867	\$102,598	\$105,465
Stamping, Spring, and Connector Manufacturing	332612	Light gauge spring manufacturing	\$2,035	\$5,242	\$7,277
	332116	Metal stamping	\$1,935	\$6,460	\$8,395
	334417	Electronic connector manufacturing	\$1,905	\$3,860	\$5,765
	336322a	Other motor vehicle electrical & electronic equipment	\$2,032	\$8,017	\$10,049
Arc and Gas Welding	331111	Iron and Steel Mills	\$3,613	\$6,764	\$10,377
	331221	Rolled Steel Shape Manufacturing	\$3,879	\$8,663	\$12,541
	331513	Steel Foundries (except Investment)	\$2,472	\$6,185	\$8,657
	332117	Powder Metallurgy Part Manufacturing	\$2,113	\$6,166	\$8,278
	332212	Hand and Edge Tool Manufacturing	\$2,234	\$4,803	\$7,037

Table IX-23, continued  
Average Costs for Small Entities Affected by the Proposed Beryllium Standard (2010 dollars)

Application Group	NAICS	Industry	PEL		Total
			Compliance (Includes Respirators)	Ancillary Provisions	
	332312	Fabricated Structural Metal Manufacturing	\$2,111	\$3,964	\$6,076
	332313	Plate Work Manufacturing	\$2,597	\$4,783	\$7,379
	332322	Sheet Metal Work Manufacturing	\$2,459	\$4,552	\$7,010
	332323	Ornamental and Architectural Metal Work Manufacturing	\$2,289	\$4,258	\$6,548
	332439	Other Metal Container Manufacturing	\$1,975	\$3,883	\$5,858
	332919	Other Metal Valve and Pipe Fitting Manufacturing	\$1,927	\$4,374	\$6,301
	332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	\$2,376	\$4,407	\$6,782
	333111	Farm Machinery and Equipment Manufacturing	\$1,304	\$2,594	\$3,899
	333414a	Heating Equipment (except Warm Air Furnaces) Manufacturing	\$1,933	\$3,836	\$5,769
	333911	Pump and Pumping Equipment Manufacturing	\$1,455	\$3,002	\$4,457
	333922	Conveyor and Conveying Equipment Manufacturing	\$2,370	\$4,439	\$6,809
	333924	Industrial Truck, Tractor, Trailer, and Stacker Machinery Manufacturing	\$3,116	\$6,006	\$9,122
	333999	All Other Miscellaneous General Purpose Machinery Manufacturing	\$1,820	\$3,463	\$5,282
	336211	Motor Vehicle Body Manufacturing	\$3,201	\$5,854	\$9,055
	336214	Travel Trailer and Camper Manufacturing	\$1,490	\$2,914	\$4,404
	336399a	All Other Motor Vehicle Parts Manufacturing	\$3,302	\$6,143	\$9,445
	336510	Railroad Rolling Stock	\$4,298	\$8,685	\$12,983
	336999	All Other Transportation Equipment Manufacturing	\$1,291	\$3,048	\$4,339
	337215	Showcase, Partition, Shelving, and Locker Manufacturing	\$2,253	\$4,713	\$6,966
	811310	Commercial and Industrial Machinery and Equipment Repair	\$1,880	\$3,565	\$5,445
Resistance Welding					
	333411	Air Purification Equipment Manufacturing	\$0	\$8,363	\$8,363
	333412	Industrial and Commercial Fan and Blower Manufacturing	\$0	\$11,780	\$11,780
	333414b	Heating Equipment (except Warm Air Furnaces) Manufacturing	\$0	\$10,186	\$10,186
		Air-Conditioning, Warm Air Heating, and Industrial Refrigeration Equipment Manufacturing	\$0	\$18,247	\$18,247
	335211	Electric Housewares and Household Fan Manufacturing	\$0	\$15,789	\$15,789
	335212	Household Vacuum Cleaner Manufacturing	\$0	\$17,638	\$17,638
	335221	Household Cooking Appliance Manufacturing	\$0	\$15,870	\$15,870
	335222	Household Refrigerator and Home Freezer Manufacturing	\$0	\$16,548	\$16,548
	335224	Household Laundry Equipment Manufacturing	\$0	\$8,274	\$8,274
	335228	Other Major Household Appliance Manufacturing	\$0	\$1,740	\$1,740
	336311	Carburetor, Piston, Piston Ring, and Valve Manufacturing	\$0	\$5,227	\$5,227
	336312	Gasoline Engine and Engine Parts Manufacturing	\$0	\$16,015	\$16,015
	336321	Vehicular Lighting Equipment Manufacturing	\$0	\$6,084	\$6,084
	336322c	Other Motor Vehicle Electrical and Electronic Equipment Manufacturing	\$0	\$16,355	\$16,355
		Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	\$0	\$17,707	\$17,707
	336330	Manufacturing	\$0	\$18,828	\$18,828
	336340	Motor Vehicle Brake System Manufacturing	\$0	\$18,037	\$18,037
	336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	\$0	\$18,037	\$18,037
	336360	Motor Vehicle Seating and Interior Trim Manufacturing	\$0	\$6,586	\$6,586

Table IX-23, continued  
Average Costs for Small Entities Affected by the Proposed Beryllium Standard (2010 dollars)

Application Group	NAICS	Industry	PEL		Total
			Compliance (Includes Respirators)	Ancillary Provisions	
	336370	Motor Vehicle Metal Stamping	\$0	\$8,894	\$8,894
	336391	Motor Vehicle Air-Conditioning Manufacturing	\$0	\$16,715	\$16,715
	336399b	All Other Motor Vehicle Parts Manufacturing	\$0	\$17,568	\$17,568
Dental Laboratories					
	339116	Dental laboratories	\$494	\$900	\$1,394
	621210	Offices of dentists	\$577	\$1,053	\$1,630
Weighted Average			\$1,969	\$6,669	\$8,638

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.

Table IX-24

## Average Costs for Very Small Entities (&lt;20 employees) Affected by the Proposed Beryllium Standard (2010 dollars)

Application Group	NAICS	Industry	PEL		Total
			Compliance (Includes Respirators)	Ancillary Provisions	
Beryllium Production					
	331419	Primary Smelting and Refining of Nonferrous Metals (Brush Wellman)	N/A	N/A	N/A
Beryllium Oxide Ceramics and Composites					
	327113a	Porcelain electrical supply manufacturing (primary)	N/A	N/A	N/A
	327113b	Porcelain electrical supply manufacturing (secondary)	\$5,176	\$1,670	\$6,846
	334220	Cellular telephones manufacturing	\$5,182	\$1,091	\$6,273
	334310	Compact disc players manufacturing	\$5,202	\$3,181	\$8,383
	334411	Electron Tube Manufacturing BeO traveling wave tubes	\$5,172	\$1,258	\$6,430
	334415	Electronic resistor manufacturing	\$5,176	\$1,673	\$6,849
	334419	Other electronic component manufacturing	\$5,179	\$1,783	\$6,962
	334510	Electromedical equipment manufacturing	\$5,171	\$1,099	\$6,271
	336322b	Other motor vehicle electrical & electronic equipment	\$5,198	\$1,170	\$6,368
Nonferrous Foundries					
	331521	Aluminum die-casting foundries	N/A	N/A	N/A
	331522	Nonferrous (except aluminum) die-casting foundries	N/A	N/A	N/A
	331524	Aluminum foundries (except die-casting)	N/A	N/A	N/A
	331525a	Copper foundries (except die-casting) (non-sand casting foundries)	N/A	N/A	N/A
	331525b	Copper foundries (except die-casting) (sand casting foundries)	N/A	N/A	N/A
Secondary Smelting, Refining, and Alloying					
	331314	Secondary smelting & alloying of aluminum	N/A	N/A	N/A
	331421b	Copper rolling, drawing, and extruding	N/A	N/A	N/A
	331423	Secondary smelting, refining, & alloying of copper	\$19,724	\$1,864	\$21,589
		Secondary Smelting, Refining, and Alloying of Nonferrous Metal (Except Copper and Aluminum)	\$9,626	\$1,430	\$11,055
Precision Machining					
	332721a	Precision turned product manufacturing (high beryllium content)	\$3,033	\$3,849	\$6,882
	332721b	Precision turned product manufacturing (low beryllium content)	\$1,023	\$4,022	\$5,046
Copper Rolling, Drawing and Extruding					
	331421a	Copper rolling, drawing, and extruding	\$1,133	\$4,550	\$5,684
	331422	Copper wire (except mechanical) drawing	\$1,304	\$6,379	\$7,682
Stamping, Spring, and Connector Manufacturing					
	332612	Light gauge spring manufacturing	\$1,839	\$1,471	\$3,310
	332116	Metal stamping	\$1,846	\$1,697	\$3,543
	334417	Electronic connector manufacturing	\$1,841	\$1,173	\$3,014
	336322a	Other motor vehicle electrical & electronic equipment	\$1,851	\$1,157	\$3,007
Arc and Gas Welding					
	331111	Iron and Steel Mills	N/A	N/A	N/A
	331221	Rolled Steel Shape Manufacturing	N/A	N/A	N/A
	331513	Steel Foundries (except Investment)	N/A	N/A	N/A
	332117	Powder Metallurgy Part Manufacturing	N/A	N/A	N/A
	332212	Hand and Edge Tool Manufacturing	\$782	\$2,389	\$3,171

Table IX-24, continued

Average Costs for Very Small Entities (<20 employees) Affected by the Proposed Beryllium Standard (2010 dollars)					
Application Group	NAICS	Industry	PEL		Total
			Compliance (Includes Respirators)	Ancillary Provisions	
	332312	Fabricated Structural Metal Manufacturing	\$715	\$1,584	\$2,299
	332313	Plate Work Manufacturing	\$935	\$1,956	\$2,891
	332322	Sheet Metal Work Manufacturing	\$834	\$1,786	\$2,620
	332323	Ornamental and Architectural Metal Work Manufacturing	\$1,032	\$2,121	\$3,153
	332439	Other Metal Container Manufacturing	\$726	\$1,745	\$2,471
	332919	Other Metal Valve and Pipe Fitting Manufacturing	\$834	\$3,469	\$4,302
	332999	All Other Miscellaneous Fabricated Metal Product Manufacturing	\$812	\$1,748	\$2,560
	333111	Farm Machinery and Equipment Manufacturing	\$715	\$1,584	\$2,299
	333414a	Heating Equipment (except Warm Air Furnaces) Manufacturing	\$732	\$1,805	\$2,536
	333911	Pump and Pumping Equipment Manufacturing	\$727	\$1,750	\$2,477
	333922	Conveyor and Conveying Equipment Manufacturing	\$717	\$1,619	\$2,335
	333924	Industrial Truck, Tractor, Trailer, and Stacker Machinery Manufacturing	\$750	\$2,011	\$2,761
	333999	All Other Miscellaneous General Purpose Machinery Manufacturing	\$715	\$1,583	\$2,298
	336211	Motor Vehicle Body Manufacturing	\$715	\$1,583	\$2,298
	336214	Travel Trailer and Camper Manufacturing	\$715	\$1,585	\$2,300
	336399a	All Other Motor Vehicle Parts Manufacturing	\$723	\$1,702	\$2,424
	336510	Railroad Rolling Stock	N/A	N/A	N/A
	336999	All Other Transportation Equipment Manufacturing	\$764	\$2,174	\$2,938
	337215	Showcase, Partition, Shelving, and Locker Manufacturing	\$771	\$2,264	\$3,035
	811310	Commercial and Industrial Machinery and Equipment Repair	\$1,327	\$2,623	\$3,949
Resistance Welding			\$0	\$0	\$0
	333411	Air Purification Equipment Manufacturing	\$0	\$2,506	\$2,506
	333412	Industrial and Commercial Fan and Blower Manufacturing	\$0	\$2,401	\$2,401
	333414b	Heating Equipment (except Warm Air Furnaces) Manufacturing	\$0	\$2,321	\$2,321
		Air-Conditioning, Warm Air Heating, and Industrial Refrigeration Equipment Manufacturing	\$0	\$1,094	\$1,094
	335211	Electric Housewares and Household Fan Manufacturing	\$0	\$1,151	\$1,151
	335212	Household Vacuum Cleaner Manufacturing	N/A	N/A	N/A
	335221	Household Cooking Appliance Manufacturing	\$0	\$1,056	\$1,056
	335222	Household Refrigerator and Home Freezer Manufacturing	N/A	N/A	N/A
	335224	Household Laundry Equipment Manufacturing	N/A	N/A	N/A
	335228	Other Major Household Appliance Manufacturing	N/A	N/A	N/A
	336311	Carburetor, Piston, Piston Ring, and Valve Manufacturing	\$0	\$1,395	\$1,395
	336312	Gasoline Engine and Engine Parts Manufacturing	\$0	\$1,331	\$1,331
	336321	Vehicular Lighting Equipment Manufacturing	\$0	\$1,056	\$1,056
	336322c	Other Motor Vehicle Electrical and Electronic Equipment Manufacturing	\$0	\$1,452	\$1,452
		Motor Vehicle Steering and Suspension Components (except Spring) Manufacturing	\$0	\$1,056	\$1,056
	336330	Manufacturing	\$0	\$1,056	\$1,056
	336340	Motor Vehicle Brake System Manufacturing	\$0	\$1,056	\$1,056
	336350	Motor Vehicle Transmission and Power Train Parts Manufacturing	\$0	\$1,056	\$1,056
	336360	Motor Vehicle Seating and Interior Trim Manufacturing	\$0	\$1,056	\$1,056

Table IX-24, continued

Average Costs for Very Small Entities (<20 employees) Affected by the Proposed Beryllium Standard (2010 dollars)					
Application Group	NAICS	Industry	PEL		Total
			Compliance (Includes Respirators)	Ancillary Provisions	
	336370	Motor Vehicle Metal Stamping	\$0	\$1,329	\$1,329
	336391	Motor Vehicle Air-Conditioning Manufacturing	\$0	\$1,056	\$1,056
	336399b	All Other Motor Vehicle Parts Manufacturing	\$0	\$1,267	\$1,267
Dental Laboratories			\$0	\$0	\$0
	339116	Dental laboratories	\$325	\$598	\$923
	621210	Offices of dentists	\$518	\$947	\$1,465
		<b>Weighted Average</b>	<b>\$862</b>	<b>\$1,350</b>	<b>\$2,212</b>

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis.

#### 6. Federal Rules Which May Duplicate, Overlap or Conflict With the Proposed Rule

Section 4(b)(1) of the OSH Act exempts the working conditions for

certain Federal and non-Federal employees from the provisions of the OSH Act to the extent that other Federal agencies exercise statutory authority to prescribe and enforce occupational safety and health standards. The

Department of Energy (DOE) issued a regulation in 1999 entitled Chronic Beryllium Disease Prevention Program (CBDPP) (10 CFR part 850, 64 FR 68854-68914, December 8, 1999). Additionally, DOE issued 10 CFR part

851, Worker Safety and Health Program (71 FR 6931–6948, February 9, 2006), which establishes requirements for worker safety and health for DOE contractors at DOE sites. The CBDPP establishes a beryllium program for DOE employees and DOE contractor employees. Therefore, under Section 4(b)(1) of the OSH Act, OSHA's beryllium standard would not apply to work subject to the CBDPP. DOE has included in its regulations a requirement for compliance with any more stringent PEL established by OSHA in rulemaking (10 CFR 850.22). OSHA requests comment on the potential overlap of DOE's rule with OSHA's proposed rule. (See I. Issues and Alternatives in this preamble).

There is also a Federal statute addressing the compensation of some employees with beryllium related illnesses—The Energy Employees Occupational Illness Compensation Program Act (EEOICPA) of 2000 and its subsequent amendments. The EEOICPA creates a Federal employees' compensation program that covers beryllium-related health effects for DOE employees and its contractor employees, including many private companies that work away from DOE sites. Several of the private companies whose employees are covered by the OSH Act, either directly in amendments to the OSH Act or identified in subsequent Department of Labor regulations on that Act, would be covered by an OSHA occupational health standard for beryllium and EEOICPA.

There would be no conflict or duplication, however, between an OSHA standard and the EEOICPA. In general, the OSHA standard would have requirements to protect employee health in the future, and the EEOICPA provides compensation for employees who have developed beryllium-related illness. There is some overlap between the two in that they may both require similar medical examinations, or require employers to provide some compensation to employees, but the proposed OSHA standard specifically contemplates and addresses that overlap to avoid conflict and duplication. The explanation for proposed paragraph (k) in Section XVIII of this preamble, Summary and Explanation, notes that employers may satisfy the both examination requirements with a single examination, and the proposed standard specifies that the amount of an employer's financial obligations will be reduced by the amount of EEOICPA payments received by that employee (see proposed paragraph (l)(4)).

#### 7. Alternatives to the Proposed Rule Which Accomplish the Stated Objectives of Applicable Statutes and Which Minimize Any Significant Economic Impact of the Proposed Rule on Small Entities

This section first discusses several provisions in the proposed standard that OSHA has adopted or modified based on comments from small entity representatives (SERs) during the SBREFA process or on recommendations made by the SBAR Panel as potentially alleviating impacts on small entities. Then, the Agency presents various regulatory alternatives to the proposed OSHA beryllium standard.

##### a. Elements of the Proposed Rule To Reduce Impacts on Small Entities

During the SBAR Panel, SERs requested a clearer definition of the triggers for medical surveillance. This concern was rooted in the cost of BeLPTs and the trigger of potential skin contact. For the proposed rule, the Agency has removed skin contact as a trigger for medical surveillance along with providing four clearly defined trigger mechanisms. The newly defined medical surveillance provision reduces the number of employees requiring a BeLPT, particularly for small businesses with low exposures.

Some of the SERs in low-exposure industries wanted to be "shielded" from "expensive" compliance with a standard they perceive to be unnecessary and suggested a PEL-only standard that triggered provisions on the PEL. The alternative of a PEL-only standard and ancillary provisions triggered only by the PEL are discussed in Chapter 8 of the PEA (and is repeated in the following section).

Some SERs were already applying many of the protective controls and practices that would be required by the ancillary provisions of the standard. However, many SERs objected to the requirements regarding hygiene facilities. For this proposed rule, OSHA has preliminarily concluded that all affected employers currently have hand washing facilities. OSHA has also preliminarily concluded that no affected employers will be required to install showers. The Agency has determined that the long-term rental of modular units was representative of costs for a range of reasonable approaches to comply with the change room part of the provision. Alternatively, employers could renovate and rearrange their work areas in order to meet the requirements of this provision.

##### b. Regulatory Alternatives

For the convenience of those persons interested only in OSHA's regulatory flexibility analysis, this section repeats the discussion of the various regulatory alternatives to the proposed OSHA beryllium standard presented in Chapter VIII of the PEA, but only for the regulatory alternatives to the proposed OSHA beryllium standard that lower costs. OSHA believes that this presentation of specific regulatory alternatives explores the possibility of less costly ways (than the proposed rule) to provide an adequate level of worker protection from exposure to beryllium.

Each regulatory alternative presented here is described and analyzed relative to the proposed rule. Where appropriate, the Agency notes whether the regulatory alternative, to be a legitimate candidate for OSHA consideration, requires evidence contrary to the Agency's preliminary findings of significant risk and feasibility. As noted above, for this chapter on the Initial Regulatory Flexibility Analysis, the Agency is only presenting regulatory alternatives that reduce costs for small entities. (See Chapter VIII for the full list of all alternatives analysed.) There are eight regulatory alternatives and an informational alternative that reduce costs for small entities (and for all businesses in total). Using the numbering scheme from Chapter VIII, these are Regulatory Alternatives #5, #6, #7, #8, #12, #16, #18, and #22. To facilitate comment, OSHA has organized these potentially less costly regulatory alternatives (and a general discussion of possible phase-ins of the rule) into four categories: (1) Exposure limits; (2) methods of compliance; (3) ancillary provisions; and (4) timing.

##### (1) Exposure limit (TWA PEL, STEL, and ACTION LEVEL) alternatives

Regulatory Alternative #5, which would set a TWA PEL at 0.5 µg/m<sup>3</sup> and an action level at 0.25 µg/m<sup>3</sup>, both higher than in the proposal, responds to an issue raised during the Small Business Advocacy Review (SBAR) process conducted in 2007 to consider a draft OSHA beryllium proposed rule that culminated in an SBAR Panel report (SBAR, 2008). That report included a recommendation that OSHA consider both the economic impact of a low TWA PEL and regulatory alternatives that would ease cost burden for small entities. OSHA has provided a full analysis of the economic impact of its proposed PELs (see Chapter VI of the PEA), and Regulatory Alternative #5

addresses the second half of that recommendation. However, the higher 0.5  $\mu\text{g}/\text{m}^3$  TWA PEL does not appear to be consistent with the Agency's mandate under the OSH Act to promulgate a lower PEL if it is feasible and could prevent additional fatalities and non-fatal illnesses. The data presented in Table IX-25 below indicate that the lower TWA PEL would prevent additional fatalities and non-fatal

illnesses, but nevertheless the Agency solicits comments on this alternative and OSHA's analysis of the costs and benefits associated with it.

Table IX-25 below presents, for informational purposes, the estimated costs, benefits, and net benefits of the proposed rule under the proposed TWA PEL of 0.2  $\mu\text{g}/\text{m}^3$  and for the regulatory alternative of a TWA PEL of 0.5  $\mu\text{g}/\text{m}^3$  (Regulatory Alternative #5), using

alternative discount rates of 3 percent and 7 percent. Table IX-25 also breaks out costs by provision and benefits by type of disease and by morbidity/mortality. As Table IX-25 shows, going from a TWA PEL of 0.5  $\mu\text{g}/\text{m}^3$  to a TWA PEL of 0.2  $\mu\text{g}/\text{m}^3$  would prevent, annually, an additional 29 beryllium-related fatalities and an additional 15 non-fatal illnesses.

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Discount Rate	Proposed PEL (PEL = 0.2 µg/m <sup>3</sup> , AL = 0.10 µg/m <sup>3</sup> )		Alternative 5 Incremental Costs/Benefits		Alternative 5 (PEL = 0.5 µg/m <sup>3</sup> , AL = 0.25 µg/m <sup>3</sup> )				
	3%	7%	3%	7%	3%	7%			
	<b>Annualized Costs</b>								
Control Costs	\$9.5	\$10.3	-\$3.6	-\$3.9	\$6.0	\$6.5			
Respirators	\$0.2	\$0.3	-\$0.1	-\$0.1	\$0.1	\$0.1			
Exposure Assessment	\$2.2	\$2.4	-\$0.3	-\$0.3	\$1.9	\$2.1			
Regulated areas and Beryllium Work Areas	\$0.6	\$0.7	-\$0.3	-\$0.3	\$0.3	\$0.4			
Medical Surveillance	\$2.9	\$3.0	-\$0.1	-\$0.1	\$2.8	\$2.9			
Medical Removal	\$0.1	\$0.2	-\$0.1	-\$0.1	\$0.1	\$0.1			
Exposure Control Plan	\$1.8	\$1.8	\$0.0	\$0.0	\$1.8	\$1.8			
Protective Clothing and Equipment	\$1.4	\$1.4	\$0.0	\$0.0	\$1.4	\$1.4			
Hygiene Areas and Practices	\$0.4	\$0.4	\$0.0	\$0.0	\$0.4	\$0.4			
Housekeeping	\$12.6	\$12.9	\$0.0	\$0.0	\$12.6	\$12.9			
Training	\$5.8	\$5.8	\$0.0	\$0.0	\$5.8	\$5.8			
<b>Total Annualized Costs (point estimate)</b>	<b>\$37.6</b>	<b>\$39.1</b>	<b>-\$4.4</b>	<b>-\$4.8</b>	<b>\$33.2</b>	<b>\$34.4</b>			
<b>Annual Benefits: Number of Cases Prevented</b>	<b>Cases</b>		<b>Cases</b>		<b>Cases</b>				
Fatal Lung Cancers (midpoint estimate)	4		0		4				
Fatal Chronic Beryllium Disease	92		-29		63				
Beryllium-Related Mortality	96	\$573.0	\$253.7	-28	-\$171.8	-\$76.1	67	\$401.2	\$177.7
Beryllium Morbidity	50	\$2.8	\$1.6	-15	-\$0.9	-\$0.5	34	\$2.0	\$1.1
<b>Monetized Annual Benefits (midpoint estimate)</b>	<b>\$575.8</b>	<b>\$255.3</b>	<b>-\$172.7</b>	<b>-\$76.6</b>	<b>\$403.1</b>	<b>\$178.8</b>			
<b>Net Benefits</b>	<b>\$538.2</b>	<b>\$216.2</b>	<b>-\$168.2</b>	<b>-\$71.9</b>	<b>\$370.0</b>	<b>\$144.4</b>			

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.

## BILLING CODE 4510-26-P

## Informational Alternative Featuring Unchanged PEL but Full Ancillary Provisions

An Informational Analysis: This proposed regulation has the somewhat unusual feature for an OSHA substance-specific health standard that most of the quantified benefits would come from the ancillary provisions rather than from meeting the PEL with engineering controls. OSHA decided to analyze for informational purposes the effect of retaining the existing PEL but applying all of the ancillary provisions, including respiratory protection. Under this approach, the TWA PEL would remain at 2.0 micrograms per cubic meter, but all of the other proposed provisions (including respiratory protection, which OSHA does not consider an ancillary provision) would be required with their triggers remaining the same as in the proposed rule—either the presence of airborne beryllium at any level (*e.g.*, initial monitoring, written exposure control plan), at certain kinds of dermal exposure (PPE), at the action level of 0.1  $\mu\text{g}/\text{m}^3$  (*e.g.*, periodic monitoring, medical removal), or at 0.2  $\mu\text{g}/\text{m}^3$  (*e.g.*, regulated areas, respiratory protection, medical surveillance).

Given the record regarding beryllium exposures, this approach is not one OSHA could legally adopt because the absence of a more protective requirement for engineering controls would not be consistent with section 6(b)(5) of the OSH Act, which requires OSHA 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.” For that reason, this additional analysis is provided strictly for informational purposes. EO 12866 and EO 13563 direct agencies to identify approaches that maximize net benefits, and this analysis is purely for the purpose of exploring whether this approach would hold any real promise to maximize net benefits if it was permissible under the OSH Act. It does not appear to hold such promise because an ancillary-provisions-only approach would not be as protective and thus offers fewer benefits than one that includes a lower PEL and engineering controls, and OSHA estimates the costs would be about the same (or slightly lower, depending on certain assumptions) under that approach as under the traditional proposed approach.

On an industry by industry basis, OSHA found that some industries would have lower costs if they could adopt the ancillary-provisions-only approach. Some employers would use engineering controls where they are cheaper, even if they are not mandatory. OSHA does not have sufficient information to do an analysis of the employer-by-employer situations in which there exist some employers for whom the ancillary-provisions-only approach might be cheaper. In the majority of affected industries, the Agency estimates there are no costs saving to the ancillary-provisions-only approach. However, OSHA estimates a total of \$2,675,828 per year in costs saving for entire industries where the ancillary-provisions-only approach would be less expensive.

The above discussion does not account for the possibility that the lack of engineering controls would result in higher beryllium exposures for workers in adjacent (non-production) work areas due to the increased level of beryllium in the air. Because of a lack of data, and because the issue did not arise in the other regulatory alternatives OSHA considered (all of which have a PEL of less than 2.0  $\mu\text{g}/\text{m}^3$ ), OSHA did not carefully examine exposure levels in non-production areas for either cost or benefit purposes. To the extent such exposure levels would be above the action level, there would be additional costs for respiratory protection.

The ancillary-provisions-only approach adds uncertainty to the benefits analysis such that the benefits of the rule as proposed may exceed, and perhaps greatly exceed, the benefits of this ancillary-provisions-only approach:

(1) Most exposed individuals would be in respirators, which OSHA considers less effective than engineering controls in preventing employee exposure to beryllium. OSHA last did an extensive review of the evidence on effectiveness of respirators for its APFs rulemaking in 2006 (71 FR 50128–45 Aug 24, 2006). OSHA has not in the past tried to quantify the size of this effect, but it could partially negate the estimated benefits of 92 CBD deaths prevented per year and 4 lung cancer cases prevented per year by the proposed standard.

(2) As noted above, in the proposal OSHA did not consider benefits caused by reductions in exposure in non-production areas. Unless employers act to reduce exposures in the production areas, the absence of a requirement for such controls would largely negate such benefits from reductions in exposure in the non-productions areas.

(3) OSHA believes that there is a strong possibility that the benefits of the ancillary provisions (a midpoint estimate of eliminating 45 percent of all remaining cases of CBD) would be partially or wholly negated in the absence of engineering controls that would reduce both airborne and surface dust levels. The measured reduction in benefits from ancillary provision was in a facility with average exposure levels of less than 0.2  $\mu\text{g}/\text{m}^3$ .

Based on these considerations, OSHA believes that the ancillary-provisions-only approach is not one that is likely to maximize net benefits. The costs saving, if any, are estimated to be small, and the difficult-to-measure declines in benefits could be substantial.

## (2) A Method-of-compliance Alternative

Paragraph (f)(2) of the proposed rule contains requirements for the implementation of engineering and work practice controls to minimize beryllium exposures in beryllium work areas. For each operation in a beryllium work area, employers must ensure that at least one of the following engineering and work practice controls is in place to minimize employee exposure: Material and/or process substitution; ventilated enclosures; local exhaust ventilation; or process controls, such as wet methods and automation. Employers are exempt from using engineering and work practice controls only when they can show that such controls are not feasible or where exposures are below the action level based on two exposure samples taken seven days apart.

These requirements, which are based on the stakeholders' recommended beryllium standard that beryllium industry and union stakeholders submitted to OSHA in 2012 (Materion and USW, 2012), address a concern associated with the proposed TWA PEL. OSHA expects that day-to-day changes in workplace conditions, such as workers' positioning or patterns of airflow, may cause frequent exposures above the TWA PEL in workplaces where periodic sampling indicates exposures are between the action level and the TWA PEL. As a result, the default under the standard is that the controls are required until the employer can demonstrate that exposures have not exceeded the action level from at least two separate measurements taken seven days apart.

OSHA believes that substitution or engineering controls such as those outlined in paragraph (f)(2)(i) provide the most reliable means to control variability in exposure levels. However, OSHA also recognizes that the requirements of paragraph (f)(2)(i) are



not typical of OSHA standards, which usually require engineering controls only where exposures exceed the TWA PEL or STEL. The Agency is therefore considering Regulatory Alternative #6, which would drop the provisions of (f)(2)(i) from the proposed standard and make conforming edits to paragraphs (f)(2)(ii) and (iii). This regulatory

alternative does not eliminate the need for engineering controls to comply with the proposed TWA PEL and STEL, but does eliminate the requirement to use one or more of the specified engineering or work practice controls where exposures equal or exceed the action level. As shown in Table IX-26, Regulatory Alternative #6 would

decrease the annualized cost of the proposed rule by about \$457,000 using a discount rate of 3 percent and by about \$480,000 using a discount rate of 7 percent. OSHA has not been able to estimate the change in benefits resulting from Regulatory Alternative #6 at this time and invites public comment on this issue.

**Table IX-26: Cost of Regulatory Alternatives, Alternative 6 (Proposed PEL=0.2, STEL=2.0, AL=0.1)**

<u>3% Discount Rate</u>	<u>Total Cost</u>	<u>Incremental Cost Relative to Proposed Rule</u>
<b>Proposed Rule</b>	\$37,597,325	—
<b>Alternative 6: Eliminate (f)(2) controls</b>	\$37,140,020	-\$457,304

<u>7% Discount Rate</u>	<u>Total Cost</u>	<u>Incremental Cost Relative to Proposed Rule</u>
<b>Proposed Rule</b>	\$39,147,434	—
<b>Alternative 6: Eliminate (f)(2) controls</b>	\$38,667,896	-\$479,538

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

**(3) Regulatory Alternatives That Affect Ancillary Provisions**

The proposed standard contains several ancillary provisions (provisions other than the exposure limits), including requirements for exposure assessment, medical surveillance, medical removal, training, and regulated areas or access control. As reported in Chapter V of the PEA, these ancillary provisions account for \$27.8 million (about 72 percent) of the total annualized costs of the rule (\$37.6 million) using a 3 percent discount rate, or \$28.6 million (about 73 percent) of the total annualized costs of the rule (\$39.1 million) using a 7 percent discount rate. The most expensive of the ancillary provisions are the requirements for housekeeping and training, with annualized costs of \$12.6 million and \$5.8 million, respectively, at a 3 percent discount rate (\$12.9 million and \$5.8 million, respectively, at a 7 percent discount rate).

OSHA's reasons for including each of the proposed ancillary provisions are explained in Section XVIII of this preamble, Summary and Explanation of

the Standards. In particular, OSHA is proposing the requirements for exposure assessment to provide a basis for ensuring that appropriate measures are in place to limit worker exposures. Medical surveillance is especially important because workers exposed above the proposed TWA PEL, as well as many workers exposed below the proposed TWA PEL, are at significant risk of death and illness. Medical surveillance would allow for identification of beryllium-related adverse health effects at an early stage so that appropriate intervention measures can be taken. OSHA is proposing regulated areas and access control because they serve to limit exposure to beryllium to as few employees as possible. OSHA is proposing worker training to ensure that employers inform employees of the hazards to which they are exposed, along with associated protective measures, so that employees understand how they can minimize their exposure to beryllium. Worker training on beryllium-related work practices is particularly important in controlling

beryllium exposures because engineering controls frequently require action on the part of workers to function effectively.

OSHA has examined a variety of regulatory alternatives involving changes to one or more of the proposed ancillary provisions. The incremental cost of each of these regulatory alternatives and its impact on the total costs of the proposed rule is summarized in Table IX-27 at the end of this section. OSHA has preliminarily determined that several of these ancillary provisions will increase the benefits of the proposed rule, for example, by helping to ensure the TWA PEL is not exceeded or by lowering the risks to workers given the significant risk remaining at the proposed TWA PEL. However, except for Regulatory Alternative #7 (involving the elimination of all ancillary provisions), OSHA did not estimate changes in monetized benefits for the regulatory alternatives that affect ancillary provisions. Two regulatory alternatives that involve all ancillary provisions are presented below (#7 and #8), followed

by regulatory alternatives for regulated areas (#12), for medical surveillance (#16 and #18), and for medical removal (#22).

(a) All Ancillary Provisions

The SBAR Panel recommended that OSHA analyze a PEL-only standard as a regulatory alternative. The Panel also recommended that OSHA consider not applying ancillary provisions of the standard where exposure levels are low so as to minimize costs for small businesses (SBAR, 2008). In response to these recommendations, OSHA analyzed Regulatory Alternative #7, a PEL-only standard, and Regulatory Alternative #8, which would apply ancillary provisions of the beryllium standard only where exposures exceed the proposed TWA PEL of 0.2 µg/m<sup>3</sup> or the proposed STEL of 2 µg/m<sup>3</sup>.

Regulatory Alternative #7 would solely update 1910.1000 Tables Z-1 and Z-2, so that the proposed TWA PEL and STEL would apply to all workers in general industry. This alternative would eliminate all of the ancillary provisions of the proposed rule, including exposure assessment, medical surveillance, medical removal, PPE, housekeeping, training, and regulated areas or access control. Under this regulatory alternative, OSHA estimates that the costs for the proposed ancillary provisions of the rule (estimated at \$27.8 million annually at a 3 percent discount rate) would be eliminated. In order to meet the PELs, employers would still commonly need to do monitoring, train workers on the use of controls, and set up some kind of regulated areas to indicate where respirator use would be required. It is also likely that, under this alternative, many employers would follow the recommendations of Materion and the United Steelworkers to provide medical surveillance, PPE, and other protective measures for their workers (Materion and USW, 2012). OSHA has not attempted to estimate the extent to which these ancillary-provision costs would be incurred if they were not formally required or whether any of these costs under Regulatory Alternative #7 would reasonably be attributable to the proposed rule. OSHA welcomes comment on the issue.

OSHA has also estimated the effect of this regulatory alternative on the benefits of the rule. As a result of eliminating all of the ancillary provisions, annualized benefits are estimated to decrease 57 percent, relative to the proposed rule, from \$575.8 million to \$249.1 million, using a 3 percent discount rate, and from \$255.3 million to \$110.4 million using

a 7 percent discount rate. This estimate follows from OSHA's analysis of benefits in Chapter VII of the PEA, which found that about 57 percent of the benefits of the proposed rule, evaluated at their mid-point value, were attributable to the combination of the ancillary provisions. As these estimates show, OSHA expects that the benefits estimated under the proposed rule will not be fully achieved if employers do not implement the ancillary provisions of the proposed rule.

Both industry and worker groups have recognized that a comprehensive standard is needed to protect workers exposed to beryllium. The stakeholders' recommended standard that representatives of the primary beryllium manufacturing industry and the United Steelworkers union provided to OSHA confirms the importance of ancillary provisions in protecting workers from the harmful effects of beryllium exposure (Materion and USW, 2012). Ancillary provisions such as personal protective clothing and equipment, regulated areas, medical surveillance, hygiene areas, housekeeping requirements, and hazard communication all serve to reduce the risks to beryllium-exposed workers beyond that which the proposed TWA PEL alone could achieve.

Moreover, where there is continuing significant risk at the TWA PEL, the decision in the *Asbestos case (Bldg. and Constr. Trades Dep't, AFL-CIO v. Brock, 838 F.2d 1258, 1274 (D.C. Cir. 1988))* indicated that OSHA should use its legal authority to impose additional requirements on employers to further reduce risk when those requirements will result in a greater than *de minimis* incremental benefit to workers' health. Nevertheless, OSHA requests comment on this alternative.

Under Regulatory Alternative #8, several ancillary provisions that the current proposal would require under a variety of exposure conditions (*e.g.*, dermal contact, any airborne exposure, exposure at or above the action level) would instead only apply where exposure levels exceed the TWA PEL or STEL. Regulatory Alternative #8 affects the following provisions of the proposed standard:

- Exposure monitoring: Whereas the proposed standard requires annual monitoring when exposure levels are at or above the action level and at or below the TWA PEL, Regulatory Alternative #8 would require annual exposure monitoring only where exposure levels exceed the TWA PEL or STEL;
- Written exposure control plan: Whereas the proposed standard

requires written exposure control plans to be maintained in any facility covered by the standard, Regulatory Alternative #8 would require only facilities with exposures above the TWA PEL or STEL to maintain a plan;

- Housekeeping: Whereas the proposed standard's housekeeping requirements apply across a wide variety of beryllium exposure conditions, Alternative #8 would limit housekeeping requirements to areas and employees with exposures above the TWA PEL or STEL;
- PPE: Whereas the proposed standard requires PPE for employees under a variety of conditions, such as exposure to soluble beryllium or visible contamination with beryllium, Alternative #8 would require PPE only for employees exposed above the TWA PEL or STEL;
- Medical Surveillance: Whereas the proposed standard's medical surveillance provisions require employers to offer medical surveillance to employees with signs or symptoms of beryllium-related health effects regardless of their exposure level, Alternative #8 would require surveillance only for those employees exposed above the TWA PEL or STEL.

To estimate the cost savings for this alternative, OSHA re-estimated the group of workers that would fall under the above provisions and the changes to their scope. Combining these various adjustments along with associated unit costs, OSHA estimates that, under this regulatory alternative, the costs for the proposed rule would decline from \$37.6 million to \$18.9 million using a 3 percent discount rate and from \$39.1 million to \$20.0 million using a 7 percent discount rate.

The Agency has not quantified the impact of this alternative on the benefits of the rule. However, ancillary provisions that offer protective measures to workers exposed below the proposed TWA PEL, such as personal protective clothing and equipment, beryllium work areas, hygiene areas, housekeeping requirements, and hazard communication, all serve to reduce the risks to beryllium-exposed workers beyond that which the proposed TWA PEL and STEL could achieve. OSHA's preliminary conclusion is that the requirements triggered by the action level and other exposures below the proposed PELs will result in very real and necessary, but difficult to quantify, further reduction in risk beyond that provided by the PELs alone.

The remainder of this section discusses additional regulatory alternatives that apply to individual

ancillary provisions. At this time, OSHA is not able to quantify the effects of these regulatory alternatives on benefits. The Agency solicits comment on the effects of these regulatory alternatives on the benefits of the proposed rule.

#### (b) Regulated Areas

Proposed paragraph (e) requires employers to establish and maintain beryllium work areas wherever employees are exposed to airborne beryllium, regardless of the level of exposure, and regulated areas wherever airborne concentrations of beryllium exceed the TWA PEL or STEL. Employers are required to demarcate beryllium work areas and regulated areas and limit access to regulated areas to authorized persons.

The SBAR Panel report recommended that OSHA consider dropping or limiting the provision for regulated areas (SBAR, 2008). In response to this recommendation, OSHA examined Regulatory Alternative #12, which would eliminate the requirement that employers establish regulated areas. This alternative is meant only to eliminate the requirement to set up and demarcate specific physical areas: All ancillary provisions would be triggered by the same conditions as under the standard's definition of a "regulated area." For example, under the current proposal, employees who work in regulated areas for at least 30 days annually are eligible for medical surveillance. If OSHA were to remove the requirement to establish regulated areas, the medical surveillance provisions would be altered so that employees who work more than 30 days annually in jobs or areas with exposures that exceed the TWA PEL or STEL are eligible for medical surveillance. This alternative would not eliminate the proposed requirement to establish beryllium work areas. As shown in Table IX-27, Regulatory Alternative #12 would decrease the annualized cost of the proposed rule by about \$522,000 using a 3 percent discount rate, and by about \$523,000 using a 7 percent discount rate.

#### (e) Medical Surveillance

The proposed requirements for medical surveillance include: (1) Medical examinations, including a test for beryllium sensitization, for employees who are exposed to beryllium in a regulated area (*i.e.*, above the proposed TWA PEL or STEL) for 30 days or more per year, who are exposed to beryllium in an emergency, or who show signs or symptoms of CBD; and (2) CT scans for employees who were exposed above the proposed TWA PEL

or STEL for more than 30 days in a 12-month period for 5 years or more. The proposed standard would require annual medical exams to be provided for employees exposed in a regulated area for 30 days or more per year and for employees showing signs or symptoms of CBD, while tests for beryllium sensitization and CT scans would be provided to eligible employees biennially.

OSHA estimated in Chapter V of the PEA that the medical surveillance requirements would apply to 4,528 workers in general industry, of whom 387 already receive that surveillance.<sup>44</sup> In Chapter V, OSHA estimated the costs of medical surveillance for the remaining 4,141 workers who would now have such protection due to the proposed standard. The Agency's preliminary analysis indicates that four workers with beryllium sensitization and six workers with CBD will be referred to pulmonary specialists annually as a result of this medical surveillance. Medical surveillance is particularly important for this rule because beryllium-exposed workers, including many workers exposed below the proposed PELs, are at significant risk of illness. OSHA did not estimate, and the benefits analysis does not include, monetized benefits resulting from early discovery of illness.

Medical surveillance was a subject of special concern to SERs during the SBAR Panel process, and the SBAR Panel offered many comments and recommendations related to medical surveillance for OSHA's consideration. Some of the Panel's concerns have been partially addressed in this proposal, which was modified since the SBAR Panel was convened (see this preamble at Section XVIII, Summary and Explanation of the Proposed Standard, for more detailed discussion). The regulatory alternatives presented in this sub-section (#16, #18, and #20) also respond to recommendations by the SBAR Panel to reduce burdens on small businesses by dropping or reducing the frequency of medical surveillance requirements. OSHA has preliminarily determined that a significant risk of beryllium sensitization, CBD, and lung cancer exists at exposure levels below the proposed TWA PEL and that there is evidence that beryllium sensitization can occur even from short-term exposures (see this preamble at Section V, Health Effects, and Section VIII, Significance of Risk). The Agency therefore anticipates that more employees would develop adverse

health effects without receiving the benefits of early intervention in the disease process because they are not eligible for medical surveillance (see this preamble at Section V, Health Effects).

In response to concerns raised during the SBAR Panel process about testing requirements, OSHA is considering two regulatory alternatives that would provide greater flexibility in the program of tests provided as part of an employer's medical surveillance program. Under Regulatory Alternative #16, employers would not be required to offer employees testing for beryllium sensitization. As shown in Table IX-27, this alternative would decrease the annualized cost of the proposed rule by about \$710,000 using a discount rate of 3 percent, and by about \$724,000 using a discount rate of 7 percent.

Regulatory Alternative #18 would eliminate the CT scan requirement from the proposed rule. This alternative would decrease the annualized cost of the proposed rule by about \$472,000 using a discount rate of 3 percent, and by about \$481,000 using a discount rate of 7 percent.

OSHA is considering several alternatives to the proposed frequency of sensitization testing, CT scans, and general medical examinations. The frequency of periodic medical surveillance is an important factor in the efficacy of the surveillance in protecting worker health. Regular, appropriately frequent medical surveillance promotes awareness of beryllium-related health effects and early intervention in disease processes among workers. In addition, the longer the time interval between when a worker becomes sensitized and when the worker's case is identified in the surveillance program, the more difficult it will be to identify and address the exposure conditions that led to sensitization. Therefore, reducing the frequency of sensitization testing would reduce the usefulness of the surveillance information in identifying problem areas and reducing risks to other workers. These concerns must be weighed against the costs and other burdens of surveillance.

Finally, under Regulatory Alternative #20, employers would only have to provide all periodic components of the medical surveillance exams biennially to eligible employees. This alternative would decrease the annualized cost of the proposed rule by about \$446,000 using a discount rate of 3 percent and by about \$433,000 using a discount rate of 7 percent.

<sup>44</sup> See current compliance rates for medical surveillance in Chapter V of the PEA, Table V-15.

(d) Medical Removal

Under paragraph (l) of the proposed standard, Medical Removal, employees in jobs with exposure at or above the action level become eligible for medical removal when they are diagnosed with CBD or confirmed positive for beryllium sensitization. When an employee chooses removal, the employer is required to remove the employee to comparable work in an environment where beryllium exposure is below the action level if such work is available and the employee is either already qualified or can be trained within one month. If comparable work is not available, paragraph (l) would require the employer to place the employee on paid leave for six months or until comparable work becomes available (whichever comes first). Or, rather than choosing removal, an eligible employee could choose to remain in a job with exposure at or above the action level and wear a respirator. The proposed medical removal protection (MRP) requirements are based on the stakeholders' recommended beryllium standard that representatives of the

beryllium production industry and the United Steelworkers union submitted to OSHA in 2012 (Materion and USW, 2012).

The scientific information on effects of exposure cessation is limited at this time, but the available evidence suggests that removal from exposure can be beneficial for individuals who are sensitized or have early-stage CBD (see this preamble at Section VIII, Significance of Risk). As CBD progresses, symptoms become serious and debilitating. Steroid treatment is less effective at later stages, once fibrosis has developed (see this preamble at Section VIII, Significance of Risk). Given the progressive nature of the disease, OSHA believes it is reasonable to conclude that removal from exposure to beryllium will benefit sensitized employees and those with CBD. Physicians at National Jewish Health, one of the main CBD research and treatment sites in the US, "consider it important and prudent for individuals with beryllium sensitization and CBD to minimize their exposure to airborne beryllium," and "recommend individuals diagnosed with beryllium

sensitization and CBD who continue to work in a beryllium industry to have exposure of no more than 0.01 micrograms per cubic meter of beryllium as an 8-hour time-weighted average" (NJMRC, 2013). However, OSHA is aware that MRP may prove costly and burdensome for some employers and that the scientific literature on the effects of exposure cessation on the development of CBD among sensitized individuals and the progression from early-stage to late-stage CBD is limited.

The SBAR Panel report included a recommendation that OSHA give careful consideration to the impacts that an MRP requirement could have on small businesses (SBAR, 2008). In response to this recommendation, OSHA analyzed Regulatory Alternative #22, which would remove the proposed requirement that employers offer MRP. As shown in Table IX-27, this alternative would decrease the annualized cost of the proposed rule by about \$149,000 using a discount rate of 3 percent, and by about \$166,000 using a discount rate of 7 percent.

Table IX-27: Cost of Regulatory Alternatives Affecting Ancillary Provisions  
(Proposed PEL=0.2, STEL=2.0, AL=0.1)

3% Discount Rate	Total Cost	Incremental Cost Relative to Proposal	Benefits	Incremental Benefits Relative to the Proposal
Proposed Rule	\$37,597,325	—	\$575,826,633	—
Alternative 7: Update Z table 1910.1000 only, (No ancillary provisions)	\$9,789,873	-\$27,807,451	\$249,099,326	-\$326,727,308
Alternative 8: Ancillary provisions apply only when exposure above PEL/STEL	\$18,917,028	-\$18,680,297		
Alternative 12: No regulated areas, ancillary provisions triggered by PEL or STEL	\$37,075,072	-\$522,252		
Alternative 16: No BeLPTs in medical surveillance	\$36,887,307	-\$710,018		
Alternative 18: No CT Scans	\$37,124,958	-\$472,367		
Alternative 20: All periodic components of medical surveillance are biannual	\$37,150,975	-\$446,349		
Alternative 22: No medical removal protection	\$37,448,499	-\$148,826		

Table IX-27: Cost of Regulatory Alternatives Affecting Ancillary Provisions, Continued  
(Proposed PEL=0.2, STEL=2.0, AL=0.1)

7% Discount Rate	Total Cost	Incremental Cost Relative to Proposal	Benefits	Incremental Benefits Relative to the Proposal
Proposed Rule	\$39,147,434	—	\$255,334,295	—
Alternative 7: Update Z table 1910.1000 only, (No ancillary provisions)	\$10,586,317	-\$28,561,116	\$110,383,499	-\$144,950,796
Alternative 8: Ancillary provisions apply only when exposure above PEL/STEL	\$19,986,867	-\$19,160,567		
Alternative 12: No regulated areas, ancillary provisions triggered by PEL or STEL	\$38,624,295	-\$523,139		
Alternative 16: No BeLPTs in medical surveillance	\$38,423,316	-\$724,117		
Alternative 18: No CT Scans	\$38,666,205	-\$481,229		
Alternative 20: All periodic components of medical surveillance are biannual	\$38,714,200	-\$433,233		
Alternative 22: No medical removal protection	\$38,981,379	-\$166,054		

Source: OSHA, Directorate of Standards and Guidance, Office of Regulatory Analysis

(5) Timing

As proposed, the new standard would become effective 60 days following publication in the **Federal Register**. The majority of employer duties in the standard would become enforceable 90 days following the effective date. Change rooms, however, would not be required until one year after the effective date, and the deadline for engineering controls would be no later than two years after the effective date.

OSHA invites suggestions for alternative phase-in schedules for engineering controls, medical surveillance, and other provisions of the standard. Although OSHA did not

explicitly develop or quantitatively analyze any other regulatory alternatives involving longer-term or more complex phase-ins of the standard (possibly involving more delayed implementation dates for small businesses), some general outcomes are likely. For example, a longer phase-in time would have several advantages, such as reducing initial costs of the standard or allowing employers to coordinate their environmental and occupational safety and health control strategies to minimize potential costs. However, a longer phase-in would also postpone and reduce the benefits of the standard. Suggestions for alternatives may apply to specific industries (e.g., industries

where first-year or annualized cost impacts are highest), specific size-classes of employers (e.g., employers with fewer than 20 employees), combinations of these factors, or all firms covered by the rule.

OSHA requests comments on all these regulatory alternatives, including the Agency's regulatory alternatives presented above, the Agency's analysis of these alternatives, and whether there are other regulatory alternatives the Agency should consider.

SBAR Panel

Table IX-28 lists all of the SBAR Panel recommendations and OSHA's response to those recommendations.

TABLE IX-28—SBAR PANEL RECOMMENDATIONS AND OSHA RESPONSES

Panel recommendation	OSHA response
<p>The Panel recommends that OSHA evaluate carefully the costs and technological feasibility of engineering controls at all PEL options, especially those at the lowest levels.</p> <p>The Panel recommends that OSHA consider alternatives that would alleviate the need for monitoring in operations with exposures far below the PEL. The Panel also recommends that OSHA consider explaining more clearly how employers may use “objective data” to estimate exposures. Although the draft proposal contains a provision allowing employers to initially estimate exposures using “objective data” (e.g., data showing that the action level is unlikely to be exceeded for the kinds of process or operations an employer has), the SERs did not appear to have fully understood how this alternative may be used.</p>	<p>OSHA has reviewed its cost estimates and the technological feasibility of engineering controls at various PEL levels. These issues are discussed in the Regulatory Alternatives Chapter of the PEA.</p> <p>OSHA has removed the initial exposure monitoring requirement for workers likely to be exposed to beryllium by skin or eye contact through routine handling of beryllium powders or dusts or contact with contaminated surfaces.</p> <p>The periodic monitoring requirement presented in the SBAR Panel report required monitoring every 6 months for airborne levels at or above the action level but below the PEL, and every 3 months for exposures at or above the PEL. The proposed standard requires annual exposure monitoring for levels at or above the action level and at or below the PEL.</p> <p>By reducing the frequency of periodic monitoring from every 6 months (version submitted to the SBAR panel) to annually where exposure levels are at or below the PEL (the proposed standard), the Agency has lessened the need for monitoring in small business operations with exposures at or below the PEL.</p> <p>In this preamble, OSHA has clarified the circumstances under which an employer may use historical and objective data in lieu of initial monitoring.</p> <p>OSHA is also considering whether to create a guidance product on the use of objective data. These issues are discussed in this preamble at Section XVIII, Summary and Explanation of the Proposed Standard, (d): Exposure Monitoring.</p>
<p>The Panel recommends that OSHA consider providing some type of guidance to describe how to use objective data to estimate exposures in lieu of conducting personal sampling.</p> <p>Using objective data could provide significant regulatory relief to several industries where airborne exposures are currently reported by SERs to be well below even the lowest PEL option. In particular, since several ancillary provisions, which may have significant costs for small entities may be triggered by the PEL or an action level, OSHA should consider encouraging and simplifying the development of objective data from a variety of sources.</p>	<p>In this preamble, OSHA has clarified the circumstances under which an employer may use historical and objective data in lieu of initial monitoring. OSHA is also considering whether to create a guidance product on the use of objective data to satisfy the requirements of the proposed rule.</p> <p>These issues are discussed in this preamble at Section XVIII, Summary and Explanation of the Proposed Standard, (d): Exposure Monitoring.</p>
<p>The Panel recommends that OSHA revisit its analysis of the costs of regulated areas if a very low PEL is proposed. Drop or limit the provision for regulated areas: SERs with very low exposure levels or only occasional work with beryllium questioned the need for separating areas of work by exposure level. Segregating machines or operations, SERs said, would affect productivity and flexibility. Until the health risks of beryllium are known in their industries, SERs challenged the need for regulated areas.</p>	<p>SERs with very low exposure levels or only occasional work with beryllium will not be required to have regulated areas unless exposures are above the proposed PEL of 0.2 µg/m<sup>3</sup>.</p> <p>The proposed standard requires the employer to establish and maintain a regulated area wherever employees are, or can be expected to be exposed to airborne beryllium at levels above a PEL of 0.2 µg/m<sup>3</sup>.</p>
<p>The Panel recommends that OSHA revisit its cost model for hygiene areas to reflect SERs’ comments that estimated costs are too low and more carefully consider the opportunity costs of using space for hygiene areas where SERs report they have no unused space in their physical plant for them. The Panel also recommends that OSHA consider more clearly defining the triggers (skin exposure and contaminated surfaces) for the hygiene areas provisions. In addition, the Panel recommends that OSHA consider alternative requirements for hygiene areas dependent on airborne exposure levels or types of processes. Such alternatives might include, for example, hand washing facilities in lieu of showers in particular cases or different hygiene area triggers where exposure levels are very low.</p>	<p>The Agency has removed skin exposure as a trigger for the hygiene provision. The requirement for washing facilities applies to each employee working in a beryllium work area. A beryllium work area means any work area where employees are, or can reasonably be expected to be, exposed to airborne beryllium. OSHA has preliminarily concluded that all affected employers currently have hand-washing facilities.</p> <p>OSHA has also preliminarily concluded that no affected employers will be required to install showers.</p> <p>Change rooms have only been costed for regulated areas or where employees are, or can reasonably be expected to be, exposed to airborne beryllium at levels above the PEL. The Agency has determined that the long-term rental of modular units was representative of costs for a range of reasonable approaches to comply with the change room part of the provision. Alternatively, employers could renovate and rearrange their work areas in order to meet the requirements of this provision.</p>

TABLE IX–28—SBAR PANEL RECOMMENDATIONS AND OSHA RESPONSES—Continued

Panel recommendation	OSHA response
<p>The Panel recommends that OSHA consider clearly explaining the purpose of the housekeeping provision and describing what affected employers must do to achieve it. For example, OSHA should consider explaining more specifically what surfaces need to be cleaned and how frequently they need to be cleaned. The Panel recommends that the Agency consider providing guidance in some form so that employers understand what they must do. The Panel also recommends that once the requirements are clarified that the Agency re-analyzes its cost estimates.</p> <p>The Panel also recommends that OSHA reconsider whether the risk and cost of all parts of the medical surveillance provisions are appropriate where exposure levels are very low. In that context, the Panel recommends that OSHA should also consider the special problems and costs to small businesses that up until now may not have had to provide or manage the various parts of an occupational health standard or program.</p>	<p>In this preamble, OSHA has clarified the purpose of the housekeeping provision. However, due to the variety of work settings in which beryllium is used, OSHA has preliminarily concluded that a highly specific directive on what surfaces need to be cleaned, and how frequently, would not provide effective guidance to businesses. Instead, at the suggestion of industry and union stakeholders (Materion and USW, 2012), OSHA’s proposed standard includes a more flexible requirement for employers to develop a written exposure control plan specific to their facilities. The written exposure control plan must include documentation of operations and jobs with beryllium exposure and housekeeping procedures, including surface cleaning and beryllium migration control. OSHA requests suggestions for examples of specific guidance that could be helpful to employers preparing written exposure control plans.</p> <p>These issues are discussed in this preamble at Section XVIII, Summary and Explanation of the Proposed Standard, (f) Methods of Compliance and (j) Housekeeping.</p> <p>Regulatory Alternative #20 would reduce the frequency of physical examinations from annual to biennial, matching the frequency of BeLPT testing in the proposed rule.</p> <p>These alternatives for medical surveillance are discussed in the Regulatory Alternatives Chapter and in this preamble at section XVIII, Summary and Explanation of the Proposed Standard, (k) Medical Surveillance.</p>
<p>The Panel recommends that OSHA consider that small entities may lack the flexibility and resources to provide alternative jobs to employees who test positive for the BeLPT, and whether MRP achieves its intended purpose given the course of beryllium disease. The Panel also recommends that if MRP is implemented, that its effects on the viability of very small firms with a sensitized employee be considered carefully.</p>	<p>Under the proposed standard, employees are only eligible for medical removal if they are sensitized or have been diagnosed with CBD; skin exposure is not a trigger for medical removal (unlike the version submitted by the SBAR Panel). After becoming eligible for medical removal an employee may choose to remain in a job with exposure at or above the action level, provided that the employee wears a respirator in accordance with the Respiratory Protection standard (29 CFR 1910.134). If the employee chooses removal, the employer is only required to place the employee in comparable work with exposure below the action level if such work is available; if such work is not available, the employer may place the employee on paid leave for six months or until such work becomes available.</p>
<p>The Panel recommends that OSHA consider more clearly defining the trigger mechanisms for medical surveillance and also consider additional or alternative triggers—such as limiting the BeLPT to a narrower range of exposure scenarios and reducing the frequency of BeLPT tests and physical exams. The Panel also recommends that OSHA reconsider whether the risk and cost of all parts of the medical surveillance provisions are appropriate where exposure levels are very low. In that context, the Panel recommends that OSHA should also consider the special problems and costs to small businesses that up until now may not have had to provide or manage the various parts of an occupational health standard or program.</p>	<p>OSHA discusses the basis of the provision and requests comments on it in this preamble at Section XVIII, Summary and Explanation of the Proposed Standard, (l) Medical Removal Protection. OSHA provides an analysis of costs and economic impacts of the provision in the PEA in Chapter 5 and Chapter 6, respectively.</p> <p>As stated above, the triggers for medical surveillance in the proposed standard have changed from those presented to the SBAR Panel. Whereas the draft standard presented at the SBAR Panel required medical surveillance for employees with skin contact—potentially applying to employees with any level of airborne exposure—the proposed standard ties medical surveillance to exposures above the proposed PEL of 0.2 µg/m<sup>3</sup> (or signs or symptoms of beryllium-related health effects, or emergency exposure). Thus, small businesses with exposures below the proposed PEL would not need to provide or manage medical surveillance for their employees unless employees develop signs or symptoms of beryllium-related health effects or are exposed in emergencies.</p>
<p>The Panel recommends that the Agency, in evaluating the economic feasibility of a potential regulation, consider not only the impacts of estimated costs on affected establishments, but also the effects of the possible outcomes cited by SERs: loss of market demand, the loss of market to foreign competitors, and of U.S. production being moved abroad by U.S. firms. The Panel also recommends that OSHA consider the potential burdens on small businesses of dealing with employees who have a positive test from the BeLPT. OSHA may wish to address this issue by examining the experience of small businesses that currently provide the BeLPT.</p>	<p>These issues are discussed in this preamble at section XVIII, Summary and Explanation of the Proposed Standard, (k) Medical Surveillance.</p> <p>OSHA has reviewed the possible effects of the proposed regulation on market demand and/or foreign production, in addition to the Agency’s usual measures of economic impact (costs as a fraction of revenues and profits). This discussion can be found in Chapter VI of the PEA (entitled Economic Feasibility Analysis and Regulatory Flexibility Determination).</p>

TABLE IX-28—SBAR PANEL RECOMMENDATIONS AND OSHA RESPONSES—Continued

Panel recommendation	OSHA response
<p>The Panel recommends that OSHA consider seeking ways of minimizing costs for small businesses where the exposure levels may be very low. Clarifying the use of objective data, in particular, may allow industries and establishments with very low exposures to reduce their costs and involvement with many provisions of a standard. The Panel also recommends that the Agency consider tiering the application of ancillary provisions of the standard according to exposure levels and consider a more limited or narrowed scope of industries.</p>	<p>The provisions in the standard presented in the SBAR panel report applied to all employees, whereas the proposed standard's ancillary provisions are only applied to employees in work areas who are, or can reasonably be expected to be, exposed to airborne beryllium.</p> <p>In addition, the scope of the proposed standard includes several limitations. Whereas the standard presented in the SBAR panel report covered beryllium in all forms and compounds in general industry, construction, and maritime, the scope of the proposed standard (1) applies only to general industry; (2) does not apply to beryllium-containing articles that the employer does not process; and (3) does not apply to materials that contain less than 0.1 percent beryllium by weight.</p> <p>In this preamble, OSHA has clarified the circumstances under which an employer may use historical and objective data in lieu of initial monitoring (Section XVIII, Summary and Explanation of this Proposed Standard, (d) Exposure Monitoring). OSHA is also considering whether to create a guidance product on the use of objective data to comply with the requirements of this proposed standard. OSHA is considering two Regulatory Alternatives that would reduce the impact of ancillary alternatives on employers, including small businesses. Regulatory Alternative #7, a PEL-only standard, would drop all ancillary provisions from the standard. Regulatory Alternative #8 would limit the application of several ancillary provisions, including Exposure Monitoring, the written exposure control plan section of Method of Compliance, PPE, Housekeeping, and Medical Surveillance, to operations or employees with exposure levels exceeding the TWA PEL or STEL. These alternatives are discussed in the Regulatory Alternatives Chapter and in this preamble at Section I, Issues and Alternatives.</p>
<p>The Panel recommends that OSHA provide an explanation and analysis for all health outcomes (and their scientific basis) upon which it is regulating employee exposure to beryllium. The Panel also recommends that OSHA consider to what extent a very low PEL (and lower action level) may result in increased costs of ancillary provisions to small entities (without affecting airborne employee exposures). Since in the draft proposal the PEL and action level are critical triggers, the Panel recommends that OSHA consider alternate action levels, including an action level set at the PEL, if a very low PEL is proposed.</p>	<p>The explanation and analysis for all health outcomes (and their scientific basis) are discussed in this preamble at Section V, Health Effects, and Section VI, Preliminary Risk Assessment. They are also reviewed in this preamble at Section VIII, Significance of Risk, and the Benefits Chapter of the PEA. OSHA requests comment on these health outcomes.</p> <p>As discussed above, OSHA is considering Regulatory Alternatives #7 and #8, which would eliminate or reduce the impact of ancillary provisions on employers, respectively. These alternatives are discussed in the Regulatory Alternatives Chapter of the PEA and in this preamble at Section I, Issues and Alternatives. OSHA seeks comment on other ways to avoid costs of ancillary provisions when they are not necessary to protect employees from exposure to beryllium.</p>
<p>The Panel recommends that OSHA consider more clearly and thoroughly defining the triggers for ancillary provisions, particularly the skin exposure trigger. In addition, the Panel recommends that OSHA clearly explain the basis and need for small entities to comply with ancillary provisions. The Panel also recommends that OSHA consider narrowing the trigger related to skin and contamination to capture only those situations where surfaces and surface dust may contain beryllium in a concentration that is significant enough to pose any risk—or limiting the application of the trigger for some ancillary provisions.</p>	<p>OSHA has removed skin exposure as a trigger for several ancillary provisions in this proposed standard, including Exposure Monitoring, Hygiene Areas and Practices, and Medical Surveillance. In addition, the language of this proposed standard regarding skin exposure has changed: for some ancillary provisions, including PPE and Housekeeping, the requirements are triggered by visible contamination with beryllium or dermal contact with soluble beryllium compounds. These requirements are discussed in this preamble at Section XVIII, Summary and Explanation of this Proposed Standard. The Agency has also explained the basis and need for compliance with ancillary provisions in this preamble at Section XVIII, Summary and Explanation.</p>
<p>Several SERs said that OSHA should first assume the burden of describing the exposure level in each industry rather than employers doing so. Others said that the Agency should accept exposure determinations made on an industry-wide basis, especially where exposures were far below the PEL options under consideration.</p>	<p>In the Technological Feasibility Analysis presented in the PEA, OSHA has described the exposure level in each industry or application group.</p>
<p>As noted above, the Panel recommends that OSHA consider alternatives that would alleviate the need for monitoring in operations or processes with exposures far below the PEL. The use of objective data is a principal method for industries with low exposures to satisfy compliance with a proposed standard. The Panel recommends that OSHA consider providing some guidance to small entities in the use of objective data.</p>	<p>In this preamble, OSHA has clarified the circumstances under which an employer may use historical and objective data in lieu of initial monitoring (section XVIII, Summary and Explanation of this Proposed Standard, (d) Exposure Monitoring). Industry-wide data may be used as objective data to support an employer's case that exposures at its facilities are far below the PEL. OSHA is also considering whether to create a guidance product on the use of objective data to comply with requirements in the proposed standard.</p>



TABLE IX-28—SBAR PANEL RECOMMENDATIONS AND OSHA RESPONSES—Continued

Panel recommendation	OSHA response
<p>The Panel recommends that OSHA consider more fully evaluating whether the BeLPT is suitable as a test for beryllium sensitization in an OSHA standard and respond to the points raised by the SERs about its efficacy. In addition, the Agency should consider the availability of other tests under development for detecting beryllium sensitization and not limit either employers' choices or new science and technology in this area. Finally, the Panel recommends that OSHA re-consider the trigger for medical surveillance where exposures are low and consider if there are appropriate alternatives.</p>	<p>OSHA has provided discussion of the BeLPT in Appendix A to the regulatory text; in this preamble at section V, Health Effects; and in this preamble at section XVIII, Summary and Explanation, (k) Medical Surveillance. In the regulatory text, OSHA has clarified that a test for beryllium sensitization other than the BeLPT may be used in lieu of the BeLPT if a more reliable and accurate diagnostic test is developed. In this preamble at Section I, Issues and Alternatives, the Agency requests comments on the BeLPT and on the reliability and accuracy of alternate tests.</p> <p>As stated above, the triggers for medical surveillance in this proposed standard have changed from those presented to the SBAR Panel. Whereas the draft standard presented during the SBREFA process required medical surveillance for employees with skin contact—potentially applying to employees with any level of airborne exposure—this proposed standard ties medical surveillance to exposures above the proposed PEL of 0.2 µg/m<sup>3</sup> (or signs or symptoms of beryllium-related health effects, or emergency exposure). The triggers for medical surveillance are discussed in this preamble at section XVIII, Summary and Explanation, (k) Medical Surveillance.</p>
<p>Seeking ways of minimizing costs to low risk processes and operations: OSHA should consider alternatives for minimizing costs to industries, operations, or processes that have low exposures. Such alternatives may include, but not be limited to: encouraging the use of objective data by such mechanisms as providing guidance for objective data; assuring that triggers for skin exposure and surface contamination are clear and do not pull in low risk operations; providing guidance on least-cost ways for low risk facilities to determine what provisions of the standard they need to comply with; and considering ways to limit the scope of 28 the standard if it can be ascertained that certain processes do not represent a significant risk.</p>	<p>OSHA is considering Regulatory Alternative #16, which would eliminate BeLPT testing requirements from this proposed standard. This alternative is discussed in the Regulatory Alternatives Chapter and in in this preamble at Section XVIII, Summary and Explanation of the Proposed Standard, (k) Medical Surveillance.</p> <p>The standard presented in the SBAR panel report had skin exposure as a trigger. The only skin exposure trigger in this proposed standard is the requirement for PPE when employees' skin is potentially exposed to soluble beryllium compounds. OSHA uses an exposure profile to determine which workers will be affected by the standard. As a result, this proposed standard establishes regulated work areas and exposure monitoring only with respect to employees who are, or can reasonably be expected to be, exposed to airborne beryllium.</p> <p>In addition, the scope of this proposed standard includes several limitations. Whereas the standard presented in the SBAR panel report covered beryllium in all forms and compounds in general industry, construction, and maritime, the scope of this proposed standard (1) applies only to general industry; (2) does not apply to beryllium-containing articles that the employer does not process; and (3) does not apply to materials that contain less than 0.1 percent beryllium by weight. In this preamble, OSHA has clarified the circumstances under which an employer may use historical and objective data in lieu of initial monitoring (Section XVIII, Summary and Explanation of this Proposed Standard, (d) Exposure Monitoring). OSHA is also considering whether to create a guidance product on the use of objective data.</p>
<p>PEL-only standard: One SER recommended a PEL-only standard. This would protect employees from airborne exposure risks while relieving the beryllium industry of the cost of the ancillary provisions. The Panel recommends that OSHA, consistent with its statutory obligations, analyze this alternative.</p>	<p>OSHA is considering Regulatory Alternative #7, a PEL-only standard. This alternative is discussed in the Regulatory Alternatives Chapter of the PEA and in this preamble at Section I, Issues and Alternatives.</p>
<p>Alternative triggers for ancillary provisions: The Panel recommends that OSHA clarify and consider eliminating or narrowing the triggers for ancillary provisions associated with skin exposure or contamination. In addition, the Panel recommends that OSHA should consider trying ancillary provisions dependent on exposure rather than have these provisions all take effect with the same trigger. If OSHA does rely on a trigger related to skin exposure, OSHA should thoroughly explain and justify this approach based on an analysis of the scientific or research literature that shows a risk of sensitization via exposure to skin. If OSHA adopts a relatively low PEL, OSHA should consider the effects of alternative airborne action levels in pulling in many low risk facilities that may be unlikely to exceed the PEL—and consider using only the PEL as a trigger at very low levels.</p>	<p>OSHA has removed skin exposure as a trigger for several ancillary provisions in this proposed standard, including Exposure Monitoring, Hygiene Areas and Practices, and Medical Surveillance. In addition, the language of this proposed standard regarding skin exposure has changed: for some ancillary provisions, including PPE and House-keeping, the requirements are triggered by visible contamination with beryllium or skin contact with soluble beryllium compounds. These requirements are discussed in this preamble at Section XVIII, Summary and Explanation. OSHA has explained the scientific basis for minimizing skin exposure to beryllium in this preamble at Section V, Health Effects, and explains the basis for specific ancillary provisions related to skin exposure in this preamble at Section XVIII, Summary and Explanation.</p>

TABLE IX-28—SBAR PANEL RECOMMENDATIONS AND OSHA RESPONSES—Continued

Panel recommendation	OSHA response
<p>Revise the medical surveillance provisions, including eliminating the BeLPT: The BeLPT was the most common complaint from SERs. The Panel recommends that OSHA carefully examine the value of the BeLPT and consider whether it should be a requirement of a medical surveillance program. The Panel recommends that OSHA present the scientific evidence that supports the use of the BeLPT as several SERs were doubtful of its reliability. The Panel recommends that OSHA also consider reducing the frequency of physicals and the BeLPT, if these provisions are included in a proposal. The Panel recommends that OSHA also consider a performance-based medical surveillance program, permitting employers in consultation with physicians and health experts to develop appropriate tests and their frequency.</p> <p>No medical removal protection (MRP): OSHA's draft proposed standard did not include any provision for medical removal protection, but OSHA did ask the SERs to comment on MRP as a possibility. Based on the SER comments, the Panel recommends that if OSHA includes an MRP provision, the agency provide a thorough analysis of why such a provision is needed, what it might accomplish, and what its full costs and economic impacts on those small businesses that need to use it might be.</p>	<p>In this proposed standard, the application of ancillary provisions is dependent on exposure, and not all provisions take effect with the same trigger. A number of requirements are triggered by exposures (or a reasonable expectation of exposures) above the PEL or action level (AL). As discussed above, OSHA is considering Regulatory Alternatives #7 and #8, which would eliminate or reduce the impact of ancillary provisions on employers, respectively. These alternatives are discussed in the Regulatory Alternatives Chapter of the PEA and in this preamble at Section I, Issues and Alternatives.</p> <p>Responding to comments from SERs, OSHA has revised the medical surveillance provision and removed the skin exposure trigger for medical surveillance. As a result, OSHA estimates that the number of small-business employees requiring a BeLPT will be substantially reduced.</p> <p>OSHA has provided discussion of the BeLPT in Appendix A to the regulatory text; in this preamble at section V, Health Effects; and in this preamble at section XVIII, Summary and Explanation, (k) Medical Surveillance. In the regulatory text, OSHA has clarified that a test for beryllium sensitization other than the BeLPT may be used in lieu of the BeLPT if a more reliable and accurate diagnostic test is developed. In this preamble at Section I, Issues and Alternatives, the Agency requests comments on the BeLPT and on the reliability and accuracy of alternate tests.</p> <p>The frequency of periodic BeLPT testing in this proposed standard is biennial, whereas annual testing was included in the draft standard presented to the SBAR Panel.</p> <p>Regulatory Alternative #20 would reduce the frequency of physical examinations from annual to biennial, matching the frequency of BeLPT testing in this proposed rule.</p> <p>In response to the suggestion to allow performance-based medical surveillance, OSHA is considering two regulatory alternatives that would provide greater flexibility in the program of tests provided as part of an employer's medical surveillance program. Regulatory Alternative #16 would eliminate BeLPT testing requirements from this proposed standard. Regulatory Alternative #18 would eliminate the CT scan requirement from this proposed standard. These alternatives are discussed in the Regulatory Alternatives Chapter and in this preamble at Section XVIII, Summary and Explanation, (k) Medical Surveillance.</p> <p>This proposed standard includes an MRP provision. OSHA discusses the basis of the provision and requests comments on it in this preamble at Section XVIII, Summary and Explanation, (l) Medical Removal Protection. OSHA provides an analysis of costs and economic impacts of the provision in the PEA in Chapter V and Chapter VI, respectively.</p> <p>The Agency is considering Alternative #22, which would eliminate the MRP requirement from the standard. This alternative is discussed in the Regulatory Alternatives Chapter and in in this preamble at section XVIII, Summary and Explanation, (l) Medical Removal Protection.</p>

## X. OMB Review Under the Paperwork Reduction Act of 1995

### A. Overview

The proposed general industry standard for occupational exposure to beryllium contains collection of information (paperwork) requirements that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA-95), 44 U.S.C. 3501 *et seq.*, and OMB's regulations at 5 CFR part 1320. PRA-95 defines "collection of information" to mean, "the obtaining, causing to be obtained, soliciting, or requiring the disclosure to third parties or the public, of facts or opinions by or

for an agency, regardless of form or format" (44 U.S.C. 3502(3)(A)).

Under PRA-95, a Federal agency cannot conduct or sponsor a collection of information unless OMB approves it, and the agency displays a currently valid OMB control number. In addition, the public is not required to respond to a collection of information unless the collection of information displays a currently valid OMB control number. Also, notwithstanding any other provision of law, no person 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.

### B. Solicitation of Comments

OSHA prepared and submitted an Information Collection Request (ICR) for the collection of information requirements identified in this NPRM to OMB for review in accordance with 44 U.S.C. 3507(d). The Agency solicits comments on the proposed collection of information requirements and the estimated burden hours and costs associated with these requirements, including comments on the following items:

- Whether the proposed collection of information requirements 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 information collection requirements, 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.

### C. Proposed Collection of Information Requirements

As required by 5 CFR 1320.5(a)(1)(iv) and 1320.8(d)(1), the following paragraphs provide information about this ICR.

#### 1. Title: Occupational Exposure to Beryllium

2. *Description of the ICR:* The proposed Beryllium standard contains collection of information requirements which are essential components of the occupational safety and health standard that will assist both employers and their employees in identifying the exposures to beryllium and beryllium compounds, the medical effects of such exposures, and the means to reduce the risk of overexposures to beryllium and beryllium compounds.

#### 3. Brief Summary of the Collection of Information Requirements

Below is a summary of the collection of information requirements identified in the Beryllium proposal. Specific details contained in the following collections of information requirements are discussed in Section XVIII: *Summary and Explanation of the Proposed Standard.*

#### § 1910.1024(d) Exposure Monitoring

Under paragraph (d)(5)(i) of the proposed standard, within 15 working days after receiving the results of any exposure monitoring completed under this standard, employers must notify each employee whose exposure is characterized by the monitoring in writing. Employers must either notify each of these employees individually in writing, or post the exposure monitoring results in an appropriate location accessible to all of these employees. In this proposed standard, the following provisions require exposure monitoring: § 1910.1024(d)(1), General; § 1910.1024(d)(2), Initial Exposure Monitoring; § 1910.1024(d)(3), Periodic Exposure Monitoring; § 1910.1024(d)(4), Additional Monitoring.

Proposed paragraph (d)(5)(ii) details additional information an employer

would need to include in the written notification in (d)(5)(i), should beryllium exposure exceed the TWA PEL or STEL: a description of the suspected or known sources of exposure, and the corrective action(s) the employer has taken or will take to reduce the employee's exposure to or below the applicable PEL.

#### § 1910.1024(e)(2)(i) & (ii) Demarcation of Beryllium Work Areas

Proposed paragraph (e)(2)(i) would require employers to identify each beryllium work area through signs or any other methods that adequately establish and inform each employee of the boundaries of each beryllium work area. Paragraph (e)(2)(ii) would require employers to identify each regulated area in accordance with paragraph (m)(2).

#### § 1910.1024(f)(1)(i), (ii), and (iii) Written Exposure Control Plan

Proposed paragraph (f)(1)(i) would require employers to establish, implement, and maintain a written exposure control plan for beryllium work areas. The plan must contain: (A) An inventory of operations and job titles reasonably expected to have exposure; (B) an inventory of operations and job titles reasonably expected to have exposure at or above the action level; (C) an inventory of operations and job titles reasonably expected to have exposure above the TWA PEL or STEL; (D) procedures for minimizing cross-contamination, including but not limited to preventing the transfer of beryllium between surfaces, equipment, clothing, materials, and articles within beryllium work areas; (E) procedures for keeping surfaces in the beryllium work area as free as practicable of beryllium; (F) procedures for minimizing the migration of beryllium from beryllium work areas to other locations within or outside the workplace; (G) an inventory of engineering and work practice controls; and (H) procedures for removal, laundering, storage, cleaning, repairing, and disposal of beryllium-contaminated personal protective clothing and equipment, including respirators.

Proposed paragraph (f)(1)(ii) would require employers to update their exposure control plans whenever any change in production processes, materials, equipment, personnel, work practices, or control methods results or can reasonably be expected to result in new or additional exposures to beryllium. Paragraph (f)(1)(ii) also requires employers to update their plans when an employee is confirmed positive for beryllium sensitization, is diagnosed

with CBD, or shows other signs or symptoms related to beryllium exposure. In addition, this paragraph requires employers to update their plans if the employer has any reason to believe that new or additional exposures are occurring or will occur. Proposed paragraph (f)(1)(iii) would require employers to make a copy of the exposure control plan accessible to each employee who is or can reasonably be expected to be exposed to airborne beryllium in accordance with OSHA's Access to Employee Exposure and Medical Records (Records Access) standard (29 CFR 1910.1020(e)).

#### § 1910.1024(g) Respiratory Protection

Proposed paragraph (g)(1) would require employers to provide at no cost and ensure that each employee uses respiratory protection during certain periods or operations. Where the proposed standard requires an employee to use respiratory protection, proposed paragraph (g)(2) requires such use to be in accordance with the Respiratory Protection Standard (29 CFR 1910.134).

The Respiratory Protection Standard's collection of information requirements indicate that employers must: develop a written respirator program; obtain and maintain employee medical evaluation records; provide the physician or other licensed health care professional (PLHCP) with information about the employee's respirator and the conditions under which the employee will use the respirator; administer fit tests for employees who will use negative- or positive-pressure, tight-fitting facepieces; and establish and retain written information regarding medical evaluations, fit testing, and the respirator program.

#### § 1910.1024(h) Personal Protective Clothing and Equipment

##### § 1910.1024(h)(2)(v) Removal and Storage

Proposed paragraph (h)(2)(v) would require employers to ensure that any protective clothing or equipment required by the standard which is removed from the workplace for laundering, cleaning, maintenance, or disposal is labeled in accordance with paragraph (m)(3) of the proposed standard and the Hazard Communication standard at 29 CFR 1910.1200.

##### § 1910.1024(h)(3)(iii) Cleaning and Replacement

Proposed paragraph (h)(3)(iii) would require employers to inform in writing the persons or the business entities who launder, clean or repair the protective clothing or equipment required by this

standard of the potentially harmful effects of exposure to airborne beryllium and contact with soluble beryllium compounds and how the protective clothing and equipment must be handled in accordance with the standard.

#### § 1910.1024(j)(3) Housekeeping

Proposed paragraph (j)(3)(i) requires waste, debris, and materials visibly contaminated with beryllium and consigned for disposal to be disposed of in sealed, impermeable enclosures. Proposed paragraph (j)(3)(ii) requires these enclosures to be labeled in accordance with proposed paragraph (m)(3) of the standard.

Proposed paragraph (j)(3)(iii) requires materials designated for recycling that are visibly contaminated with beryllium to be cleaned to remove the visible particulate or placed in sealed, impermeable enclosures that are labeled in accordance with proposed paragraph (m)(3) of the standard.

#### § 1910.1024(k) Medical Surveillance

##### § 1910.1024(k)(1), (2), and (3) Employee Medical Surveillance

Proposed paragraph (k)(1) details when and under what conditions an employer must make medical surveillance available to its employees. Paragraph (k)(2) of the proposed standard specifies the frequency of medical examinations that are to be offered to those employees covered by the medical surveillance program, and proposed paragraph (k)(3) details the content of the medical examinations.

##### § 1910.1024(k)(4) Information Provided to the PLHCP

Proposed paragraph (k)(4) would require employers to provide a copy of this standard and its appendices to the examining PLHCP. In addition, the proposed paragraph would require employers to provide the following information, if known, to the PLHCP: (A) A description of the employee's former and current duties that relate to the employee's occupational exposure; (B) the employee's former and current levels of occupational exposure; (C) a description of any protective clothing and equipment, including respirators, used by the employee, including when and for how long the employee has used that protective clothing and equipment; and (D) information from records of employment-related medical examinations previously provided to the employee, currently within the control of the employer, after obtaining a medical release from the employee.

##### § 1910.1024(k)(5)(i), (ii), and (iii) Licensed Physician's Written Medical Opinion

Under proposed paragraph (k)(5)(i), the employer must obtain a written medical opinion from the licensed physician within 30 days of the employee's medical examination. The written medical opinion must contain the following information: (A) The licensed physician's opinion as to whether the employee has any detected medical condition that would place the employee at increased risk of CBD from further exposure; (B) any recommended limitations on the employee's exposure, including the use and limitations of protective clothing or equipment, including respirators; and (C) a statement that the PLHCP has explained the results of the medical examination to the employee, including any tests conducted, any medical conditions related to exposure that require further evaluation or treatment, and any special provisions for use of protective clothing or equipment.

Proposed paragraph (k)(5)(ii) would require the employer to ensure that neither the licensed physician nor any other PLHCP reveals to the employer findings or diagnoses which are unrelated to beryllium exposure.

Proposed paragraph (k)(5)(iii) would require the employer to provide a copy of the licensed physician's written medical opinion to the employee within two weeks after receiving it.

##### § 1910.1024(k)(7) Beryllium Sensitization Test Results Research

Proposed paragraph (k)(7) would require employers, upon request by OSHA, to convey employees' beryllium sensitization test results to OSHA for evaluation and analysis.

##### § 1910.1024(m) Communication of Hazards

Proposed paragraph (m)(1)(i) would require chemical manufacturers, importers, distributors, and employers to comply with all applicable requirements of the Hazard Communication Standard (HCS) for beryllium (29 CFR 1910.1200). Proposed paragraph (m)(1)(ii) requires that when classifying the hazards of beryllium, the employer must address at least the following: cancer; lung effects (chronic beryllium disease and acute beryllium disease); beryllium sensitization; skin sensitization; and skin, eye, and respiratory tract irritation.

Proposed paragraph (m)(1)(iii) would require employers to include beryllium in the hazard communication program established to comply with the HCS,

and ensure that each employee has access to labels on containers and safety data sheets for beryllium.

Proposed paragraph (m)(2)(i) would require employers to post warning signs at each approach to a regulated area so that each employee is able to read and understand the signs and take necessary protective steps before entering the area. Proposed paragraph (m)(2)(ii) would require these signs to be legible and readily visible, and contains language that would be required to appear on each warning sign.

Proposed paragraph (m)(3) would require employers to label each bag and container of clothing, equipment, and materials visibly contaminated with beryllium consistent with the Hazard Communication standard at 29 CFR 1910.1200. Proposed paragraph (m)(3) also contains language that would be required to appear on every such label.

Proposed paragraph (m)(4)(iv) would require employers to make copies of the standard and its appendices readily available at no cost to each employee and designated employee representative.

##### § 1910.1024(m)(4)(iv) Employee Information

Paragraph (m)(4)(iv) requires that employers make copies of the standard and its appendices readily available at no cost to each employee and designated employee representative.

##### § 1910.1024(n) Recordkeeping

##### § 1910.1024(n)(1)(i), (ii), and (iii) Exposure Measurements.

Proposed paragraph (n)(1)(i) would require employers to keep records of all measurements taken to monitor employee exposure to beryllium as required by paragraph (d) of the standard.

Proposed paragraph (n)(1)(ii) would require employers to include at least the following information in the records: (A) The date of measurement for each sample taken; (B) the operation that is being monitored; (C) the sampling and analytical methods used and evidence of their accuracy; (D) the number, duration, and results of samples taken; (E) the type of personal protective clothing and equipment, including respirators, worn by monitored employees at the time of monitoring; and, (F) the name, social security number, and job classification of each employee represented by the monitoring, indicating which employees were actually monitored.

Proposed paragraph (n)(1)(iii) would require employers to maintain employee exposure monitoring records in

accordance with 29 CFR 1910.1020(d)(1)(ii).

§ 1910.1024(n)(2)(i), (ii), and (iii) Historical Monitoring Data

Proposed paragraph (n)(2)(i) would require employers to establish an accurate record of any historical monitoring data used to satisfy the initial monitoring requirements in paragraph (d)(2) of the proposed standard. Paragraph (n)(2)(ii) would require the employer to demonstrate that the data comply with the requirements of paragraph (d)(2) of the standard. Paragraph (n)(2)(iii) would require the employer to maintain historical monitoring data in accordance with 29 CFR 1910.1020.

§ 1910.1024(n)(3)(i), (ii), and (iii) Objective Data

Proposed paragraph (n)(3)(i) would require employers to establish accurate records of any objective data relied upon to satisfy the requirement for initial monitoring in proposed paragraph (d)(2). Proposed paragraph (n)(3)(ii) would require employers to have at least the following information in such records: (A) The data relied upon; (B) the beryllium-containing material in question; (C) the source of the objective data; (D) a description of the operation exempted from initial monitoring and how the data support the exemption; and (E) other information demonstrating that the data meet the requirements for objective data contained in paragraph (d)(2)(ii) of the proposed standard. Proposed paragraph (n)(3)(iii) would require employers to maintain objective data records in accordance with 29 CFR 1910.1020.

§ 1910.1024(n)(4)(i), (ii), & (iii) Medical Surveillance

Proposed paragraph (n)(4)(i) would require employers to establish accurate records for each employee covered by the medical surveillance requirements in proposed paragraph (k). Proposed paragraph (n)(4)(ii) would require employers to include in employee medical records the following information about the employee: (A) Name, social security number, and job classification; (B) a copy of all licensed physicians' written opinions; and (C) a copy of the information provided to the PLHCP as required by paragraph (k)(4) of the proposed standard. Proposed paragraph (n)(4)(iii) would require employers to maintain medical records in accordance with 29 CFR 1910.1020.

§§ 1910.1024(n)(5)(i) & (ii) Training

Proposed paragraph (n)(5)(i) would require employers to prepare an

employee training record at the completion of any training required by the proposed standard. The training record must contain the following information: The name, social security number, and job classification of each employee trained; the date the training was completed; and the topic of the training. Proposed paragraph (n)(5)(ii) would require employers to maintain employee training records for three years after the completion of training. This record maintenance requirement would also apply to records of annual retraining or additional training as described in paragraph (m)(4) of the proposed standard.

§ 1910.1024(n)(6) Access to Records

Under proposed paragraph (n)(6), employers must make all records maintained as a requirement of the standard available for examination and copying to the Assistant Secretary, the Director of NIOSH, each employee, and each employee's designated representative(s) in accordance with the *Access to employee exposure and medical records* standard (29 CFR 1910.1020).

§ 1910.1024(n)(7) Transfer of Records

Paragraph (n)(7) of the proposed standard would require employers to comply with the transfer requirements contained in the *Access to employee exposure and medical records* standard (29 CFR 1910.1020(h)). That existing standard requires employers either to transfer records to successor employers or, if there is no successor employer, to inform employees of their access rights at least three months before the cessation of the employer's business.

4. *Affected Public*: Business or other for-profit. This standard applies to employers in general industry who have employees that may have occupational exposures to any form of beryllium, including compounds and mixtures, except those articles and materials exempted by paragraphs (a)(2) and (a)(3) of the proposed standard. This standard does not apply to articles, as defined in the Hazard Communication standard (HCS) (29 CFR 1910.1200(c)), that contain beryllium and that the employer does not process. Also, this standard does not apply to materials containing less than 0.1% beryllium by weight.

5. *Number of respondents*: Employers in general industry that have employees working in jobs affected by beryllium exposure (4,088 employers).

6. *Frequency of responses*: Frequency of response varies depending on the specific collection of information.

7. *Number of responses*: 155,818.

8. *Average time per response*: Varies from 5 minutes (.08 hours) for a clerical worker to generate and maintain an employee medical record, to 8 hours for a human resource manager to develop and implement a written exposure control plan.

9. *Estimated total burden hours*: 80,776.

10. *Estimated cost (capital-operation and maintenance)*: \$10,900,579.

#### D. Submitting Comments

Members of the public who wish to comment on the paperwork requirements in this proposal must send their written comments to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for the Department of Labor, OSHA (RIN-1218-AB76), Office of Management and Budget, Room 10235, Washington, DC 20503, Fax: 202-395-5806 (this is not a toll-free numbers), email: [OIRA\\_submission@omb.eop.gov](mailto:OIRA_submission@omb.eop.gov). The Agency encourages commenters also to submit their comments on these paperwork requirements to the rulemaking docket (Docket Number OSHA-H005C-2006-0870), along with their comments on other parts of the proposed rule. For instructions on submitting these comments to the rulemaking docket, see the sections of this **Federal Register** notice titled **DATES** and **ADDRESSES**.

#### E. Docket and Inquiries

To access the docket to read or download comments and other materials related to this paperwork determination, including the complete Information Collection Request (ICR) (containing the Supporting Statement with attachments describing the paperwork determinations in detail) use the procedures described under the section of this notice titled **ADDRESSES**. You also may obtain an electronic copy of the complete ICR by visiting the Web page at <http://www.reginfo.gov/public/do/PRAMain>, scroll under "Currently Under Review" to "Department of Labor (DOL)" to view all of the DOL's ICRs, including those ICRs submitted for proposed rulemakings. To make inquiries, or to request other information, contact Mr. Todd Owen, Directorate of Standards and Guidance, OSHA, Room N-3609, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693-2222.

#### XI. Federalism

The Agency reviewed the proposed beryllium rule according to the Executive Order (E.O.) on Federalism (E.O. 13132, 64 FR 43255, Aug. 10, 1999), 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. The E.O. allows Federal agencies to preempt State law only with the expressed 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 (the "Act" or "OSH Act," 29 U.S.C. 667), Congress expressly provides that States may adopt, with Federal approval, a plan for the development and enforcement of occupational safety and health standards; States that obtain Federal approval for such a plan are referred to as "State-Plan States." (29 U.S.C. 667). 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.

While OSHA drafted this proposed rule to protect employees in every State, Section 18(c)(2) of the OSHA Act permits State-Plan States to develop and enforce their own standards, provided the requirements in these standards are at least as safe and healthful as the requirements specified in this proposed rule if it is promulgated.

In summary, this proposed rule complies with E.O. 13132. 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 rulemaking does not significantly limit State policy options.

## XII. State-Plan States

When Federal OSHA promulgates a new standard or a more stringent amendment to an existing standard, the 27 State 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 CFR 1953.5(a).

The State may demonstrate that a standard change is not necessary because, for example, the State standard

is already the same as or at least as effective as the Federal standard change. 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 makes a timely demonstration that good cause exists for extending the time limitation. 29 CFR 1953.5(a).

Of the 27 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. The five states and territories whose OSHA-approved State plans cover only public-sector employees are: Connecticut, Illinois, New Jersey, New York, and the Virgin Islands.

This proposed beryllium rule applies to general industry. If adopted as proposed, all State Plan States would be required to revise their general industry standard appropriately within six months of Federal promulgation.

## XIII. Unfunded Mandates Reform Act

Under Section 202 of the Unfunded Mandates Reform Act of 1995 (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 issuing a notice of proposed rulemaking. OSHA's proposal 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 (*see* 29 U.S.C. 652(5)). Under voluntary agreement with OSHA, some States enforce compliance with their State standards on public sector entities, and these agreements specify that these State standards must be equivalent to OSHA standards. The OSH Act also does not cover tribal governments in the performance of traditional governmental functions, though it does when tribal governments engage in commercial activity. However, the proposal would not require tribal governments to expend, in the aggregate, \$100,000,000 or more in any one year for their commercial activities. Thus, although OSHA may include compliance costs for affected governmental entities in its

analysis of the expected impacts associated with a proposal, the proposal does not trigger the requirements of UMRA based on its impact on State, local, or tribal governments.

Based on the analysis presented in the Preliminary Economic Analysis (*see* Section IX above), OSHA concludes that the proposal would impose a Federal mandate on the private sector in excess of \$100 million in expenditures in any one year. The Preliminary Economic Analysis constitutes the written statement containing a qualitative and quantitative assessment of the anticipated costs and benefits required under Section 202(a) of the UMRA (2 U.S.C. 1532).

## XIV. Protecting Children From Environmental Health and Safety Risks

E.O. 13045 (66 FR 19931 (Apr. 23, 2003)) requires that Federal agencies submitting covered regulatory actions to OMB's Office of Information and Regulatory Affairs (OIRA) for review pursuant to E.O. 12866 (58 FR 51735 (Oct. 4, 1993)) 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. E.O. 13045 defines "covered regulatory actions" as rules that may (1) be economically significant under E.O. 12866 (*i.e.*, a rulemaking that has an annual effect on the economy of \$100 million or more, or would 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), 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 proposed beryllium rule is economically significant under E.O. 12866 (*see* Section IX of this preamble). However, after reviewing the proposed beryllium rule, OSHA has determined that the rule would not impose environmental health or safety risks to children as set forth in E.O. 13045. The proposed rule would require employers to limit employee exposure to beryllium and take other precautions to protect employees from adverse health effects

associated with exposure to beryllium. OSHA is not aware of any studies showing that exposure to beryllium disproportionately affects children or that employees under 18 years of age who may be exposed to beryllium are disproportionately affected by such exposure. Based on this preliminary determination, OSHA believes that the proposed beryllium rule does not constitute a covered regulatory action as defined by E.O. 13045. However, if such conditions exist, children who are exposed to beryllium in the workplace would be better protected from exposure to beryllium under the proposed rule than they are currently.

#### **XV. Environmental Impacts**

OSHA has reviewed the beryllium proposal according to the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*), the regulations of the Council on Environmental Quality (40 CFR part 1500), and the Department of Labor's NEPA procedures (29 CFR part 11). Based on that review, OSHA does not expect that the proposed rule, in and of itself, would create additional environmental issues. OSHA has made a preliminary determination that the proposed standard will have no impact on air, water, or soil quality; plant or animal life; the use of land or aspects of the external environment. Therefore, OSHA concludes that the proposed beryllium standard would have no significant environmental impacts.

#### **XVI. Consultation and Coordination With Indian Tribal Governments**

OSHA reviewed this proposed rule in accordance with E.O. 13175 on Consultation and Coordination with Indian Tribal Governments (65 FR 67249, November 9, 2000), and determined that it does not have "tribal implications" as defined in that order. The rule, if promulgated, would 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.

#### **XVII. Public Participation**

OSHA encourages members of the public to participate in this rulemaking by submitting comments on the proposal.

*Written Comments.* OSHA invites interested persons to submit written data, views, and arguments concerning this proposal. In particular, OSHA encourages interested persons to comment on the issues raised at the end of each section. When submitting

comments, persons must follow the procedures specified above in the sections titled **DATES** and **ADDRESSES**.

*Informal public hearings.* The Agency will schedule an informal public hearing on the proposed rule if requested during the comment period.

#### **XVIII. Summary and Explanation**

##### *Introduction*

This section of the preamble explains the requirements that OSHA proposes to control occupational exposure to beryllium, including the purpose of these requirements and how they will protect workers from hazardous beryllium exposures.

OSHA believes, based on currently available information, that the proposed requirements are necessary and appropriate to protect workers exposed to beryllium. In developing this proposed rule, OSHA has considered many sources of data and information, including responses to the Request for Information (RFI) for "Occupational Exposure to Beryllium" (OSHA, 2002); the responses from Small Entity Representatives (SERs) who participated in the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA) (5 U.S.C. 601 *et seq.*) process (OSHA, 2007a); recommendations of the Small Business Advocacy Review (SBAR) Panel (OSHA, 2008b); the Department of Energy (DOE) Chronic Beryllium Disease Prevention Program rule (DOE, 1999); and numerous scientific studies, professional journal articles, and other data obtained by the Agency.

The provisions in the proposed standard are generally consistent with other recent OSHA health standards, such as chromium (VI) (29 CFR 1910.1026) and cadmium (29 CFR 1910.1027). Using a similar approach across health standards, when possible, makes them more understandable and easier for employers to follow, and helps to facilitate uniformity of interpretation. This approach is also consistent with section 6(b)(5) of the OSH Act, which states that health standards shall consider "experience gained under this and other health and safety laws" (29 U.S.C. 655(b)(5)). However, to the extent that protecting workers from occupational exposure to beryllium requires different or unique approaches, the Agency has formulated proposed requirements to address the specific hazards and working conditions associated with beryllium exposure.

Also pursuant to section 6(b)(5), OSHA has expressed the proposed requirements in performance-based language, where possible, to provide

employers with greater flexibility in determining the most effective strategies for controlling beryllium hazards in their workplaces. OSHA believes this approach allows employers to incorporate changes and advancements in control strategy, technology, and industry practice, thereby reducing the need to revise the rule when those changes occur.

##### (a) Scope and Application

In paragraph (a)(1), OSHA proposes to apply this standard to occupational exposure to beryllium in all forms, compounds, and mixtures in general industry.

For the purpose of the proposed rule, OSHA is treating beryllium generally, instead of individually addressing specific compounds, forms, and mixtures. Based on a review of scientific studies, OSHA has preliminarily determined that the toxicological effects of beryllium exposure on the human body are similar regardless of the form of beryllium (see the Health Effects section of this preamble at V.B.5; V.G). OSHA is not aware of any information that would lead the Agency to conclude that exposure to different forms of beryllium necessitates different regulatory approaches or requirements.

OSHA has preliminarily decided to limit the scope of the rulemaking to general industry. This proposal is modeled on a suggested rule that was crafted by two major stakeholders in general industry, Materion Brush and the United Steelworkers Union (Materion and USW, 2012). In the course of developing this proposal, they provided OSHA with data on exposure and control measures and information on their experiences with handling beryllium in general industry settings. At this time, the information available to OSHA on beryllium exposures outside of general industry is limited, but suggests that most operations in other sectors are unlikely to involve beryllium exposure. The Agency hopes to expedite the rulemaking process by limiting the scope of this proposal to general industry and relying on already existing standards to protect workers in those operations outside of general industry where beryllium exposure may exist.

The proposed rule would not apply to marine terminals, longshoring, or agriculture. OSHA has not found evidence indicating that beryllium is used or handled in these sectors in a way that might result in beryllium exposure. The proposed rule also excludes the construction and shipyard sectors. OSHA believes that occupational exposures to beryllium in

the construction and shipyard sectors occur primarily in abrasive blasting operations.

Abrasive blasters and ancillary abrasive blasting workers are exposed to beryllium from coal slag and other abrasive blast material that may contain beryllium as a trace contaminant. Airborne concentrations of beryllium have been measured above the current TWA PEL of 2 µg/m<sup>3</sup> when blast material containing beryllium is used as intended (see Appendix IV–C in the PEA, OSHA 2014). Abrasive blasters, pot tenders, and cleanup workers have the potential for significant airborne exposure during blasting operations and during cleanup of spent material that may contain beryllium as a trace contaminant.

To address high concentrations of various hazardous chemicals in abrasive blasting material, employers must already be using engineering and work practice controls to limit workers' exposures and must be supplementing these controls with respiratory protection when necessary. For example, abrasive blasters in the construction industry fall under the protection of the Ventilation standard (29 CFR 1926.57). The Ventilation standard includes an abrasive blasting subsection (29 CFR 1926.57(f)), which requires that abrasive blasting respirators be worn by all abrasive blasting operators when working inside blast-cleaning rooms (29 CFR 1926.57(f)(5)(ii)(A)), or when using silica sand in manual blasting operations where the nozzle and blast are not physically separated from the operator in an exhaust-ventilated enclosure (29 CFR 1926.57(f)(5)(ii)(B)), or when needed to protect workers from exposures to hazardous substances in excess of the limits set in § 1926.55 (29 CFR 1926.57(f)(5)(ii)(C); ACGIH, 1971)). For maritime, standard 29 CFR 1915.34(c) covers similar requirements for respiratory protection needed in blasting operations. Due to these requirements, OSHA believes that abrasive blasters already have controls in place and wear respiratory protection during blasting operations. Thus, in estimating costs for Regulatory Alternatives #2a and #2b, OSHA judged that the reduction of the TWA PEL would not impose costs for additional engineering controls or respiratory protection in abrasive blasting (see Appendix VIII–C in this chapter for details). OSHA requests comment on this issue—in particular, whether abrasive blasters using blast material that may contain beryllium as a trace contaminant are already using all feasible engineering and work practice

controls, respiratory protection, and PPE that would be required by Regulatory Alternatives #2a and #2b.

OSHA requests comment on the limitation of the scope to general industry, as well as information on beryllium exposures in all industry sectors. The Agency requests information on whether employees in the construction, maritime, longshoring, shipyard, and agricultural sectors are exposed to beryllium in any form and, if so, their levels of exposure and what types of exposure controls are currently in place. In particular, OSHA requests comment on whether abrasive blasters using blast material that may contain beryllium as a trace contaminant are already using all feasible engineering and work practice controls, respiratory protection, and PPE. OSHA also requests comment on Regulatory Alternatives #2a and #2b, presented at the end of this section, that would provide protection to workers in sectors outside of general industry. Regulatory Alternative #2a would expand the scope of the proposed standard to include employers in construction and maritime. Regulatory #2b would change the Z tables in 29 CFR 1910.1000 and 29 CFR 1915.1000, and Appendix A of 29 CFR 1926.55, to lower the permissible exposure limits for beryllium for workers in all beryllium-exposed occupations. Another regulatory alternative that would impact the scope of affected industries, extending eligibility for medical surveillance to employees in shipyards, construction, and parts of general industry excluded from the scope of the proposed standard, is discussed along with other medical surveillance alternatives (see this preamble at Section XVIII, paragraph (k), Regulatory Alternative #21). Depending on the nature of the data and comments provided, OSHA envisions possible expansions of its regulation of beryllium either as part of this rulemaking or at a later time.

Paragraph (a)(2) specifies that the proposed rule would not apply to articles, as defined in the Hazard Communication standard (HCS) (29 CFR 1910.1200(c)), that contain beryllium and that the employer does not process. The HCS defines an article as “a manufactured item other than a fluid or particle: (i) Which is formed to a specific shape or design during manufacture; (ii) which has end use function(s) dependent in whole or in part upon its shape or design during end use; and (iii) which under normal conditions of use does not release more than very small quantities *e.g.*, minute or trace amounts of a hazardous

chemical (as determined under paragraph (d) of this section), and does not pose a physical hazard or health risk to employees.” For example, items or parts containing beryllium that employers assemble where the physical integrity of the item is not compromised are unlikely to release more than a very small quantity of beryllium that would not pose a physical or health hazard for workers. These items would be considered articles that are exempt from the scope of the proposed standard. Similarly, finished or processed items or parts containing beryllium that employers are simply packing in containers or affixing with shipping tags or labels are unlikely to release more than a minute or trace amount of beryllium. These items would also come within the proposed exemption. By contrast, if an employer performs operations such as machining, grinding, blasting, sanding, or other processes that physically alter an item, these operations would not fall within the exemption in proposed paragraph (a)(2) because they involve processing of the item and could result in significant exposure to beryllium-containing material.

Paragraph (a)(3) specifies that the proposed rule would not apply to materials containing less than 0.1% beryllium by weight. A similar exemption is included in several previously promulgated standards, including Benzene (29 CFR 1910.1028), Methyleneedianiline (MDA) (29 CFR 1910.1050), and 1,3-Butadiene (BD) (29 CFR 1910.1051). These exemptions were established to limit the regulatory burden on employers who do not use materials containing 0.1 percent or more of the substance in question, on the premise that workers in exempted industries are not exposed at levels of concern. In the preamble to the MDA standard, OSHA states that the Agency relied on data showing that worker exposure to mixtures or materials of MDA containing less than 0.1 percent MDA did not create any hazards other than those expected from worker exposure beneath the action level (57 FR 35630, 35645–46, August 10, 1992). The exemption in the BD standard does not apply where airborne concentrations generated by such mixtures can exceed the action level or STEL. The exemption in the Benzene standard was based on indications that exposures resulting from substances containing trace amounts of benzene would generally be below the exposure limit, and on OSHA's belief that the exemption would encourage employers to reduce the concentration of benzene in certain



substances (43 FR 27962, 27968, June 27, 1978).

OSHA is aware of two industries in the general industry sector that would be exempted from the proposed standard under proposed paragraph (a)(3): Coal-fired electric power generation and primary aluminum production. As discussed in the PEA, Chapter IV, Appendices A and B, most employees' TWA exposures in these industries do not exceed the proposed action level of 0.1  $\mu\text{g}/\text{m}^3$ . However, exposures above the proposed PEL of 0.2  $\mu\text{g}/\text{m}^3$  have been found in some jobs and in facilities with poor housekeeping and work practices. In coal-fired electric power generation, these higher exposures are associated with intermittent exposure to fly ash during maintenance work in and around baghouses and boilers. Fly ash contains less than 0.01% beryllium; however, exposures between 0.1 and 0.4  $\mu\text{g}/\text{m}^3$  were observed among workers maintaining boilers. Exposures for baghouse cleaning frequently exceeded the current PEL, reaching as high as 13  $\mu\text{g}/\text{m}^3$ . In aluminum production, the bauxite ore used as a raw material contains naturally occurring beryllium in the part per million range (*i.e.* <0.0001%); however, a study of four smelters showed that the arithmetic mean exposure was slightly above the proposed PEL, and the 95th percentile exposure (of 965 samples) was above 1  $\mu\text{g}/\text{m}^3$ . BeLPT testing in a group of 734 aluminum workers found two cases of confirmed beryllium sensitization (0.27%) and an additional few abnormal results that could not be confirmed, either because the worker was not retested or the retest appeared normal (Taiwo et al., 2008).

OSHA requests comment on the exemption proposed for the beryllium standard. Is it appropriate to include an exemption for operations where beryllium exists only as a trace contaminant, but some workers can nevertheless be significantly exposed? Should the Agency consider dropping the exemption, or constraining it to operations where exposures are below the proposed action level and STEL? OSHA requests additional data describing the levels of airborne beryllium in workplaces that fall under this exemption and comments on regulatory alternatives, discussed at the end of this section, that would eliminate or modify the exemption.

A number of stakeholders, including SERs who participated in the SBREFA process, urged OSHA to exempt certain industries or processes and activities from the proposed standard. In support of this request, SERs from the stamping

industry argued that their exposures are low, below 0.2  $\mu\text{g}/\text{m}^3$  (OSHA, 2007a). In addition, some SERs requested exemptions from particular requirements. SERs from the dental laboratory industry requested exemptions from all requirements other than training and the permissible exposure limit (PEL). In support of this request, they also argued that their exposures are very low, around 0.02  $\mu\text{g}/\text{m}^3$  when ventilation is used. They indicated that they already have sufficient engineering and work practice controls in place to keep exposures low (OSHA, 2008b). The SBREFA Panel recommended that OSHA consider a more limited scope of industries (OSHA, 2008b).

The Panel's recommendation is addressed in part in this proposed standard, which has a much more limited scope than the draft standard reviewed by the SBREFA Panel. Whereas the draft reviewed by the Panel covered beryllium in all forms and compounds in general industry, construction, and maritime, the scope of the current beryllium proposal includes general industry only, and does not apply to employers in construction and maritime. In addition, it provides an exemption for those working with materials that contain beryllium only as a trace contaminant (less than 0.1 percent composition by weight).

Although much narrower than the scope in the SBREFA draft, the current proposal's scope includes industries of concern for some SERs. OSHA's preliminary feasibility analysis indicates that worker exposures in both dental laboratories and stamping facilities exceed or have the potential to exceed the proposed TWA PEL where appropriate controls are not in place (see section IX of this preamble, Summary of the Preliminary Economic Analysis and Initial Regulatory Flexibility Analysis). Accordingly, OSHA has not exempted them from the proposed standard. However, if employers in these industries have historical or objective data that meet the requirements set forth in proposed paragraph (d)(2) demonstrating that they have no exposures or that exposures are below the action level and at or below the STEL, these employers may be able to satisfy many of their obligations under this proposed standard by reference to these data.

Some stakeholders, including employers who do stripping operations, urged that OSHA exempt them from the proposed rule because any beryllium exposures generated in their facilities were comprised of larger-sized particles, which they contended were not as

harmful as smaller ones (OSHA, 2008b). OSHA has decided not to exempt operations based on particle size. As discussed in this preamble at section V, Health Effects, there is not sufficient evidence to demonstrate that particle size has a significant bearing on health outcomes.

While acknowledging the concerns raised by SERs that the scope of the standard might be too broad, OSHA is concerned that the scope of the current proposal might be too narrow. Exposures have the potential to exceed the proposed PEL in some blasting operations in construction and maritime, and in some general industry operations where beryllium exists as a trace contaminant. Abrasive blasters and ancillary abrasive blasting workers are exposed to beryllium from coal slags and other abrasive blast material, which contain beryllium in amounts less than 0.1 percent. Airborne concentrations of beryllium have been measured above the current TWA PEL of 2  $\mu\text{g}/\text{m}^3$  when the blast material is used as intended. Abrasive blasters, pot tenders, and cleanup workers working primarily in construction and shipyards have the potential for significant airborne exposure during blasting operations and during cleanup of spent blast material. Coal fly ash in coal powered utility facilities is also known to contain trace amounts of beryllium, which may become airborne during furnace and bag house operations and result in exposures exceeding the current PELs. Similarly, beryllium exists as a contaminant in aluminum ore and may result in exposures above the proposed PELs during aluminum refining and production.

OSHA invites comment on the proposed scope of the standard and on Regulatory Alternatives 1 and 2 below, which would increase protection for workers in maritime and construction industries and in occupations dealing with beryllium as a trace contaminant.

#### Regulatory Alternatives 1a and 1b

Regulatory Alternative #1a would modify the proposed scope to eliminate the exemption for materials containing less than 0.1 percent beryllium by weight. Under this alternative, the scope of the rule would cover employers in general industry, including industries or occupations where beryllium exists as a trace contaminant. Regulatory Alternative #1a would expand the scope of the proposed standard to include all operations in general industry where beryllium exists only as a trace contaminant; that is, where the materials used contain no more than 0.1 percent beryllium by weight. Regulatory

Alternative #1b is similar to Regulatory Alternative #1a, but exempts operations where the employer can show that employees' exposures will not meet or exceed the action level or exceed the STEL. Where the employer has objective data demonstrating that a material containing beryllium or a specific process, operation, or activity involving beryllium cannot release beryllium in concentrations at or above the proposed action level or above the proposed STEL under any expected conditions of use, the specific process, operation, or activity would be exempt from the proposed standard except for recordkeeping requirements pertaining to the objective data. Alternative #1a and Alternative #1b, like the proposed rule, would not cover employers or employees in construction or shipyards.

#### Regulatory Alternatives 2a and 2b

These two alternatives would increase protections for workers in the construction and maritime sectors. Regulatory alternative #2a would expand the scope of the proposed standard to also include employers in construction and maritime. For example, this alternative would cover abrasive blasters, pot tenders, and cleanup staff working in construction and shipyards who have the potential for airborne beryllium exposure during blasting operations and during cleanup of spent media. Regulatory alternative #2b would amend 29 CFR 1910.1000 Table Z-1, 29 CFR 1915.1000 Table Z, and 29 CFR 1926.55 Appendix A to replace the current permissible exposure limits for beryllium and beryllium compounds (and the reference in 1910.1000 Table Z-1 to Table Z-2) with the TWA PEL and STEL adopted through this rulemaking. This alternative would also delete the entry for beryllium and beryllium compounds in 29 CFR 1910.1000 Table Z-2 because the entry would instead be listed in Table Z-1 as described above. Note that OSHA is proposing an 8-hour TWA PEL of 0.2  $\mu\text{g}/\text{m}^3$  and a 15-minute STEL of 2  $\mu\text{g}/\text{m}^3$ , and is also considering alternative TWA PELs of 0.1  $\mu\text{g}/\text{m}^3$  and 0.5  $\mu\text{g}/\text{m}^3$ , and alternative STELs of 0.5  $\mu\text{g}/\text{m}^3$ , 1  $\mu\text{g}/\text{m}^3$ , and 2.5  $\mu\text{g}/\text{m}^3$ . This alternative would limit permissible airborne beryllium exposures for workers in all beryllium-exposed occupations including construction, maritime and other industries where beryllium is a trace contaminant.

The Z Tables and 1926.55 Appendix A do not incorporate ancillary provisions such as exposure monitoring, medical surveillance, medical removal, and PPE. However, many of the occupations excluded from the scope of

the proposed beryllium standard receive some ancillary provision protections from other rules, such as Personal Protective Equipment (1910 Subpart I, 1915 Subpart I, 1926.28, also 1926 Subpart E), Ventilation (1926.57), Hazard Communication (1910.1200), and specific provisions for welding (1910 Subpart Q, 1915 Subpart D, 1926 Subpart J) and abrasive blasting (1910.109, 1926 Subpart U).

#### (b) Definitions

Proposed paragraph (b) includes definitions of key terms used in the proposed standard. To the extent possible, OSHA uses the same terms and definitions in the proposed standard as the Agency has used in other OSHA health standards. Using similar terms across health standards, when possible, makes them more understandable and easier for employers to follow. In addition, using similar terms and definitions helps to facilitate uniformity of interpretation.

“*Action level*” means an airborne concentration of beryllium of 0.1 micrograms per cubic meter of air ( $\mu\text{g}/\text{m}^3$ ) calculated as an eight-hour time-weighted average (TWA). Exposures at or above the action level but below the TWA PEL trigger the proposed requirements for periodic exposure monitoring (see paragraph (d)(3)). In addition, paragraph (f)(1)(i)(B) requires employers to list as part of their Written Exposure Control Plan the operations and job titles reasonably expected to have exposure at or above the action level. Paragraph (f)(2)(i) requires employers to ensure that at least one of the controls listed in paragraph (f)(2)(i)(A) is in place unless employers can demonstrate for each operation or process either that such controls are not feasible, or that employee exposures do not exceed the action level based on at least two representative personal breathing zone samples taken seven days apart. Furthermore, whenever an employer allows employees to consume food or beverages in a beryllium work area, the employer must ensure that no employee is exposed to beryllium at or above the action level (paragraph (i)(4)(ii)). The action level is also relevant to the proposed medical removal requirements. Employees eligible for removal can choose to remain in environments with exposures above the action level provided they wear respirators (paragraph (l)(2)(ii)). These employees may also choose to be transferred to comparable work in environments with exposures below the action level (or if comparable work is not available, they may choose to be

placed on paid leave for a period of at least six months (paragraph (l)(3)).

OSHA's preliminary risk assessment indicates that significant risk remains at the proposed TWA PEL (see this preamble at section VI, Significance of Risk). When there is a continuing exposure risk at the PEL, the courts have ruled that OSHA has the legal authority to impose additional requirements, such as action levels, on employers to further reduce risk when those requirements will result in a greater than minimal incremental benefit to workers' health (*Asbestos II*, 838 F.2d at 1274). OSHA's preliminary conclusion is that an action level for beryllium exposure will result in a further reduction in risk beyond that provided by the PEL alone.

Another important reason for proposing an action level involves the variable nature of employee exposures to beryllium. Because of this fact, OSHA believes that maintaining exposures below the action level provides reasonable assurance that employees will not be exposed to beryllium above the TWA PEL on days when no exposure measurements are made. This consideration is discussed later in this section of the preamble regarding proposed paragraph (d)(3).

OSHA's decision to propose an action level of one-half of the TWA PEL is consistent with previous standards, including those for inorganic arsenic (29 CFR 1910.1018), chromium (VI) (29 CFR 1910.1026), benzene (29 CFR 1910.1028), ethylene oxide (29 CFR 1910.1047), and methylene chloride (29 CFR 1910.1052).

“*Assistant Secretary*” means the Assistant Secretary of Labor for Occupational Safety and Health, United States Department of Labor, or designee. Proposed paragraph (k)(7) requires employers to report employee BeLPT results to OSHA for evaluation and analysis if requested by the Assistant Secretary. Proposed paragraph (n)(6) requires employers to make all records required under this section available, if requested, to the Assistant Secretary for examination and copying.

“*Beryllium lymphocyte proliferation test (BeLPT)*” means the measurement of blood lymphocyte proliferation in a laboratory test when lymphocytes are challenged with a soluble beryllium salt. A confirmed positive test result indicates the person has beryllium sensitization. For additional explanation of the BeLPT, see the Health Effects section of this preamble (section V), and Appendix A of this proposed standard. Under paragraph (f)(1)(ii)(B), employers must update the exposure control plan when an employee is confirmed positive. The BeLPT could be used to

determine whether an employee is confirmed positive (see definition of confirmed positive in paragraph (b) of this proposed standard). Paragraph (k)(3)(ii)(E) requires the BeLPT unless a more reliable and accurate test becomes available (see section I of this preamble, Issues and Alternatives, for discussion and request for comment regarding how OSHA should determine whether a test is more reliable and accurate than the BeLPT). Under paragraph (k)(7), employers must convey the results of medical tests such as the BeLPT to OSHA if requested.

“*Beryllium work area*” means any work area where employees are, or can reasonably be expected to be, exposed to airborne beryllium, regardless of the level of exposure. OSHA notes both a distinction and some overlap between the definitions of beryllium work area and regulated area in this proposal. Beryllium work areas are areas where employees are or can reasonably be expected to be exposed to airborne beryllium *at any level*, whereas an area is a regulated area only if employees are or can reasonably be expected to be exposed *above the TWA PEL or STEL*. Therefore, while not all beryllium work areas are regulated areas, all regulated areas are beryllium work areas because they are areas with exposure to beryllium. Accordingly, all requirements for beryllium work areas also apply in all regulated areas, but requirements specific to regulated areas apply only to regulated areas and not to beryllium work areas where exposures do not exceed the TWA PEL or STEL.

The presence of a beryllium work area triggers a number of the requirements in this proposal. Under paragraphs (d)(1)(ii) and (iii), employers must determine exposures for each beryllium work area. Furthermore, paragraphs (e)(1)(i) and (e)(2)(i) require employers to establish, maintain, identify, and demarcate the boundaries of each beryllium work area. Under paragraph (f)(1)(i), employers must establish and maintain a written exposure control plan for beryllium work areas. And paragraph (f)(2)(i) requires employers to implement at least one of the controls listed in (f)(2)(i)(A)(1) through (4) for each operation in a beryllium work area unless one of the exemptions in (f)(2)(i)(B) applies. In addition, paragraph (i)(1) requires employers to provide readily accessible washing facilities to employees working in a beryllium work area, and to instruct employees to use these facilities when necessary. Where employees are allowed to eat or drink in beryllium work areas, employers must ensure that surfaces in these areas are as free as

practicable of beryllium, that exposures are below the action level, and that these areas comply with the Sanitation standard (29 CFR 1910.141) (paragraph (i)(4)). Employers must maintain surfaces in all beryllium work areas as free as practicable of beryllium (paragraph (j)(1)(i)). Paragraph (j)(2) requires certain practices and prohibits other practices for cleaning surfaces in beryllium work areas.

“*CBD Diagnostic Center*” means a medical facility that has the capability of performing an on-site clinical evaluation for the presence of chronic beryllium disease (CBD) that includes bronchoalveolar lavage, transbronchial biopsy and interpretation of the biopsy pathology, and the beryllium bronchoalveolar lavage lymphocyte proliferation test (BeBALLPT). For purposes of this proposal, the term “*CBD Diagnostic Center*” refers to any medical facility that meets these criteria, whether or not the medical facility formally refers to itself as a CBD diagnostic center. For example, if a hospital has all of the capabilities required by this proposal for CBD diagnostic centers, the hospital would be considered a CBD diagnostic center for purposes of this proposal.

Proposed paragraph (k)(6) requires employers to offer employees who have been confirmed positive a referral to a CBD diagnostic center for a clinical evaluation.

“*Chronic beryllium disease (CBD)*” means a chronic lung disease associated with exposure to airborne beryllium. The Health Effects section of this preamble, section V, contains more information on CBD. CBD is relevant to several provisions of this proposal. Paragraph (f)(1)(ii)(B) requires employers to update the exposure control plan whenever an employee is diagnosed with CBD. Under paragraph (k)(1)(i)(B), employers must make medical surveillance available at no cost to employees who show signs and symptoms of CBD. Paragraph (k)(3)(ii)(B) requires medical examinations conducted under this standard to emphasize screening for respiratory conditions, which would include CBD. Under paragraph (k)(5)(i)(A), the licensed physician’s opinion must advise the employee on whether or not the employee has any detected medical condition that would place the employee at an increased risk of CBD from further exposure to beryllium. Furthermore, CBD is a criterion for medical removal under paragraph (l)(1). Under paragraph (m)(1)(ii), employers must address CBD in classifying beryllium hazards under the HCS. Employers must also train

employees on the signs and symptoms of CBD (see paragraph (m)(4)(ii)(A)).

“*Confirmed positive*” means two abnormal test results from consecutive BeLPTs or a second abnormal BeLPT result within a two-year period of the first abnormal result. The definition of confirmed positive also includes a single result of a more reliable test indicating that a person has been identified as sensitized to beryllium. OSHA recognizes that diagnostic tests for beryllium sensitization could eventually be developed that would not require a second test to confirm sensitization. OSHA requests comment on how best to determine whether a new method is more reliable and accurate than the BeLPT for detecting beryllium sensitization (see section I of this preamble, Issues and Alternatives).

Paragraph (f)(1)(ii)(B) requires employers to update the exposure control plan whenever an employee is confirmed positive or is diagnosed with CBD. Under proposed paragraph (k)(3)(ii)(E), employers are required to ensure that a BeLPT is offered to each eligible employee at the employee’s first medical examination under this proposed standard, and every two years from the date of the first examination unless the employee receives an abnormal BeLPT result. If the employee’s first BeLPT result is abnormal, the employer must provide the employee a second test within one month of the first test. If the employee’s second BeLPT result is also abnormal, the employee is considered confirmed positive for purposes of this proposed standard. OSHA requests comment on the methods used to determine when a BeLPT test result is abnormal, and on standardizing the use and interpretation of the BeLPT (see section I of this preamble, Issues and Alternatives).

A confirmed positive result will indicate to the licensed physician that the employee is sensitized to beryllium and is at increased risk of developing CBD (see paragraph (k)(5)(i)(A)). Employees who are confirmed positive are eligible for medical removal under proposed paragraph (l)(1).

“*Director*” means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee. The proposed recordkeeping requirements mandate that, upon request, employers make all records required by this standard available to the Director (as well as the Assistant Secretary) for examination and copying (see paragraph (n)(6)). Typically, the Assistant Secretary sends representatives to review workplace safety and health records. However, the

Director may also review these records while conducting studies such as Health Hazard Evaluations of workplaces, or for other purposes.

“*Emergency*” means any uncontrolled release of airborne beryllium. An emergency could result from equipment failure, rupture of containers, or failure of control equipment, among other causes.

Emergencies trigger several requirements of this proposed standard. Under paragraph (g)(1)(iv), respiratory protection is required during emergencies to protect employees from potential overexposures. Emergencies also trigger clean-up requirements under paragraph (j)(1)(ii), and medical surveillance under paragraph (k)(1)(i)(C). In addition, under paragraph (m)(4)(ii)(D), employers must train employees in applicable emergency procedures.

“*Exposure*” and “*exposure to beryllium*” mean the exposure to airborne beryllium that would occur if the employee were not using a respirator. This definition is consistent with the term “employee exposure” in other OSHA standards such as Asbestos (29 CFR 1910.1001), Benzene (29 CFR 1910.1028), Chromium (VI) (29 CFR 1910.1026), Butadiene (29 CFR 1910.1051), and Methylene chloride (29 CFR 1910.1052). Many OSHA standards establish action levels and permissible exposure limits based on quantitative airborne exposures, and many of these standards’ requirements are tied to exposures at or above the applicable action level, or above the applicable permissible exposure limit(s). This definition is also consistent with OSHA’s hierarchy of controls policy, which requires employers to implement engineering and work practices controls to control exposure before resorting to respiratory protection. For additional discussion of OSHA’s hierarchy of controls policy, see the discussion of paragraph (f) in this section of the preamble.

“*High-efficiency particulate air (HEPA) filter*” means a filter that is at least 99.97 percent effective in removing particles 0.3 micrometers in diameter (see Department of Energy Technical Standard DOE–STD–3020–2005). HEPA filtration is an effective means of removing hazardous beryllium particles from the air. The proposed standard requires beryllium-contaminated surfaces to be cleaned by HEPA vacuuming or other methods that minimize the likelihood of exposure (see paragraphs (j)(2)(i) and (ii)). Other OSHA health standards also require the use of vacuum systems equipped with HEPA filtration (see Chromium (VI) (29

CFR 1910.1026) and Lead in construction (29 CFR 1926.62)).

“*Physician or other licensed health care professional (PLHCP)*” means an individual whose legally permitted scope of practice, such as license, registration, or certification, allows the person to independently provide or be delegated the responsibility to provide some or all of the health care services required in proposed paragraph (k). The Agency recognizes that personnel qualified to provide medical surveillance may vary from State to State, depending on State licensing requirements. Whereas all licensed physicians would meet this proposed definition of PLHCP, not all PLHCPs must be physicians.

Under paragraph (k)(5) of the proposed standard, the written medical opinion must be completed by a licensed physician. However, other requirements of paragraph (k) may be performed by a PLHCP under the supervision of a licensed physician (see paragraphs (k)(1)(ii), (k)(3)(i), (k)(3)(ii)(G), (k)(5)(i)(C), and (k)(5)(ii)). The proposed standard also identifies what information must be given to the PLHCP providing the services listed in this standard, and requires that employers maintain a record of this information (see paragraphs (k)(4) and (n)(4)(ii)(C)).

Allowing a PLHCP to provide some of the services required under this rule is consistent with other recent OSHA health standards, such as bloodborne pathogens (29 CFR 1910.1030), respiratory protection (29 CFR 1910.134), and methylene chloride (29 CFR 1910.1052).

“*Regulated area*” means an area that the employer must demarcate where employee exposure to airborne concentrations of beryllium exceeds, or can reasonably be expected to exceed, either the TWA PEL or STEL. These areas include temporary work areas where maintenance or non-routine tasks are performed. For an explanation of the distinction and overlap between beryllium work areas and regulated areas, see the explanation of beryllium work areas earlier in this section of the preamble. The requirements triggered by regulated areas are discussed below.

Paragraphs (e)(1)(ii) and (e)(2)(ii) require employers to establish and demarcate regulated areas. Note that the demarcation requirements for regulated areas are more specific than those for other beryllium work areas (see also proposed paragraph (m)). Paragraph (e)(3) requires employers to restrict access to regulated areas to authorized persons, and paragraph (e)(4) requires employers to provide all employees in

regulated areas appropriate respiratory protection and personal protective clothing and equipment, and to ensure that these employees use the required respiratory protection and protective clothing and equipment. Proposed paragraph (i)(5)(i) prohibits employers from allowing employees to eat, drink, smoke, chew tobacco or gum, or apply cosmetics in regulated areas.

Under proposed paragraph (k)(1)(i)(A), employees who have worked in a regulated area for more than 30 days in the previous 12 months are eligible for medical surveillance. In addition, proposed paragraph (m)(2) requires warning signs associated with regulated areas to meet certain specifications. Proposed paragraph (m)(4) requires employers to train employees in the written exposure control plan required by paragraph (f)(1), including the location of regulated areas.

This proposed definition of regulated areas is consistent with other substance-specific health standards, such as Cadmium (29 CFR 1910.1027), Butadiene (29 CFR 1910.1051), and Methylene Chloride (29 CFR 1910.1052).

“*This standard*” means this beryllium standard, 29 CFR 1910.1024.

#### (c) Permissible Exposure Limits (PELs)

Paragraph (c) of the proposed standard establishes two permissible exposure limits (PELs) for beryllium in all forms, compounds, and mixtures: An 8-hour time-weighted average (TWA) PEL of 0.2  $\mu\text{g}/\text{m}^3$  (proposed paragraph (c)(1)), and a 15-minute short-term exposure limit (STEL) of 2.0  $\mu\text{g}/\text{m}^3$  (proposed paragraph (c)(2)).

The TWA PEL section of the proposed standard requires employers to ensure that each employee’s exposure to beryllium, averaged over the course of an 8-hour work shift, does not exceed 0.2  $\mu\text{g}/\text{m}^3$ . The STEL section of the proposed standard requires employers to ensure that each employee’s exposure sampled over any 15-minute period during the work shift does not exceed 2.0  $\mu\text{g}/\text{m}^3$ . The existing Air Contaminants standard (29 CFR 1910.1000 Table Z–2) has two PELs for “beryllium and beryllium compounds”: (1) a 2  $\mu\text{g}/\text{m}^3$  TWA PEL, and (2) a ceiling concentration of 5  $\mu\text{g}/\text{m}^3$  that employers must ensure is not exceeded during the 8-hour work shift, except for a maximum peak of 25  $\mu\text{g}/\text{m}^3$  over a 30-minute period in an 8-hour work shift. OSHA adopted the current PELs in 1972 pursuant to section 6(a) of the OSH Act (29 U.S.C. 655(a)). Section 6(a) permitted OSHA, during the first two years after the OSH Act became

effective, to adopt as OSHA standards any established Federal standard or national consensus standard. The existing PELs were based on the American National Standards Institute (ANSI) Beryllium and Beryllium Compounds standard (ANSI, 1970), which in turn was based on a 1949 U.S. Atomic Energy Commission adoption of a threshold limit for beryllium of  $2.0 \mu\text{g}/\text{m}^3$  and was included in the 1971 American Conference of Governmental Industrial Hygienists Documentation of the Threshold Limit Values for Substances in Workroom Air (ACGIH, 1971).

**TWA PEL.** OSHA is proposing the new TWA PEL because published studies and more recent exposure data submitted in the record from industrial facilities involved in beryllium work provide evidence that occupational exposure to a variety of beryllium compounds at levels below the current PELs pose a significant risk to workers (see this preamble at section VIII, Significance of Risk). OSHA's preliminary risk assessment, presented in section VI of this preamble, indicates that there is significant risk of beryllium sensitization<sup>45</sup> and CBD from a 45-year (working life) exposure to beryllium at the current TWA PEL of  $2 \mu\text{g}/\text{m}^3$ . The risk assessment further indicates that there is significant risk of lung cancer to workers exposed to beryllium at the current TWA PEL of  $2 \mu\text{g}/\text{m}^3$ .

OSHA believes this proposed PEL would be feasible across all affected industry sectors (see section IX.D of this preamble, Technological Feasibility) and that compliance with the proposed PEL would substantially reduce employees' risks of beryllium sensitization, CBD, and lung cancer (see section VI of this preamble, Preliminary Beryllium Risk Assessment). OSHA's confidence in the feasibility of the proposed PEL is high, based both on the preliminary results of the Agency's feasibility analysis and on the recommendation of the proposed PEL by Materion Corporation and the United Steelworkers. Materion is the sole beryllium producer in the U.S., and its facilities include some of the processes where OSHA expects it will be most challenging to control beryllium exposures. As with several other provisions of the proposed standard, OSHA's proposal for the TWA PEL follows the draft recommended standard submitted to the Agency by Materion and the Steelworkers Union (see this

preamble at section III, Events Leading to the Proposed Standard).

OSHA's preliminary risk assessment indicates that the risks remaining at the proposed TWA PEL—while much lower than risks at the current PEL—are still significant (see this preamble at section VIII, Significance of Risk). In addition to the proposed PEL, the Agency is considering an alternative PEL of  $0.1 \mu\text{g}/\text{m}^3$  that would reduce risks to workers further than the proposed PEL would, although significant risk remains at  $0.1 \mu\text{g}/\text{m}^3$  as well (see section VIII of this preamble, Significance of Risk, and Regulatory Alternatives presented at the end of this discussion). Compared with the proposed PEL, OSHA has less confidence in the feasibility of a PEL of  $0.1 \mu\text{g}/\text{m}^3$ . In some industry sectors it is difficult to determine whether a PEL of  $0.1 \mu\text{g}/\text{m}^3$  could be achieved in most operations, most of the time. However, OSHA believes this uncertainty could be resolved with additional information on current exposure levels and exposure control technologies. OSHA requests additional data and information to inform its final determinations on feasibility (see section IX.D of this preamble, Technological Feasibility) and the alternative PELs under consideration.

Because significant risks of sensitization and CBD remain at both  $0.1 \mu\text{g}/\text{m}^3$  and  $0.2 \mu\text{g}/\text{m}^3$ , OSHA is also proposing a variety of ancillary provisions to help reduce risk to workers. These ancillary provisions include implementation of feasible engineering controls in beryllium work areas, respiratory protection, personal protective clothing and equipment, exposure monitoring, regulated areas, medical surveillance, medical removal, hygiene areas, housekeeping requirements, and hazard communication. The Agency believes these provisions will reduce the risk beyond that which the proposed TWA PEL alone could achieve. These provisions are discussed later in this section of the preamble.

Other federal agencies and organizations have recommended occupational exposure limits for beryllium. As mentioned in this preamble at section III, Events Leading to the Proposed Standard, in 1999 the Department of Energy (DOE) issued its Chronic Beryllium Disease Prevention Program rule (10 CFR part 850). The DOE rule established a beryllium action level of  $0.2 \mu\text{g}/\text{m}^3$ . This action level triggers many of the same requirements found in OSHA's proposed standard such as regulated areas, periodic exposure monitoring, hygiene facilities and practices, respiratory protection,

and protective clothing and equipment (10 CFR 850.23(b)). Although the DOE rule retained OSHA's current TWA PEL, it also stated that employers would be required to ensure that employees are not exposed above any "more stringent TWA PEL" that OSHA may promulgate (10 CFR 850.22; 64 FR 68873 and 68906, December 8, 1999).

NIOSH has published a Recommended Exposure Limit (REL) of  $0.5 \mu\text{g}/\text{m}^3$  as a Ceiling Limit and a NIOSH Alert on preventing CBD and beryllium sensitization (NIOSH, 1977; NIOSH, 2011). The NIOSH Alert provides guidance to workers and employers on the hazards of exposure to beryllium and ways to reduce or minimize exposure. In 2009, ACGIH adopted a revised Threshold Limit Value (TLV) for beryllium that lowered the TWA to  $0.05 \mu\text{g}/\text{m}^3$  from  $2 \mu\text{g}/\text{m}^3$  (ACGIH, 2009).

The SERs who participated in the SBREFA process had few comments about the proposed PELs (OSHA, 2008b). The major concerns about a reduced TWA PEL were economic impact and belief that beryllium-related health effects did not frequently occur in their industries (OSHA, 2008b). The Panel recommended that OSHA consider to what extent a very low PEL may result in increased costs to small entities. In section V of the Preliminary Economic Analysis (OSHA, 2014), OSHA considers the costs of the proposed PEL and ancillary provisions triggered by the PEL to all affected entities. In addition, the Agency is considering an alternative PEL of  $0.5 \mu\text{g}/\text{m}^3$  (see Regulatory Alternative 5 below). The Agency seeks comment on whether different PELs should be considered and the justification for the PELs.

**STEL.** OSHA is also proposing a STEL of  $2.0 \mu\text{g}/\text{m}^3$ , as determined over a sampling period of 15 minutes. Where a significant risk of material impairment of health remains at the TWA PEL, OSHA has the authority to impose a STEL if doing so would further reduce risk and is feasible to implement. *Pub. Citizen Health Research Grp. v. Tyson*, 796 F.2d 1479, 1505 (D.C. Cir. 1986) (*Ethylene Oxide*).

As discussed in section VIII of this preamble, Significance of Risk, significant risk of CBD remains at the proposed TWA PEL of  $0.2 \mu\text{g}/\text{m}^3$  and the proposed alternative TWA PEL of  $0.1 \mu\text{g}/\text{m}^3$ . OSHA believes the proposed STEL would further reduce this risk. The goal of a STEL is to protect employees from the risk of harm that can occur as a result of brief exposures that exceed the TWA PEL. Without a STEL, the only protection workers would have from high short-duration

<sup>45</sup> As discussed in section VIII of this preamble, Significance of Risk, beryllium sensitization is a necessary precursor to developing CBD.

exposures is that, when those exposures are factored in, they cannot exceed the cumulative 8-hour exposure at the proposed 0.2  $\mu\text{g}/\text{m}^3$  TWA PEL (*i.e.*, 1.6  $\mu\text{g}/\text{m}^3$ ). Since there are 32 15-minute periods in an 8-hour work shift, exposures could be as high as 6.4  $\mu\text{g}/\text{m}^3$  ( $32 \times 0.2 \mu\text{g}/\text{m}^3$ ) for 15 minutes under the proposed TWA PEL without a STEL, if exposures during the remainder of the 8-hour work shift are non-detectable. A STEL serves to minimize high task-based exposures by requiring feasible controls in these situations, and has the added effect of further reducing the TWA exposure.

OSHA believes a STEL for beryllium will help reduce the risk of sensitization and CBD in beryllium-exposed employees. As discussed in this preamble at section V, Health Effects, beryllium sensitization is the initial step in the development of CBD. Sensitization has been observed in some workers that were only exposed to beryllium for a few months (see section V.D.1 of this preamble), and tends to be more strongly associated with 'peak' and highest-job-worked exposure metrics than cumulative exposure (see section V.D.5 of this preamble). Short-term exposures to beryllium have been shown to contribute to the development of lung disease in experimental animals. Beagle dogs that were administered a single short-term perinatal exposure to aerosolized beryllium oxide developed a granulomatous lung inflammation similar to CBD, accompanied by an abnormal BeLPT response (Haley *et al.*, 1989). These study findings indicate that adverse effects to the lung may occur from beryllium exposures of relatively short duration. OSHA believes that a STEL in combination with a TWA PEL adds further protection from risk of harm than that afforded by the proposed 0.2  $\mu\text{g}/\text{m}^3$  TWA PEL alone.

STEL exposures are typically associated with, and need to be measured during, the highest-exposure operations that an employee performs (see proposed paragraph (d)(1)(iii)). OSHA has preliminarily determined that the proposed STEL of 2.0  $\mu\text{g}/\text{m}^3$  can be measured for this brief period of time using OSHA's available sampling and analytical methodology, and feasible means exist to maintain 15-minute short-term exposures at or below the proposed STEL (see section IX.D of this preamble, Technological Feasibility).

The current entry for beryllium and beryllium compounds (as Be) in 29 CFR 1910.1000 Table Z-1 directs the reader to the entry for beryllium and beryllium compounds in 29 CFR 1910.1000 Table Z-2. Table Z-2's entry for beryllium and beryllium compounds includes the

current TWA PEL of 2  $\mu\text{g}/\text{m}^3$ , an acceptable ceiling concentration of 5  $\mu\text{g}/\text{m}^3$ , and an acceptable maximum peak above the acceptable ceiling concentration of 25  $\mu\text{g}/\text{m}^3$ , allowable for 30 minutes in an 8-hour shift. Table Z in 29 CFR 1915.1000, and 29 CFR 1926.55 Appendix A each include the current TWA PEL of 2  $\mu\text{g}/\text{m}^3$  beryllium and beryllium compounds for construction and maritime industries, but no ceiling or peak exposure limit.

As discussed in this Summary and Explanation section of the preamble regarding paragraph (a), the scope of the proposed rule is limited to general industry. In addition, it provides an exemption for those working with materials that contain beryllium only as a trace contaminant (less than 0.1 percent composition by weight). The proposal would amend the entry for beryllium and beryllium compounds (as Be) in 29 CFR 1910.1000 Table Z-1, to add a cross reference to the new standard for operations or sectors that fall within the scope of the proposed standard, and note that industries not covered under the proposed standard would continue to be covered by the entry in 29 CFR 1910.1000 Table Z-2. The TWA, ceiling, and maximum peak exposure limits in 29 CFR 1910.1000 Table Z-2 would still apply to general industry applications and sectors exempted from the proposed standard. Under the proposed standard, the exposure limits in the current 29 CFR 1915.1000 Table Z and 29 CFR 1926.55 Appendix A would continue to apply in construction and maritime industries. As discussed previously in this preamble at Section I, Issues and Alternatives, and Section XVIII, paragraph (a), OSHA is considering Regulatory Alternative #2b, which would update 29 CFR 1915.1000 Tables Z-1 and Z-2, 29 CFR 1915.1000 Table Z, and 29 CFR 1926.55 Appendix A to the PEL and STEL adopted through this rulemaking to the general industry, construction, and maritime sectors and applications that do not fall within the scope of the proposed rule. Note that OSHA is proposing a TWA PEL of 0.2  $\mu\text{g}/\text{m}^3$  and a STEL of 2  $\mu\text{g}/\text{m}^3$ , and OSHA is also considering alternative TWA PELs of .1  $\mu\text{g}/\text{m}^3$  and .5  $\mu\text{g}/\text{m}^3$ , and alternative STELs of .5  $\mu\text{g}/\text{m}^3$ , 1  $\mu\text{g}/\text{m}^3$ , and 2.5  $\mu\text{g}/\text{m}^3$ .

OSHA invites comment on the proposed TWA PEL and STEL and on Regulatory Alternatives 3, 4, and 5 below, which specify a lower STEL, a lower TWA PEL, and a higher TWA PEL than those proposed, respectively. OSHA also requests comments and data on the range of TWA and short-term exposures in covered industries and the

types of operations and engineering or work practice controls in place where these exposures are occurring.

#### Regulatory Alternative 3

This alternative would modify the proposed STEL to be five times the TWA PEL, rather than ten times the TWA PEL. Thus, if OSHA promulgates the proposed TWA PEL of 0.2  $\mu\text{g}/\text{m}^3$ , the STEL would be 1  $\mu\text{g}/\text{m}^3$ ; if OSHA promulgates the alternative TWA PEL of 0.1  $\mu\text{g}/\text{m}^3$ , the STEL would be 0.5  $\mu\text{g}/\text{m}^3$ ; and if OSHA promulgates the alternative TWA PEL of 0.5  $\mu\text{g}/\text{m}^3$ , the STEL would be 2.5  $\mu\text{g}/\text{m}^3$ .

As discussed above, OSHA has preliminarily determined that short-term exposures to beryllium can cause beryllium sensitization, and that therefore a STEL in combination with a TWA PEL adds further protection from risk of harm than that afforded by the proposed 0.2  $\mu\text{g}/\text{m}^3$  TWA PEL alone.

When OSHA regulations in the past have included a STEL, it is typically five times the PEL. For example, OSHA's standard for methylene chloride (29 CFR 1910.1052) specifies an 8-hour TWA PEL of 25 ppm, and a short-term limit of 125 ppm averaged over 15 minutes. The standard for acrylonitrile (29 CFR 1910.1045) sets an 8-hour TWA PEL of 2 ppm, and a short-term limit of 10 ppm averaged over 15 minutes. The final standards for benzene (29 CFR 1910.1028), for ethylene oxide (29 CFR 1910.1047) and for 1,3-Butadiene (29 CFR 1910.1051) specify an 8-hour time-weighted average TWA PEL of 1 ppm and short-term limits of 5 ppm averaged over 15 minutes. OSHA has occasionally deviated from its usual practice of setting a STEL at five times the TWA PEL, as in the cases of formaldehyde (29 CFR 1910.1048) (TWA PEL 0.75 ppm, STEL 2 ppm) and methylenedianiline (29 CFR 1910.1050) (TWA PEL 10 ppb, STEL 100 ppb). OSHA requests comment on whether the beryllium standard should set a STEL at ten times the TWA PEL, as suggested by the Materion-USW joint proposed rule and specified in this proposal, or should it maintain its more usual practice of setting a STEL at five times the PEL.

#### Regulatory Alternative 4

This alternative would modify the proposed TWA PEL to be 0.1  $\mu\text{g}/\text{m}^3$ . As discussed above, OSHA believes a PEL of 0.1  $\mu\text{g}/\text{m}^3$  would better protect workers from significant risk of CBD and lung cancer than the proposed TWA PEL of 0.2  $\mu\text{g}/\text{m}^3$ . OSHA's preliminary risk assessment indicates that the risk of CBD and lung cancer remaining at the proposed TWA PEL are significant, and

that an alternative PEL of 0.1  $\mu\text{g}/\text{m}^3$  would reduce these risks to workers further than the proposed PEL would. However, compared with the proposed PEL, OSHA has less confidence in the feasibility of a PEL of 0.1  $\mu\text{g}/\text{m}^3$  (see section IX.D of this preamble, Technological Feasibility). This alternative would also lower the action level from 0.1  $\mu\text{g}/\text{m}^3$  to .05  $\mu\text{g}/\text{m}^3$ .

#### Regulatory Alternative 5

This alternative would modify the proposed TWA PEL to be 0.5  $\mu\text{g}/\text{m}^3$ . This alternative would also raise the proposed action level to 2.5  $\mu\text{g}/\text{m}^3$ . As discussed above, the SBREFA Panel recommended that OSHA consider the economic impact of a reduced PEL and consider regulatory alternatives that would ease cost burden for small entities. The economic impact of a reduced PEL is considered in section VIII of the Preliminary Economic Analysis (OSHA, 2014). However, OSHA's preliminary risk assessment indicates significant risk to workers exposed at a PEL of 0.5  $\mu\text{g}/\text{m}^3$ , and OSHA's preliminary feasibility analysis indicates that a lower PEL is feasible. Unless OSHA receives new evidence showing that a PEL lower than 0.5  $\mu\text{g}/\text{m}^3$  is not feasible or not needed to reduce significant risk, OSHA cannot adopt this alternative PEL due to its statutory obligation to set the PEL at the lowest feasible level to reduce or eliminate significant risk.

#### (d) Exposure Monitoring

Paragraph (d) of the proposed standard imposes monitoring requirements pursuant to section 6(b)(7) of the OSH Act (29 U.S.C. 655(b)(7)), 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."

The purposes of requiring assessment of employee exposures to beryllium include determination of the extent and degree of exposure at the worksite; identification and prevention of employee overexposure; identification of the sources of exposure to beryllium; 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. Exposure assessment enables employers to meet their legal obligation to ensure that their employees are not exposed to beryllium in excess of the permissible exposure limits and to notify employees of their exposure

levels, including any overexposures as required by section 8(c)(3) of the Act (29 U.S.C. 657(c)(3)). In addition, the availability of exposure data enables PLHCPs performing medical examinations to be informed of the extent of an employee's occupational exposures.

Paragraph (d)(1) contains proposed general requirements for exposure monitoring. Under paragraph (d)(1)(i), the monitoring requirements apply whenever there is actual exposure to airborne beryllium at any level, or a reasonable expectation of such exposure. As reflected in the definition of "exposure" in paragraph (b) of this standard, exposure monitoring results must reflect the amount of beryllium an employee would be exposed to without the use of a respirator.

Under paragraph (d)(1)(ii), monitoring to determine employee time-weighted average exposures must represent the employee's average exposure to airborne beryllium over an eight-hour workday. Under paragraph (d)(1)(iii), short term exposures must be characterized by sampling periods of 15 minutes for each operation likely to produce exposures above the STEL.<sup>46</sup> Samples taken pursuant to paragraphs (d)(1)(ii) and (d)(1)(iii) must reflect the exposure of employees on each work shift, for each job classification, in each beryllium work area. Samples must be taken within an employee's breathing zone.

Employers must accurately characterize the exposure of each employee. In some cases, this will entail monitoring all exposed employees. In other cases, monitoring of "representative" employees is sufficient. Under paragraph (d)(1)(iv), representative exposure sampling is permitted when a number of employees perform essentially the same job under the same conditions. For such situations, it may be sufficient to monitor a fraction 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 beryllium exposure of similar frequency and duration can be achieved by monitoring the employee(s) reasonably expected to have the highest exposures. For example, this may

<sup>46</sup> Although OSHA has used the phrase "most likely to produce exposures" in other standards in the past (e.g., Ethylene Oxide (29 CFR 1910.1047)), OSHA's intended meaning for previous standards and for the proposed standard is that employers must characterize exposures for all operations likely to produce exposures above the STEL. Accordingly, OSHA is using the phrase "likely to produce exposures" rather than "most likely to produce exposures" in this proposed standard to clarify this longstanding intent.

involve monitoring the beryllium exposure of the employee closest to an exposure source. This exposure result may then be attributed to the remaining employees in the group.

Representative exposure monitoring must at a minimum include one full-shift sample taken for each job classification, in each beryllium 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 tasks under the same conditions, representative sampling will not adequately characterize actual exposures, and employers must monitor each employee individually.

Under paragraph (d)(1)(v), the employer would be required to use monitoring and analytical methods that can measure airborne levels of beryllium to an accuracy of plus or minus 25 percent (+/- 25 percent and can produce accurate measurements at a statistical confidence level of 95 percent for airborne concentrations at or above the action level. OSHA believes the following methods could meet these criteria: NIOSH 7704 (also ASTM D7202), ASTM D7439, OSHA 206, OSHA 125G, and OSHA 125G using ICP-MS. All of these methods are available to commercial laboratories analyzing beryllium samples. It should be noted that most of these analytical methods were validated using soluble beryllium compounds and hence the efficacy of the sample preparation (specifically digestion of particulate beryllium in mineral acids) step must be verified prior to use (Stefaniak et al., 2008). Verification can be aided, in part, through use of an appropriate reference material. However, not all of these methods are appropriate for measuring beryllium oxide, so employers must verify that the analytical methods they use are appropriate for measuring the form(s) of beryllium present in the workplace. A certified reference material consisting of high-fired beryllium oxide is available from the National Institute of Standards and Technology as Standard Reference Material 1877: Beryllium oxide powder. This reference material carries a certified value for beryllium content and was developed to meet the need to demonstrate analytical method efficacy for poorly soluble forms of beryllium (Winchester et al., 2009). OSHA requests comment on whether these methods would satisfy the requirements of proposed paragraph (d)(1)(v), and whether other methods would also meet these criteria.

Rather than specifying a particular method that must be used, OSHA proposes to take a performance-oriented approach and instead allow the employer to use the method of its choosing as long as that method meets the accuracy specifications in paragraph (d)(1)(v), and the reported results represent the total airborne concentration of beryllium for the operation and worker being characterized. For example, a respirable fraction sample or size selective sample would not be directly comparable to either PEL, and therefore would not be considered valid.

Paragraph (d)(2) contains proposed requirements for initial monitoring. OSHA proposes that employers characterize the 8-hour TWA exposure and 15-minute short-term exposure for each employee who is known to be exposed to airborne beryllium at any level or whose exposure is reasonably expected. Further obligations under the standard would be based on the results of this assessment. These obligations may include periodic monitoring, establishment of regulated areas, and implementation of control measures.

Initial monitoring need not be conducted in two circumstances. First, under paragraph (d)(2)(i), initial monitoring is not required where the employer has previously monitored for beryllium exposure and the data were obtained during work operations and under workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions used and prevailing in the employer's current operations. In addition, the characteristics of the beryllium-containing material being handled when the employer previously monitored must closely resemble the characteristics of the beryllium-containing material used in the employer's current operations. Such historical monitoring must satisfy all other requirements of this section, including the accuracy and confidence requirements in paragraph (d)(1)(v). If these requirements are satisfied, the employer may rely on such earlier monitoring results to satisfy the initial monitoring requirements of this section. This provision is designed to make it clear that OSHA does not intend to require employers who have recently performed appropriate employee monitoring to conduct initial monitoring. For historical data to satisfy the employer's obligation to monitor for 8-hour TWA exposures under paragraph (d)(1)(ii), these data must characterize 8-hour TWA exposures that satisfy the requirements of paragraph (d)(2)(i). For

historical monitoring to satisfy an employer's obligation to monitor for 15-minute short-term exposures under paragraph (d)(1)(iii), these data must reflect 15-minute short-term exposures. OSHA anticipates that paragraph (d)(2)(i) will reduce the compliance burden on employers, since redundant monitoring would not be required.

Second, under paragraph (d)(2)(ii), where the employer has objective data demonstrating that a particular product or material containing beryllium or a specific process, operation, or activity involving beryllium cannot release dust, fumes, or mist in concentrations at or above the action level or STEL under any reasonably expected conditions of use, the employer may rely upon such data to satisfy initial monitoring requirements. The data must reflect workplace conditions closely resembling the processes, types of material, control methods, work practices, and environmental conditions in the employer's current operations.

Objective data used in place of initial monitoring under paragraph (d)(2) must demonstrate that the work operation or the product cannot reasonably be foreseen to release beryllium in airborne concentrations at or above the action level or above the STEL under the expected conditions of use that will cause the greatest possible release. The data must demonstrate that exposures cannot meet or exceed the action level and that exposures cannot exceed the STEL; if the data do not satisfy both of these requirements, they do not meet the criteria of paragraph (d)(2)(ii) and would not exempt the employer from conducting initial monitoring. When using the term "objective data," OSHA is referring to manufacturers' case studies, laboratory studies, and other research that demonstrates, usually by means of exposure data, that exposures above the action level or STEL cannot occur. The objective data may include monitoring data, or mathematical modeling or calculations based on the chemical and physical properties of a material. For example, data collected by a trade association from its members that reflect workplace conditions closely resembling the processes, material, control methods, work practices, and environmental conditions in the employer's current operations may be used. OSHA has allowed employers to use objective data in lieu of initial monitoring in other standards, such as those for formaldehyde (29 CFR 1910.1048) and asbestos (29 CFR 1910.1001).

Paragraph (d)(3) contains requirements for periodic monitoring. The requirement for this continued

monitoring depends on the results of initial monitoring. If the initial monitoring indicates that employee exposures are below the action level, no further monitoring would be required unless, under paragraph (d)(4), changes in the workplace could result in new or additional exposures. If the initial determination reveals employee exposures to be at or above the action level and at or below the TWA PEL, the employer must perform periodic monitoring at least annually. In stating "at least annually," OSHA intends that employers must monitor at least once during the 12-month period after initial monitoring is performed, and then at least once in every subsequent 12-month period. Of course, the proposed requirement for annual monitoring does not preclude employers from monitoring more frequently.

OSHA recognizes that exposures in the workplace can vary from day to day, between shifts, and even within the same operation. Beryllium exposures for many operations have been shown to be highly variable, with some exposures exceeding the current TWA PEL. When airborne concentrations fluctuate in this way, the probability of exceeding the PELs increases. Periodic monitoring provides the employer with additional and up-to-date information to use to make informed decisions on whether additional control measures are necessary.

Periodic monitoring provides the employer with exposure information for additional use beyond that of determining compliance with the PELs. Periodic monitoring will provide data to determine whether or not engineering controls are working properly and work practices are effective in preventing exposure. Selection of appropriate respiratory protection also depends on adequate knowledge of employee exposures obtained through periodic monitoring.

This proposal does not require periodic monitoring where exposures are above the TWA PEL, which represents a departure from past OSHA standards such as Chromium (29 CFR 1910.1026) and Cadmium (29 CFR 1910.1027). OSHA has eliminated the requirement for periodic monitoring where exposures are above the PEL in response to a multi-stakeholder proposal to this effect (Materion and Steelworkers, 2012). OSHA anticipates this could be an appropriate way to reduce costs for employers where exposures are above the TWA PEL after the employer has implemented all feasible engineering and work practice controls. However, the employer must continue to assess the status of available



feasible engineering and work practice controls to ensure that the employer has reduced exposures to the lowest level feasible. And even where this standard does not explicitly require periodic monitoring, employers may need to conduct periodic monitoring to ensure that controls are working properly, and that employees are adequately protected and are receiving the services and benefits to which they are entitled under this standard such as medical surveillance and medical removal. OSHA requests comment on whether the proposed annual periodic monitoring for exposures at or above the action level but below the TWA PEL is sufficiently protective for employees, or whether annual periodic monitoring should be required when exposures exceed the TWA PEL (see Section I of this preamble, Issues and Alternatives).

Under paragraph (d)(4), employers are to perform additional monitoring when there is a change in production processes, materials, equipment, personnel, work practices, or control methods, that may result in new or additional exposures to beryllium. In addition, there may be other situations that can result in new or additional exposures that are unique to an employer's work situation. In order to cover those special situations, OSHA requires the employer to perform additional monitoring whenever the employer has any reason to believe that a change has occurred that may result in new or additional exposures. For example, an employer would be required to perform additional monitoring when an employee has a confirmed positive result for beryllium sensitization, exhibits signs or symptoms of CBD, or is diagnosed with CBD. These conditions necessitate additional monitoring to ascertain if airborne exposures contributed to the positive results of the medical testing. Another example of a situation requiring additional monitoring would be a process modification that would increase the amount of beryllium-containing material used thereby possibly increasing employee exposure. Once additional monitoring has been performed and exposures characterized, the employer can take appropriate action to protect exposed employees.

Under paragraph (d)(5) employers must notify each employee of his or her monitoring results within 15 working days after receiving the results. Employees who must be notified include both the employees whose exposures were monitored directly and those whose exposures are represented by the monitoring. The employer must either notify each employee

individually in writing, or post the monitoring results in an appropriate location accessible to all employees required to be notified. This proposed requirement is consistent with other OSHA standards, such as those for methylenedianiline (29 CFR 1910.1050), 1,3-butadiene (29 CFR 1910.1051), and methylene chloride (29 CFR 1910.1052). In addition, whenever the TWA PEL or STEL has been exceeded, the written notification required by paragraph (d)(5)(i) must contain a description of the suspected or known sources of exposure as well as the corrective action(s) being taken by the employer to reduce the employee's exposure to or below the applicable PEL. This requirement 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 Act (29 U.S.C. 657(c)(3)).

Paragraph (d)(6) requires the employer to provide employees and their designated representatives an opportunity to observe any monitoring of employee exposure to beryllium. Employees who must be allowed to observe monitoring include both the employees whose exposures are being monitored and those whose exposures are represented by the monitoring. When observation of monitoring requires entry into an area where the use of protective clothing or equipment is required, the employer must provide the observer with that protective clothing or equipment, at no cost. The employer must also assure that the observer uses such clothing or equipment appropriately and complies with all other applicable safety and health requirements and procedures.

The requirement for employers to provide employees and their representatives the opportunity to observe monitoring is consistent with the OSH Act. Section 8(c)(3) of the Act (29 U.S.C. 657(c)(3)) mandates that regulations requiring employers to keep records of employee exposures to toxic materials or harmful physical agents provide employees or their representatives with the opportunity to observe monitoring or measurements. Also, Section 6(b)(7) of the Act (29 U.S.C. 655(b)(7)) states that, where appropriate, OSHA standards are to prescribe suitable protective equipment to be used in dealing with hazards. 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).

After reviewing commenter responses to the SBREFA inquiry and the Agency's RFI on beryllium, OSHA has learned that the amount of employer effort and diligence in assessing exposure levels is proportional to the presumed degree of exposure (OSHA, 2008b). Commenters whose companies make products with high-content beryllium are much more likely to have incorporated considerable sampling into their exposure assessment protocol. (Brush Wellman, 2003, Honeywell, 2003). In other instances, where manufacturers use less beryllium or low-content beryllium alloys, such as in specialty or precision products, sampling occurs less frequently. (OSHA, 2007a).

Representatives of various stamping firms who are currently experiencing low levels of exposure felt that their industry as a whole should be exempt from the initial exposure assessment provision of this standard and any additional requirements related to exposure monitoring. (OSHA, 2007a). However, available information demonstrates that initial exposure assessment needs to be applied to all industries where beryllium is processed or otherwise handled (see this preamble at section V, Health Effects). For example, OSHA's technological feasibility analysis for fabrication of beryllium alloy products summarizes exposures for workers in the stamped and formed metal products sector (see this preamble at Section IX.D, Technological Feasibility). Exposure monitoring data indicate that while for most production tasks, the median baseline exposure is less than the proposed action level of 0.1  $\mu\text{g}/\text{m}^3$ , some tasks have the potential to generate exposures greater than 0.1  $\mu\text{g}/\text{m}^3$ . Initial exposure monitoring will help identify the areas and job tasks needing additional controls, or demonstrate that no additional controls are needed. Initial monitoring also aids the employer in determining whether controls currently in use to prevent or reduce beryllium exposure are effective.

To address many of these comments, OSHA has established performance-oriented language for the exposure assessment provisions of this standard, allowing employers to choose any method of exposure monitoring that meets the accuracy specifications in paragraph (d)(1)(v) of this standard, and that measures the total airborne concentration of beryllium for the operation and worker exposures being characterized. In addition, employers may use historical or objective data in accordance with proposed paragraph (d)(2) of this standard to satisfy their initial monitoring obligations. OSHA

believes this flexibility in the proposal accommodates commenters' concerns without jeopardizing beryllium-exposed workers' health.

SERs also commented that exposure monitoring is costly and that OSHA should consider alternatives that allow employers with very low exposures to be exempt from monitoring. As a possible means of alleviating costs, the Panel recommended that OSHA encourage the use of objective data and explain more clearly the requirements for its use. (OSHA, 2008b). OSHA has clarified in this preamble the circumstances under which an employer may use historical and objective data in lieu of initial monitoring. OSHA is also considering whether to create a guidance product on the use of objective data. The Agency requests comments on whether a guidance product on the use of objective data would be helpful to businesses seeking to comply with the beryllium standard, and what questions or areas of information it should address.

In addition, OSHA has reduced to annually the frequency of periodic monitoring where exposures are at or above the action level and at or below the TWA PEL, rather than the six-month frequency proposed during the SBREFA process. OSHA has also removed the requirement for periodic monitoring every three months where exposures exceed the PEL. The new provisions were suggested in the Materion-USW recommended standard submitted to OSHA in 2012 (Materion and USW, 2012). While these changes to the proposed standard reduce the cost burden of exposure monitoring for employers, they also may reduce employees' protection from overexposure to beryllium.

OSHA notes that the frequency and performance of exposure monitoring in the draft proposal presented to the SBREFA Panel are similar to OSHA's typical approach to periodic exposure monitoring. Most OSHA standards require monitoring at least every six months where exposure levels meet or exceed the action level, and every three months where exposures are above the TWA PEL. For example, the standards for vinyl chloride (29 CFR 1910.1017), inorganic arsenic (29 CFR 1910.1018), lead (29 CFR 1910.1025), cadmium (29 CFR 1910.1027), methylene chloride (29 CFR 1910.1052), acrylonitrile (29 CFR 1910.1045), ethylene oxide (29 CFR 1910.1047), formaldehyde (29 CFR 1910.1048), all specify periodic monitoring at least every six months where exposures are above the action level. Periodic exposure monitoring is also required where exposures exceed

the PEL in most health standards issued since OSHA began specifying frequency for periodic monitoring. In many cases monitoring is required every three months where exposures exceed the PEL (methylene chloride (29 CFR 1910.1052), ethylene oxide (29 CFR 1910.1047), acrylonitrile (29 CFR 1910.1045), inorganic arsenic (29 CFR 1910.1018), lead (29 CFR 1910.1025), and vinyl chloride (29 CFR 1910.1017)); in other cases, it is required at least every six months (cadmium (29 CFR 1910.1027), 1,3-Butadiene (29 CFR 1910.1051), formaldehyde (29 CFR 1910.1048), benzene (29 CFR 1910.1028) and asbestos (29 CFR 1910.1001)). Thus, the periodic monitoring requirements outlined in this proposal and in the Materion-USW recommended standard depart significantly from OSHA's usual requirements.

OSHA requests comment on the proposed schedule for periodic monitoring. Are the proposed requirements both practical for employers and protective for employees? OSHA also requests comment on Regulatory Alternatives 9, 10, and 11 below, which would modify the frequency and performance of exposure monitoring to be more similar to previous standards and to the draft proposal presented to the SBREFA Panel.

#### Regulatory Alternative 9

This alternative would require employers to perform exposure monitoring at least every 180 days where exposures are at or above the action level or above the STEL, and at or below the TWA PEL. If the initial monitoring required by paragraph (d)(2) of this section reveals employee 8-hour TWA exposure at or above the action level, the employer shall repeat such monitoring for each such employee at least every 180 days to evaluate the employee's TWA exposures. If the initial 15-minute short-term exposure monitoring reveals employee exposure above the STEL, the employer shall repeat such monitoring for each such employee at least every 180 days to evaluate the employee's 15-minute short-term exposures. Where 8-hour TWA exposures are above the TWA PEL, no monitoring would be required.

#### Regulatory Alternative 10

This alternative would require employers to perform monitoring at least every 180 days where exposures are at or above the action level or above the STEL. Unlike the periodic monitoring requirement in the current proposal, this alternative would include periodic monitoring where exposures

are above the TWA PEL. If the initial 8-hour TWA exposure monitoring required by paragraph (d)(2) of this section reveals employee exposure at or above the action level, the employer shall repeat such monitoring for each such employee at least every 180 days to evaluate the employee's TWA exposures. If the initial 15-minute short-term exposure monitoring reveals employee exposure above the STEL, the employer shall repeat such monitoring for each such employee at least every 180 days to evaluate the employee's short-term exposures.

#### Regulatory Alternative 11

This alternative would require employers to perform monitoring at least every 180 days where exposures are at or above the action level and at or below the TWA PEL. It would require employers to perform monitoring at least every 90 days where exposures are above the TWA PEL or STEL.

If the initial 8-hour TWA exposure monitoring required by paragraph (d)(2) of this section reveals employee TWA exposure at or above the action level and at or below the TWA PEL, the employer shall repeat such monitoring for each such employee at least every 180 days to evaluate the employee's TWA exposures. If this initial monitoring reveals employee exposure above the TWA PEL or STEL, the employer shall repeat such monitoring for each such employee at least every 90 days to evaluate the employee's 8-hour TWA and 15-minute short-term exposures.

#### (e) Beryllium Work Areas and Regulated Areas

Proposed paragraph (e) requires employers to establish and maintain beryllium work areas wherever employees are, or can reasonably be expected to be, exposed to airborne beryllium, regardless of the level of exposure, and regulated areas wherever employees are, or can reasonably be expected to be, exposed to airborne concentrations of beryllium in excess of the TWA PEL or STEL. Paragraph (e) would also require employers to demarcate beryllium work areas and regulated areas, and limit access to regulated areas to authorized persons.

The proposed requirements for these areas serve several important purposes. First, requiring employers to establish and demarcate beryllium work areas and regulated areas ensures that workers and other persons are aware of the potential presence of airborne beryllium. Second, the demarcation of regulated areas must include warning signs describing the dangers of

beryllium exposure in accordance with paragraph (m) of this standard, which ensures that persons entering regulated areas will be aware of these dangers. Third, limiting access to regulated areas restricts the number of people potentially exposed to beryllium at levels above the TWA PEL or STEL, and the serious health effects associated with such exposure. Limiting access to regulated areas has the added benefit of reducing the employer's obligation to implement certain provisions of the proposed rule triggered by employee exposure in a regulated area.

Proposed paragraph (e)(1)(i) would require employers to establish beryllium work areas where employees are, or can reasonably be expected to be, exposed to airborne beryllium. OSHA intends this provision to apply to all areas and situations where employees are actually exposed to airborne beryllium and to areas and situations where the employer has reason to anticipate or believe that airborne exposures may occur. The requirements for beryllium work areas under proposed paragraph (e)(1)(i) are not tied to a particular level of exposure, but rather are triggered by the presence of airborne beryllium at any exposure level.

Proposed paragraph (e)(1)(ii) would require employers to establish regulated areas wherever employees are actually exposed to airborne beryllium above either the TWA PEL or STEL, and wherever such exposure can reasonably be expected. This requirement would apply if any exposure monitoring or historical or objective data indicate that airborne exposures are in excess of either the TWA PEL or STEL, or if the employer has reason to anticipate or believe that airborne exposures may be above the TWA PEL or STEL, even if the employer has not yet characterized or monitored those exposures. For example, if newly introduced processes involving beryllium appear to be creating dust and have not yet been monitored, the employer should reasonably anticipate that airborne exposures could exceed the TWA PEL or STEL. In this situation the employer must designate and demarcate the area as a regulated area to protect workers and other persons until monitoring results establish that exposures are at or below the TWA PEL and STEL. The employer may then remove the regulated area designation.

Proposed paragraph (e)(2)(i) requires employers to demarcate each beryllium work area to distinguish it from the rest of the workplace. The proposal specifies that employers must identify beryllium work areas "through signs or any other methods that adequately establish and

inform each employee of the boundaries of each beryllium work area." This means that the demarcation must effectively alert workers and other persons that airborne beryllium may be present. Proposed paragraph (e)(2)(ii) requires employers to identify regulated areas and post warning signs at each approach to the regulated area in accordance with proposed paragraph (m)(2) of this standard.

This proposed rule gives employers flexibility in determining the best means to demarcate beryllium work areas and regulated areas (with the exception of paragraph (m), which sets forth specific requirements for warning signs at entry points to regulated areas). OSHA is aware that employers use various methods to demarcate certain areas in the workplace, including barricades, textured flooring, roped-off areas, "No entry"/"No access" signs, and painted boundary lines (AIA, 2003, Honeywell, 2003, DOD, 2003). Allowing employers to choose the methods that best demarcate beryllium work areas and regulated areas is consistent with OSHA's belief that employers are in the best position to make such determinations, based on the specific conditions in their workplaces.

Whatever demarcation methods the employer selects must be clear and understandable enough to alert workers to the boundaries of the beryllium work area or regulated area. This may mean, for example, including more than one language on a sign, if the inclusion of a second language would make the sign understandable to workers with limited English reading skills.

In determining what demarcation might be necessary and effective, employers should consider factors including:

- The configuration of the beryllium work area or regulated area;
- Whether the beryllium work area or regulated area is permanent or temporary;
- The airborne concentrations of beryllium in the beryllium work area or regulated area;
- The number of employees working in areas adjacent to any beryllium work area or regulated area; and
- The period of time the beryllium work area or regulated area is expected to have hazardous exposures.

OSHA requests comment on the proposed requirement to demarcate beryllium work areas and regulated areas. OSHA also requests comment on whether the standard should allow the performance-based approach indicated in the proposal or whether the rule should specify what types of demarcation employers must use.

Proposed paragraph (e)(3) requires employers to limit access to regulated areas. Because of the potentially serious health effects of exposure to beryllium and the need for persons entering the regulated area to be properly protected, OSHA believes that the number of persons allowed to access regulated areas should be limited to those individuals listed in proposed paragraph (e)(3). Specifically, this provision would require employers to limit access to regulated areas to: (i) persons the employer authorizes or requires to be in a regulated area to perform work duties; (ii) persons entering a regulated area as designated representatives of employees for the purposes of exercising the right to observe exposure monitoring procedures under paragraph (d)(6) of this standard; and (iii) persons authorized by law 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, may include workers and other persons whose jobs involve operating machinery, equipment, and processes located in regulated areas; performing maintenance and repair operations on machinery, equipment, and processes in those areas; conducting inspections or quality control tasks; and supervising those who work in regulated areas.

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)(6). As explained in this section of the preamble regarding paragraph (d), 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 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 would fall into this group.

Proposed paragraph (e)(4) requires employers to provide and ensure that each employee entering a regulated area uses personal protective clothing and equipment, including respirators, in accordance with paragraphs (g) and (h) of this standard.

In general, commenters did not oppose the concept of regulated areas. Stakeholders responding to the RFI supported the need for regulated areas

(ASAS, 2002; AFL-CIO, 2003; Honeywell, 2003). For example, the Department of Defense thought the use of regulated areas was a good way to limit the number of workers potentially exposed to beryllium (DOD, 2003).

Most small entity representatives (SERs) who participated in the SBREFA process were not concerned about the impact of tying the regulated area requirements to one of the PEL options presented in the SBREFA draft proposed standard (OSHA, 2007b). Only one of the SERs indicated that it may have a process where typical or average exposures are above the lowest PEL option of  $0.1 \mu\text{g}/\text{m}^3$  (OSHA, 2007a), which is one half the currently proposed TWA PEL.

SERs were divided on the issue of whether it was possible to isolate or segregate operations to meet the conditions of a regulated area. Most of the SERs did not currently isolate or segregate their beryllium processes, and several expressed concern about the difficulty and costs associated with isolating or segregating their beryllium processes (OSHA, 2008b). Some SERs said they have large, open plant floors making it difficult to isolate specific beryllium operations (OSHA, 2008b). Other SERs said the proposed requirement for a regulated area would be difficult and costly because they move machinery and equipment for production purposes. They said that segregating or restricting processes or machines and equipment to certain areas would affect productivity to some extent (OSHA, 2008b). SERs who use beryllium-containing materials only occasionally, frequently as part of a larger order, said that it would be impractical to isolate specific areas or machines for beryllium work (OSHA, 2008b). SERs in the precision metal products industry indicated their beryllium operations already were well controlled with machine enclosures (e.g., lathes and forming machines) and therefore would not need to segregate these operations (OSHA, 2008b). The Panel recommended that OSHA revisit the cost analysis of regulated areas if the lowest PEL option ( $0.1 \mu\text{g}/\text{m}^3$ ) is proposed (OSHA, 2008b). The Panel also recommended that OSHA consider dropping or limiting the provision for regulated areas (OSHA, 2008b). In response to this recommendation, OSHA analyzed Regulatory Alternative #12, which would not require employers to establish regulated areas.

The proposed rule presented during the SBREFA process did not contain any requirements for beryllium work areas. These requirements were added by OSHA after the SBREFA process in

response to a proposal OSHA received from a stakeholder group (Materion and USW, 2012). However, because the proposal presented during the SBREFA process included a range of proposed TWA PELs down to  $0.1 \mu\text{g}/\text{m}^3$ , SERs had the opportunity to comment on the requirements for regulated areas at very low exposure levels. OSHA believes that SER comments about regulated areas should reflect SER concerns about beryllium work areas as well. OSHA has also made the establishment and demarcation requirements for beryllium work areas flexible and performance-based to address SER concerns. OSHA invites comment on the proposed requirements for beryllium work areas and regulated areas, and on Regulatory Alternative 12 below. OSHA also requests comments and information on work settings where establishing regulated areas could be problematic or infeasible and what other approaches might be used to warn employees in such work settings of high risk areas.

#### Regulatory Alternative 12

This alternative would eliminate the requirement to establish and demarcate regulated areas within facilities where there is beryllium exposure. It does not eliminate the proposal's requirement to establish and demarcate beryllium work areas.

OSHA is aware that eliminating the requirement for regulated areas may ease the costs and burdens of compliance for some employers. However, this potential benefit of Alternative #12 must be considered in light of the reasons regulated areas were included in the proposal, and are a feature of most OSHA health regulations. As discussed previously, the proposed requirements for regulated areas serve to ensure that access to areas where beryllium exposures exceed the TWA PEL or STEL is restricted, reducing the number of people exposed to beryllium at levels that create a high risk of adverse health effects. Second, the requirement for warning signs ensures that persons who enter areas where exposures exceed the TWA PEL or STEL will be aware of the hazards present and take appropriate precautions such as the proper use of personal protective equipment.

OSHA believes the proposed requirements for beryllium work areas and regulated areas balance commenters' concerns with the need to reduce the number of employees exposed to beryllium and notify those exposed of the risks involved. The proposed standard does not require employers to establish and demarcate beryllium work areas or regulated areas

by permanently segregating and isolating processes generating airborne beryllium. Instead, the standard allows employers to use temporary or flexible methods to demarcate beryllium work areas and regulated areas.

OSHA believes that these flexible, performance-based requirements could accommodate open work spaces, changeable plant layouts, and sporadic or occasional beryllium use without imposing undue costs or burdens. For example, the standard does not prohibit employers from moving machinery or equipment for production purposes as occurs in the beryllium-copper alloy industry (OSHA, 2008b). Where employers need to move machinery and equipment, the proposed rule allows employers to use methods such as temporary designations and flexible demarcations. OSHA also notes that some employers have enclosed machines (e.g., lathes) to prevent the release of airborne beryllium into the workplace, thereby potentially eliminating the need for the machine to be in a regulated area (OSHA, 2008b).

#### (f) Methods of Compliance

Paragraph (f) of the proposed rule establishes methods for reducing employee exposure to beryllium through the use of a written exposure control plan and engineering and work practice controls.

Under proposed paragraph (f)(1)(i), employers must establish, implement, and maintain a written exposure control plan for beryllium work areas. OSHA believes that adherence to the written exposure control plan will help reduce skin contact with beryllium, which can lead to beryllium sensitization, and airborne exposure, which can lead to beryllium sensitization, CBD, and lung cancer. Because skin contact and airborne exposure can occur in any workplace within the scope of the standard, OSHA has made the preliminary determination to require a written exposure control plan for all employers within the scope of the standard. In addition, requiring employers to establish and maintain a written exposure control plan is consistent with other OSHA health standards, including 1,3 butadiene (29 CFR 1910.1051) and bloodborne pathogens (29 CFR 1910.1030).

OSHA's proposal to require a written exposure control plan is based in part on the recommendation of two stakeholders, Materion Corporation and the Steelworkers Union. Materion and the Steelworkers submitted a joint proposal for a standard to the Agency (Materion and Steelworkers, 2012) that includes a requirement for a written

exposure control plan. In the stakeholders' joint proposal, the written exposure control plan included requiring documentation of operations and jobs likely to have exposure to beryllium at various levels; procedures for minimizing the migration of beryllium; procedures for keeping work surfaces clean; and documentation of engineering and work practice controls. OSHA's proposed requirements for maintaining and implementing a written exposure control plan follow the example of the stakeholders' proposal in most respects.

Under proposed paragraphs (f)(1)(i)(A), (B), and (C), the written exposure control plan must contain inventories of operations and job titles reasonably expected to have any exposure to airborne beryllium, exposure at or above the action level, and exposure above the TWA PEL or STEL. And, under proposed paragraph (f)(1)(i)(G), the plan must include an inventory of engineering and work practice controls required by paragraph (f)(2) of this standard.

A record of which operations and job titles are likely to have exposures at certain levels and which engineering and work practice controls the company has selected to control exposures will make it easier for employers to implement monitoring, hygiene practices, housekeeping, engineering and work practice controls, and other measures. These inventories will also help to assure employees' awareness of the exposures associated with their jobs, their eligibility for medical surveillance, and the controls that should be in use throughout the workplace. This will enable employees to work together with employers to ensure that the appropriate engineering controls and work practices are in use and functioning and that provisions such as medical surveillance, housekeeping, and PPE are properly implemented. In addition, these inventories, like all of the items required to be included in the written exposure control plan, will help safety and health personnel, including OSHA Compliance Officers, carry out their duties. A written plan provides detailed information to interested parties including employees, employee representatives, supervisors, and safety consultants of the employer's determination of the jobs and operations that may place employees at risk of exposure and the measures the employer has selected to control exposure.

Under proposed paragraph (f)(1)(D) through (F) and (H), the exposure control plan must contain procedures for: minimizing cross-contamination,

including preventing the transfer of beryllium between surfaces, equipment, clothing, materials, and articles within beryllium work areas; keeping surfaces in the beryllium work area as free as practicable of beryllium; minimizing the migration of beryllium from beryllium work areas to other locations within or outside the workplace; and removal, laundering, storage, cleaning, repairing, and disposal of beryllium-contaminated personal protective clothing and equipment, including respirators. Each of these procedures serves to minimize the spread of beryllium throughout and outside the workplace. They also work to reduce the likelihood of skin contact and re-entrainment of beryllium particulate into the workplace atmosphere. Additional discussion of some of these requirements may be found in this section of the preamble, Summary and Explanation, at paragraph (h), Personal Protective Clothing and Equipment; paragraph (i), Hygiene Areas and Practices; and paragraph (j), Housekeeping.

The requirement to document these procedures in writing, as part of the exposure control plan, will help to ensure that employees are advised of their responsibilities and can easily review the procedures if they have questions. Because employees play an important part in exposure control through compliance with the rules regarding hygiene practices, housekeeping, and other measures, employees should have easy access to documentation detailing the procedures in place in their workplace. A review of the written exposure control plan should be part of the hazard communication training for employees as required by 1910.1200 and proposed paragraph (m). Additionally, the documentation of the procedures will help OSHA Compliance Officers assess employers' procedures.

Proposed paragraph (f)(1)(ii) requires that employers update their exposure control plans whenever any change in production processes, materials, equipment, personnel, work practices, or control methods results or can reasonably be expected to result in new or additional exposures to beryllium. Paragraph (f)(1)(ii) also requires employers to update their plans when an employee is confirmed positive for beryllium sensitization, is diagnosed with CBD, or shows other signs and symptoms related to beryllium exposure. In addition, the paragraph requires employers to update their plans if the employer has any reason to believe that new or additional exposures are occurring or will occur.

The requirements to update the exposure control plan if changes in the workplace result in or can be expected to result in new or additional exposures, or where the employer has any reason to believe that such exposures are occurring or will occur, ensure that an employer's plan reflects the current conditions in the workplace. If an employee becomes sensitized or develops CBD, the employer should investigate the source(s) of exposure responsible, and must make any necessary changes to address the source(s) of exposure, and update the written exposure control plan as necessary to reflect any new information or corrective action resulting from the employer's investigation. For example, the employer may find that housekeeping procedures in the employee's area need improvement, or that more appropriate PPE could be used. In some cases, the employer may find that additional engineering or work practice controls are appropriate to the processes in use. When the employer discovers new sources of exposure or makes changes in its control strategy, the employer must update its written exposure control plan to reflect current conditions in the workplace. Employers such as Materion and Axsys Technologies, who have worked to identify and document the exposure sources associated with cases of sensitization and CBD in their facilities, have used this information to develop and update beryllium exposure control plans (Bailey *et al.*, 2010; Schuler *et al.*, 2012; Madl *et al.*, 2007). OSHA believes this proposed process, whereby an employer uses employee health outcome data to check and improve the effectiveness of the employer's exposure control plan, is consistent with other performance-oriented aspects of this proposed standard.

Proposed paragraph (f)(1)(iii) requires employers to make a copy of the exposure control plan accessible to each employee who is or can reasonably be expected to be exposed to airborne beryllium in accordance with OSHA's Access to Employee Exposure and Medical Records Standard (29 CFR 1910.1020). As mentioned above, access to the exposure control plan will enable employees to partner with their employers in keeping the workplace safe.

Paragraph (f)(2) of the proposed rule contains requirements for the implementation of engineering and work practice controls to minimize beryllium exposures in beryllium work areas. The proposed rule relies on engineering and work practice controls as the primary means to reduce

exposures. Where, after the implementation of feasible engineering and work practice controls, exposures exceed or can reasonably be expected to exceed the TWA PEL or STEL, employers are required to supplement these controls with respiratory protection, according to the requirements of paragraph (g) of the proposed rule. OSHA proposes to require primary reliance on engineering and work practice controls because reliance on these methods is consistent with good industrial hygiene practice, with the Agency's experience in ensuring that workers have a healthy workplace, and with OSHA's traditional adherence to a hierarchy of controls.

OSHA requires adherence to this hierarchy of controls in a number of standards, including the Air Contaminants (29 CFR 1910.1000) and Respiratory Protection (29 CFR 1910.134) standards, as well as other substance-specific standards. The Agency's adherence to the hierarchy of controls has been successfully upheld by the courts (see *AFL-CIO v. Marshall*, 617 F.2d 636 (D.C. Cir. 1979) (cotton dust standard); *United Steelworkers v. Marshall*, 647 F.2d 1189 (D.C. Cir. 1980), cert. denied, 453 U.S. 913 (1981) (lead standard); *ASARCO v. OSHA*, 746 F.2d 483 (9th Cir. 1984) (arsenic standard); *Am. Iron & Steel v. OSHA*, 182 F.3d 1261 (11th Cir. 1999) (respiratory protection standard); *Pub. Citizen v. U.S. Dep't of Labor*, 557 F.3d 165 (3rd Cir. 2009) (hexavalent chromium standard)).

The Agency understands that engineering controls are reliable, provide consistent levels of protection to a large number of workers, can be monitored continually and inexpensively, allow for predictable performance levels, and can efficiently remove toxic substances from the workplace. Once removed, the toxic substances no longer pose a threat to employees. The effectiveness of engineering controls does not generally depend to any substantial degree on human behavior, and the operation of control equipment is not as vulnerable to human error as is personal protective equipment. For these reasons, engineering controls are preferred by OSHA and the safety and health professional community in general.

The provisions related to engineering and work practice controls begin in paragraph (f)(2)(i)(A). For each operation in a beryllium work area, employers must ensure that at least one of the following engineering and work practice controls is in place to minimize employee exposure:

(1) Material and/or process substitution;

(2) Ventilated partial or full enclosures;

(3) Local exhaust ventilation at the points of operation, material handling, and transfer; or

(4) Process control, such as wet methods and automation. OSHA has included a non-mandatory appendix presenting a non-exhaustive list of engineering controls employers may use to comply with paragraph (f)(2)(i) (Appendix B).

Proposed paragraph (f)(2)(i)(B) offers two exemptions from the engineering and work practice controls requirements. First, under paragraph (f)(2)(i)(B)(1), an employer is exempt from using engineering and work practice controls where the employer can establish that the controls are not feasible.

Second, under paragraph (f)(2)(i)(B)(2), an employer is exempt from using the controls where the employer can demonstrate that exposures are below the action level, using no fewer than two representative personal breathing zone samples taken 7 days apart, for each affected operation.

The engineering work practice control requirement in paragraph (f)(2)(i)(A), like the written exposure control plan requirement, was proposed by the United Steelworkers and Materion as part of their joint submission to OSHA (Materion and United Steelworkers, 2012). The inclusion of the engineering work practice control provision in paragraph (f)(2)(i)(A) addresses a concern regarding the proposed PEL. OSHA expects that day-to-day changes in workplace conditions may cause frequent excursions above the PEL in workplaces where periodic sampling indicates exposures are between the action level and the PEL. Normal variability in the workplace and work processes, such as workers' positioning or patterns of airflow, can lead to excursions above the PEL. OSHA believes that substitution or engineering controls such as those outlined in paragraph (f)(2)(i)(A) provide the most reliable means to control variability in exposure levels. OSHA therefore included this requirement in the proposal. The Agency included the exemption in paragraph (f)(2)(i)(B)(2) to reduce the cost burden to employers with operations where measured exposures are below the action level, and therefore less likely to exceed the PEL in the course of typical exposure fluctuations. This exemption is similar to a provision in 1,3 Butadiene (29 CFR 1910.1051), which requires an exposure

goal program where exposures exceed the action level.

OSHA recognizes that the requirements of paragraph (f)(2)(i) are not typical of OSHA standards, which usually require engineering controls only where exposures exceed the PEL(s). The Agency is therefore considering Regulatory Alternative #6, which would drop the provisions of paragraph (f)(2)(i) from the proposed standard. OSHA requests comments on the potential benefits of including such a provision in the beryllium standard, the potential costs and burdens associated with it, and whether OSHA should include or exclude this provision in the final standard.

Proposed paragraph (f)(2)(ii) applies when exposures exceed the TWA PEL or STEL after employers have implemented the control(s) required by paragraph (f)(2)(i). It requires employers to implement additional or enhanced engineering and work practice controls to reduce exposures to or below the PELs. For example, an enhanced engineering control may entail a redesigned hood on a local ventilation system to more effectively capture airborne beryllium at the source.

However, under proposed paragraph (f)(2)(iii), wherever the employer demonstrates that it is not feasible to reduce exposures to or below the PELs by the engineering and work practice controls required by paragraphs (f)(2)(i) and (f)(2)(ii), the employer shall implement and maintain engineering and work practice controls to reduce exposures to the lowest levels feasible and supplement these controls by using respiratory protection in accordance with paragraph (g) of this standard.

Paragraph (f)(3) of the proposed rule would prohibit the employer from rotating workers to different jobs to achieve compliance with the PELs. Worker rotation can potentially reduce exposures to individual employees, but increases the number of employees exposed. Because OSHA has made a preliminary determination that exposure to beryllium can result in sensitization, CBD, and cancer, the Agency considers it inappropriate to place more workers at risk. Since no absolute threshold has been established for sensitization or resulting CBD or the carcinogenic effects of beryllium, it is prudent to limit the number of workers exposed at any concentration.

This provision is not a general prohibition of worker rotation wherever workers are exposed to beryllium. It is only intended to restrict its use as a compliance method for the proposed PEL; worker rotation may be used as deemed appropriate by the employer in

activities such as to provide cross-training or to allow workers to alternate physically demanding tasks with less strenuous activities. This same provision was used for the asbestos (29 CFR 1910.1001 and 29 CFR 1926.1101), chromium (VI) (29 CFR 1910.1026), 1,3 butadiene (29 CFR 1910.1051), methylene chloride (29 CFR 1910.1052), cadmium (29 CFR 1910.1027 and 29 CFR 1926.1127), and methylenedianiline (29 CFR 1926.60) OSHA standards.

The SERs who participated in the SBREFA process did not voice opposition to a requirement for a written exposure control program or challenge the utility of a written program in helping to control exposures (OSHA, 2008b). Several indicated that they already had a beryllium exposure control program in place. Some SERs suggested that OSHA should tie the written exposure control program requirement to exposures exceeding a revised PEL (OSHA, 2008b). The SERs' request to tie the written exposure control program requirement to the PEL appears to emerge from their belief that employees exposed below the proposed PEL are not at risk from beryllium exposure (OSHA, 2008b).

As stated earlier, OSHA's proposed standard would require a written exposure control plan for all beryllium work areas; *i.e.*, wherever airborne beryllium is found in the workplace. OSHA believes a written exposure control plan is needed to reduce employees' risks in low-exposure areas, where the proposed standard does not require employers to install engineering controls, as well as in high-risk areas. The Agency's preliminary risk assessment shows that adverse health effects from beryllium exposure occur at levels below the proposed PEL, and even below the proposed action level (see this preamble at Section VIII, Significance of Risk). In addition, dermal contact with beryllium can occur in jobs where exposures are below the PEL or the action level. Dermal exposure to beryllium can cause beryllium sensitization, a necessary first step in the development of CBD (see this preamble at Section V, Health Effects, and Section VIII, Significance of Risk). However, in response to the SERs' comments on the written exposure control plan and other requirements that may affect workplaces with exposure levels below the proposed PEL, OSHA is considering Regulatory Alternative #8 (see chapter VIII of the PEA). Where the proposed standard requires written exposure control plans to be maintained in any facility covered by the standard, Regulatory Alternative #8 would require

only facilities with exposures above the TWA PEL or STEL to maintain a plan. OSHA requests comment on the proposed written exposure control plan requirement and on Regulatory Alternative #8.

Several SERs expressed doubt that material substitution could be an effective means of reducing beryllium exposures in their facilities. One SER stated that substitutes for beryllium alloys are not presently viable for industrial uses that require certain high-performance electrical characteristics, or wear resistance (OSHA, 2007a). Another SER commented that substitutes for beryllium alloys in the dental appliance industry have also been associated with occupational disease (OSHA, 2007a).

OSHA recognizes that the use of substitutes for beryllium may not be feasible or appropriate for some employers. The Agency's intent is to offer material substitution as one possible means of compliance with the proposed standard. Employers must determine whether material substitution is an effective and appropriate means of exposure control for their facilities. In addition, it is employers' responsibility to check the toxicity of any material they may use in their facilities, including potential substitutes for beryllium.

OSHA anticipates that most small businesses will be able to comply with the proposed standard regardless of whether they choose to substitute other materials for beryllium in their facilities.

#### (g) Respiratory Protection

Paragraph (g) of the proposed standard lays out the situations in which employers are required to protect employees' health through the use of respiratory protection. Specifically, this paragraph would require that employers provide respiratory protection at no cost and ensure that employees utilize the protection during the situations listed in paragraph (g)(1). As detailed in proposed paragraph (g)(2), the required respiratory protection must comply with the Respiratory Protection standard (29 CFR 1910.134).

Proposed paragraph (g)(1) requires employers to ensure that each employee required to use a respirator does so. Accordingly, simply providing respirators to employees will not satisfy an employer's obligations under proposed paragraph (g)(1) unless the employer also ensures that its employees wear the respirators when required. Proposed paragraph (g)(1) would also require employers to provide required respirators at no cost to employees. This requirement is

consistent with OSHA's Respiratory Protection standard, which also requires employers to provide required respiratory protection to employees at no cost (29 CFR 1910.134(c)(4)).

Paragraph (g)(1) requires appropriate respiratory protection during certain enumerated situations. Proposed paragraph (g)(1)(i) requires respiratory protection during the installation and implementation of engineering and/or work practice controls where exposures exceed or can reasonably be expected to exceed the TWA PEL or STEL. The Agency realizes that changing workplace conditions may require employers to install new engineering controls, modify existing controls, or make other workplace changes to reduce employee exposure to beryllium to at or below the TWA PEL and STEL. In these cases, the proposed standard recognizes that installing appropriate engineering controls and implementing proper work practices may take time. During this time, employers must demonstrate that they are making prompt, good faith efforts to purchase and install appropriate engineering controls and implement effective work practices, and to evaluate their effectiveness for reducing exposure to beryllium to at or below the TWA PEL and STEL.

Proposed paragraph (g)(1)(ii) requires the provision of respiratory protection during any operations, including maintenance and repair operations and other non-routine tasks, when engineering and work practice controls are not feasible and exposures exceed or can reasonably be expected to exceed the TWA PEL or STEL. OSHA included this provision because the Agency realizes that certain operations may take place when engineering and work practice controls are not operational or capable of controlling exposures to at or below the TWA PEL and STEL. For example, during maintenance and repair operations, engineering controls may lose their full effectiveness or require partial or total breach, bypass, or shutdown. Under these circumstances, if exposures exceed or can reasonably be expected to exceed the TWA PEL or STEL, the employer must provide and ensure the use of respiratory protection.

Proposed paragraph (g)(1)(iii) requires the provision of respiratory protection where beryllium exposures exceed the TWA PEL or STEL even after the employer has installed and implemented all feasible engineering and work practice controls. OSHA anticipates that there will be very few situations where feasible engineering and work practice controls are incapable of lowering employee exposure to beryllium to at or below the TWA PEL

or STEL (see this preamble at section IX.D, Technological Feasibility). In such cases, the proposed standard requires that employers install and implement all feasible engineering and work practice controls and supplement those controls by providing respiratory protection (proposed paragraph (f)(2)(iii)). OSHA reiterates that paragraph (f)(2)(iii) would also require employers to demonstrate that engineering and work practice controls are not feasible or sufficient to reduce exposure to levels at or below the TWA PEL and STEL. OSHA requests comment about the proposed situations during which employers should be required to provide and ensure the use of respiratory protection.

Proposed paragraph (g)(1)(iv) requires the provision of respiratory protection in emergencies. At such times, engineering controls may not be functioning fully or may be overwhelmed or rendered inoperable. Also, emergencies may occur in areas where there are no engineering controls. The proposed standard recognizes that the provision of respiratory protection is critical in emergencies, as beryllium exposures may be very high and engineering controls may not be adequate to control an unexpected release of beryllium.

The situations in which respiratory protection is required are generally consistent with the requirements in other OSHA health standards, such as those for chromium (VI) (29 CFR 1910.1026), butadiene (29 CFR 1910.1051), and methylene chloride (29 CFR 1910.1052). Those standards and this proposed standard also reflect the Agency's traditional adherence to a hierarchy of controls in which engineering and work practice controls are preferred to respiratory protection (see the discussion of proposed paragraph (f) earlier in this section of the preamble).

Whenever respirators are used to comply with the requirements of this proposed standard, paragraph (g)(2) requires that the employer implement a comprehensive written respiratory protection program in accordance with OSHA's Respiratory Protection standard (29 CFR 1910.134). The Respiratory Protection standard is designed to ensure that employers properly select and use respiratory protection in a manner that effectively protects exposed workers. Under 29 CFR 1910.134(c)(1), the employer's respiratory protection program must include:

- Procedures for selecting appropriate respirators for use in the workplace;
- Medical evaluations of employees required to use respirators;

- Respirator fit testing procedures;
- Procedures for proper use of respirators in routine and reasonably foreseeable emergency situations;
  - Procedures and schedules for maintaining respirators;
  - Procedures to ensure adequate quality, quantity, and flow of breathing air for atmosphere-supplying respirators;
  - Training of employees in the respiratory hazards to which they are potentially exposed during routine and emergency situations, and in the proper use of respirators; and
  - Procedures for evaluating the effectiveness of the program.

In accordance with the Agency's policy to avoid duplication and to establish regulatory consistency, proposed paragraph (g)(2) incorporates by reference the requirements of 29 CFR 1910.134 rather than reprinting those requirements in this proposed standard. OSHA notes that the respirator selection provisions in 1910.134 include requirements for Assigned Protection Factors (APFs) and Maximum Use Concentrations (MUCs) that OSHA adopted in 2006 (71 FR 50122–50192, August 24, 2006). The APFs and MUCs provide employers with critical information for the selection of respirators to protect workers from exposure to atmospheric workplace contaminants.

OSHA believes that the proposed respiratory protection requirements are feasible even for small employers. Although none of the SERs who participated in the SBREFA process made specific recommendations about respiratory protection, some said that they currently have existing respiratory protection programs in place as supplemental support to engineering and work practice controls (OSHA, 2008b).

OSHA requests comment on the proposed requirement to establish and maintain a respiratory protection program that complies with 29 CFR 1910.134. OSHA would like to hear from companies of all sizes regarding whether they have respiratory protection programs to protect employees from beryllium exposures. If so, please explain the parameters of your program including types of respirators used, when and where respirators are required, program evaluation, and annual costs.

#### (h) Personal Protective Clothing and Equipment

Paragraph (h) of the proposed standard requires employers to provide employees with personal protective clothing and equipment (PPE) where

employee exposure exceeds or can reasonably be expected to exceed the TWA PEL or STEL; where work clothing or skin may become visibly contaminated with beryllium, including during maintenance and repair activities or during non-routine tasks; and where employees are exposed to soluble beryllium compounds. These PPE requirements are intended to prevent adverse health effects associated with dermal exposure to beryllium, and accumulation of beryllium on clothing, shoes, and equipment that can result in additional inhalation exposure. The requirements also protect employees in other work areas from exposures that could occur if contaminated clothing carried beryllium to those areas, as well as employees and other individuals outside the workplace. The proposed standard requires the employer to provide PPE at no cost to employees, and to ensure that employees use the provided PPE in accordance with the written exposure control plan as described in paragraph (f)(1) of this proposed standard and OSHA's Personal Protective Equipment standards (29 CFR part 1910 subpart I).

Proposed paragraph (h)(1)(i) requires the provision and use of PPE for employees exposed to airborne beryllium in any form exceeding the TWA PEL or STEL because such exposure would likely result in skin contact by means of deposits on employees' skin or clothes or on surfaces touched by employees. And, OSHA believes that regardless of the level of exposure, the use of PPE further reduces exposure where employees' clothing or skin could become visibly contaminated with beryllium (paragraph (h)(1)(ii)).

The term "visibly contaminated with beryllium" means visibly contaminated with any material that contains beryllium. The proposed standard does not specify criteria for determining whether work clothing or skin may become visibly contaminated with beryllium. When evaluating whether this definition is satisfied, OSHA expects that the employer will assess the workplace in a manner consistent with the Agency's general requirements for the use of personal protective equipment in general industry (29 CFR part 1910 subpart I). These standards require the employer to assess the workplace to determine if hazards associated with dermal or inhalation exposure to a substance such as beryllium are, or are likely to be, present.

The proposed standard also requires the provision and use of PPE where employees are exposed to soluble



beryllium compounds, regardless of the level of airborne exposure (paragraph (h)(1)(iii)). Solubility is a concern because dermal absorption may occur at a greater rate for soluble beryllium than for insoluble beryllium. Once absorbed through the skin, beryllium can induce a sensitization response that is a necessary first step toward CBD (See the Health Effects section of this preamble, section V.A.2). However, there is also evidence that beryllium in other forms can be absorbed through the skin and cause sensitization (see this preamble at section V.B.2, Health Effects). OSHA requests comment on this provision, and whether employers should also be required to provide PPE to limit dermal contact with insoluble forms of beryllium as specified in Regulatory Alternative #13 below.

Requiring PPE is consistent with section 6(b)(7) of the OSH Act which states that, where appropriate, standards shall prescribe suitable protective equipment to be used in connection with hazards. The proposed requirements for PPE are based upon widely accepted principles and conventional practices of industrial hygiene, and in some respects are similar to other OSHA health standards such as those for chromium (VI) (29 CFR 1910.1026), lead (29 CFR 1910.1025), cadmium (29 CFR 1910.1027), and methylenedianiline (MDA; 29 CFR 1910.1050). However, the requirement to use PPE where work clothing or skin may become “visibly contaminated” with beryllium differs from prior health standards, which do not require contamination to be visible in order for PPE to be required. For example, the standard for chromium (VI) requires the employer to provide appropriate PPE where a hazard is present or is likely to be present from skin or eye contact with chromium (VI) (29 CFR 1910.1026). The lead (29 CFR 1910.1025) and cadmium (29 CFR 1910.127) standards require PPE where employees are exposed above the PEL or where there is potential for skin or eye irritation, regardless of airborne exposure level. In the case of MDA, PPE must be provided where employees are subject to dermal exposure to MDA, where liquids containing MDA can be splashed into the eyes, or where airborne concentrations of MDA are in excess of the PEL (29 CFR 1910.1050). While OSHA’s language regarding PPE requirements varies somewhat from standard to standard, previous standards tend to emphasize potential for contact with a substance that can trigger health effects via dermal

exposure, rather than “visible contamination” with the substance.

The employer must exercise reasonable judgment in selecting appropriate PPE. This requirement is consistent with OSHA’s current standards for provision of personal protective equipment for general industry (29 CFR part 1910 subpart I). As described in the non-mandatory appendix providing guidance on conducting a hazard assessment for OSHA general industry standards (29 CFR 1910 subpart I appendix B), the employer should “exercise common sense and appropriate expertise” in assessing hazards. By “appropriate expertise,” OSHA expects individuals conducting hazard assessments to be familiar with the employer’s work processes, materials, and work environment. A thorough hazard assessment should include a walk-through survey to identify sources of hazards to employees, wipe sampling to detect beryllium contamination on surfaces, review of injury and illness data, and employee input on the hazards to which they are exposed. Information obtained in this manner provides a basis for the identification and evaluation of potential hazards. OSHA believes that the implementation of a comprehensive and thorough program to determine areas of potential exposure, consistent with the employer’s written exposure control plan, is a sound safety and health practice and a necessary element of ensuring overall worker protection.

Based on the hazard assessment results, the employer must determine what PPE is necessary to protect employees. The proposed requirement is performance-oriented, and is designed to allow the employer flexibility in selecting the PPE most suitable for each particular workplace. The type of PPE needed will depend on the potential for exposure, the physical properties of the beryllium-containing material used, and the conditions of use in the workplace. For example, shipping and receiving activities may necessitate only work uniforms and gloves. In other situations such as when a worker is performing facility maintenance, gloves, work uniforms, coveralls, and respiratory protection may be appropriate. Beryllium compounds can exist in acidic or alkaline form, and these characteristics may influence the choice of PPE. Face shields may be appropriate in situations where there is a danger of being splashed in the face with soluble beryllium or a liquid containing beryllium. Coveralls with a head covering may be appropriate when a sudden release of airborne beryllium could result in beryllium contamination

of clothing, hair, or skin. Respirators are addressed separately in the explanation of proposed paragraph (g) earlier in this section of the preamble.

Note that paragraph (i)(2) of this proposed standard requires change rooms only where employees are required to remove their personal clothing. Although some personal protective clothing may be worn over street clothing, it is not appropriate for workers to wear protective clothing over street clothing if doing so could reasonably result in contamination of the workers’ street clothes. In situations in which it is not appropriate for workers to wear protective clothing over their street clothes, the employer must select and ensure the use of protective clothing that is worn in lieu of (rather than over) street clothing.

Paragraph (h)(2) contains proposed requirements for removal and storage of PPE. This provision is intended to reduce beryllium contamination in the workplace and limit beryllium exposure outside the workplace. Wearing contaminated clothing outside the beryllium work area could lengthen the duration of exposure and carry beryllium from beryllium work areas to other areas of the workplace. In addition, contamination of personal clothing could result in beryllium being carried to employees’ cars and homes, increasing employees’ exposure as well as exposing others to beryllium hazards. A National Jewish Medical and Research Center collaborative study with NIOSH documented inadvertent transfer of beryllium from the workplace to workers’ automobiles, and stressed the need for separating clean and contaminated (“dirty”) PPE (Sanderson, 1999). Toxic metals brought by workers into the home via contaminated clothing and vehicles continue to result in exposure to children and other household members. A recent study of battery recycling workers found that lead surface contamination above the Environmental Protection Agency level of concern (> 40 µg/ft<sup>2</sup>) was common in the workers’ homes and vehicles (Centers for Disease Control and Prevention, 2012).

Under proposed paragraph (h)(2)(i)(A), beryllium-contaminated PPE must be removed at the end of the work shift or at the completion of tasks involving beryllium exposure, whichever comes first. This language is intended to convey that PPE contaminated with beryllium should not be worn when tasks involving beryllium exposure have been completed for the day. For example, if employees perform work tasks involving beryllium exposure for the first two hours of a

work shift, and then perform tasks that do not involve exposure, they should remove their PPE after the exposure period to avoid the possibility of increasing the duration of exposure and contamination of the work area from beryllium residues on the PPE (*i.e.*, re-entrainment of beryllium particulate). If, however, employees are performing tasks involving exposure intermittently throughout the day, or if employees are exposed to other contaminants where PPE is needed, this provision is not intended to prevent them from wearing the PPE until the completion of their shift, unless it has become visibly contaminated with beryllium (paragraph (h)(2)(i)(B)).

Paragraph (h)(2)(i)(B) would require employers to ensure that employees remove PPE that has become visibly contaminated with beryllium. This language is intended to convey that PPE that is visibly contaminated with beryllium should be changed at the earliest reasonable opportunity, for example, at the end of the task during which it became visibly contaminated. This language is intended to protect employees working with beryllium and their co-workers from exposure due to accumulation of beryllium on PPE, and reduces the likelihood of cross-contamination from beryllium-contaminated PPE.

Proposed paragraph (h)(2)(ii) requires employees to remove PPE consistent with the written exposure control plan required by proposed paragraph (f)(1). Paragraph (f)(1) specifies that the employer's written exposure control plan must contain procedures for minimizing cross-contamination, and procedures for the storage of beryllium-contaminated PPE, among other provisions (see (f)(1)(i)(D) & (H)). Paragraph (h)(2)(iii) would require employers to ensure that protective clothing is stored separately from employees' street clothing. OSHA believes these provisions are necessary to prevent the spread of beryllium throughout and outside the workplace.

To further limit exposures outside the workplace, OSHA proposes in paragraph (h)(2)(iv) that the employer ensure that beryllium-contaminated PPE is only removed by employees who are authorized to do so for the purpose of laundering, cleaning, maintaining, or disposing of such PPE. These items must be brought to an appropriate location away from the workplace. To be an appropriate location for purposes of paragraph (h)(2)(iv), the facility must be equipped to handle beryllium-contaminated items in accordance with this proposed standard. The standard would further require in paragraph

(h)(2)(v) that PPE removed from the workplace for laundering, cleaning, maintenance, or discarding be placed in closed, impermeable bags or containers. These requirements are intended to minimize cross-contamination and migration of beryllium, and to protect employees or other individuals who later handle beryllium-contaminated items. Required warning labels would alert those handling the contaminated PPE of the potential hazards of exposure to beryllium. Such labels must conform with the HCS (29 CFR 1910.1200) and paragraph (m)(3) of this proposed standard. These warning requirements are meant to reduce confusion and ambiguity regarding critical information communicated in the workplace by requiring that this information be presented in a clear and uniform manner.

Proposed paragraph (h)(3)(i) would require the employer to ensure that reusable PPE is cleaned, laundered, repaired, and replaced as needed to maintain its effectiveness. These requirements must be completed at a frequency, and in a manner, necessary to ensure that PPE continues to serve its intended purpose of protecting workers from beryllium exposure.

In keeping with the performance-orientation of the proposed standard, OSHA does not specify how often PPE should be cleaned, repaired or replaced. The Agency believes that appropriate time intervals may vary widely based on the types of PPE used, the nature of the beryllium exposures, and other circumstances in the workplace. However, even in the absence of a mandated schedule, the employer is still obligated to keep the PPE in the condition necessary to perform its protective function. A number of Small Entity Representatives (SERS) from OSHA's SBREFA panel noted they now use low maintenance Tyvek disposable protective suits for some high exposure areas to address potential contamination situations (OSHA, 2007a).

Under paragraph (h)(3)(ii), removal of beryllium from PPE by blowing, shaking, or any other means which disperses beryllium in the air would be prohibited as this practice could result in unnecessary exposure to airborne beryllium.

Paragraph (h)(3)(iii) would require the employer to inform in writing any person or business entity who launders, cleans, or repairs PPE required by this standard of the potentially harmful effects of exposure to airborne beryllium and dermal contact with soluble beryllium compounds, and of the need to handle the PPE in accordance with this standard. This provision is

intended to limit dermal or inhalation exposure to beryllium, and to emphasize the need for hazard awareness and protective measures consistent with the proposed standard among persons who clean, launder, or repair beryllium-contaminated items.

Comments from SERs indicate that a number of beryllium-related businesses already have comprehensive protocols in place for the use and maintenance of PPE (OSHA, 2007a). One commenter indicated that it has effectively reduced sensitization and CBD through the use of respirators, other PPE, and engineering controls (OSHA, 2007a). Another commenter stated that it utilizes PPE to reduce skin exposure (OSHA, 2007a). These existing PPE programs achieve many of the Agency's goals and incorporate many of the requirements of this proposed standard.

The primary objections from SERs came from companies that raised concerns regarding the "trigger" (*e.g.*, exposure level or surface contamination) for PPE in the draft standard, and particularly the use of such terms as "anticipated," "routine," and "contaminated surface area" in connection with the requirements to protect against dermal exposure to beryllium (OSHA, 2007a). They also contend that for certain processes such as stamping, change rooms, PPE, and other hygiene practices are not necessary (OSHA, 2007a). Much of this criticism was based on early pre-proposal drafts in circulation to the SBREFA Panel (OSHA, 2007b). Since that time, OSHA has endeavored to refine the regulatory text to reflect the concerns and comments submitted on this topic. "Contaminated surface area" is no longer a trigger for PPE; however, employers must provide PPE if a contaminated surface presents the potential for workers' skin or clothing to become visibly contaminated with beryllium (paragraph (h)(1)(ii)). The term "routine" has been removed as a trigger, and paragraph (h)(1)(ii) makes clear that protections are required where skin or clothing may become visibly contaminated whether during routine or non-routine tasks. OSHA clarified that dermal protections are required only where the skin may become visibly contaminated with beryllium. OSHA believes that this proposed standard addresses commenters' objections with textual changes and this explanation of the text, which together provide further guidance to those who would be covered by the standard.

However, OSHA is concerned that the requirement to use PPE where work clothing or skin may become "visibly contaminated" with beryllium or where

soluble forms of beryllium are used may not be sufficiently protective of beryllium-exposed workers. OSHA has preliminarily concluded that sensitization can occur through dermal exposure. And although solubility may play a role in the level of sensitization risk, the available evidence suggests that contact with insoluble as well as soluble beryllium can cause sensitization via dermal contact (see this preamble at section V, Health Effects). Furthermore, at exposure levels below the current or proposed PEL, beryllium surface contamination is unlikely to be visible yet may still cause sensitization. The specification of “visible contamination” is a departure from most OSHA standards, which do not specify that contamination must be visible in order for PPE to be required. OSHA is therefore considering Regulatory Alternative #13, which would require appropriate PPE wherever there is potential for skin contact with beryllium or beryllium-contaminated surfaces. Please provide comments on this alternative, including the benefits and drawbacks of a comprehensive PPE requirement, and any relevant data or studies the Agency should consider.

#### (i) Hygiene Areas and Practices

Paragraph (i) of the proposed standard requires that, when certain conditions are met, employers must provide employees with readily accessible washing facilities, change rooms, and showers. Proposed paragraph (i) also requires employers to take certain steps to minimize exposure in eating and drinking areas, and prohibits certain practices that may contribute to beryllium exposure. OSHA believes that strict compliance with these provisions would substantially reduce employee exposure to beryllium.

The proposed standard requires certain hygiene facilities and procedures in beryllium work areas, and additional hygiene facilities and procedures when airborne exposures exceed the TWA PEL or STEL. OSHA believes that skin contact with beryllium can occur even at low airborne exposures. Skin wipe sample analysis of dental laboratory technicians performing grinding operations demonstrated that beryllium was present on the hands of workers even when airborne exposures were well below the PEL (ERG, 2006).

As discussed in the Health Effects section of this preamble, section V, respiratory tract, skin, eye, or mucosal contact with beryllium can result in sensitization, which is a necessary first step toward the development of CBD. Also, beryllium can contaminate employees' clothing, shoes, skin, and

hair, prolonging workers' beryllium exposure and exposing others such as family members if proper hygiene practices are not observed. A study by the National Jewish Medical and Research Center of Denver, Colorado, measured the levels of beryllium on workers' skin and vehicle surfaces at a machining plant where many workers did not change out of their clothes and shoes at the end of their shifts. The study showed elevated surface levels of beryllium were present on workers' skin and in their vehicles, demonstrating that workers carried residual beryllium on their hands and shoes when leaving work (Sanderson *et al.*, 1999). Paragraph (i) of the proposed standard would reduce employees' skin contact with beryllium, the possibility of accidental ingestion and inhalation of beryllium, and the spread of beryllium within and outside the workplace.

Paragraph (i)(1) would require the employer to provide readily accessible washing facilities capable of removing beryllium from the hands, face, and neck, and to ensure that employees working in beryllium work areas use these facilities when necessary. This requirement is performance-oriented, and does not specify any particular frequency. At a minimum, employees working in a beryllium work area must wash their hands, faces, and necks at the end of the shift to remove any residual beryllium. Likewise, washing prior to eating, drinking, smoking, chewing tobacco or gum, applying cosmetics, or using the toilet would also protect employees against beryllium ingestion and inhalation.

Typically, washing facilities would consist of one or more sinks, soap or another cleaning agent, and a means for employees to dry themselves after washing. OSHA does not intend to require the use of any particular soap or cleaning agent. Employers can provide whatever washing materials and equipment they choose, as long as those materials and equipment are effective in removing beryllium from the skin and do not themselves cause skin or eye problems.

Washing reduces exposure by limiting the period of time that beryllium is in contact with the skin, and helps prevent accidental ingestion. Although engineering and work practice controls and protective clothing and equipment are designed to prevent hazardous skin and eye contact, OSHA realizes that in some circumstances exposure will nevertheless occur. For example, an employee who wears gloves to protect against hand contact with beryllium may inadvertently touch his or her face with the contaminated glove during the

course of the day. The purpose of requiring washing facilities is to mitigate adverse health effects when skin or eye contact with beryllium occurs.

Under proposed paragraph (i)(2), where employees are required to remove their personal clothing in order to use personal protective clothing, the employer must provide designated change rooms with separate storage facilities for street and work clothing to prevent cross contamination. Change rooms must be in accordance with the Sanitation standard (29 CFR 1910.141). OSHA intends the change rooms requirement to apply to all covered workplaces where employees must change their clothing (*i.e.*, take off their street clothes) to use protective clothing. In situations where removal of street clothes is not necessary (*e.g.*, in a workplace where only gloves are used as protective clothing), change rooms are not required. Note that paragraph (h) of this proposed standard requires employers to provide “appropriate” personal protective clothing. It is not appropriate for employees to wear protective clothing over street clothing if doing so results in contamination of the employee's street clothes. In such situations, the employer must ensure that employees wear protective clothing in lieu of (rather than over) street clothing, and provide change rooms.

Change rooms must be designed in accordance with the written exposure control plan required by paragraph (f)(1) of this proposed standard, and with the Sanitation standard (29 CFR 1910.141). These provisions require change rooms to be equipped with storage facilities (*e.g.*, lockers) for protective clothing, and separate storage facilities for street clothes, to prevent cross-contamination. Minimizing contamination of employees' personal clothes will also reduce the likelihood that beryllium will contaminate employees' cars and homes, and other areas outside the workplace.

Because of the risk of beryllium sensitization via the skin as described in section V of this preamble, Health Effects, OSHA has determined that employers must provide showers if their employees could reasonably be expected to be exposed above the TWA PEL or STEL (paragraph (i)(3)(i)(A)), and if employees' hair or body parts other than hands, face, and neck could reasonably be expected to be contaminated with beryllium (paragraph (i)(3)(i)(B)). Employers are only required to provide showers if paragraphs (i)(3)(i)(A) and (B) both apply. Other OSHA health standards, such as the standards for cadmium (29 CFR

1910.1027) and lead (29 CFR 1910.1025), also require showers when exposures exceed the PEL. OSHA's standard for coke oven emissions (29 CFR 1910.1029) requires employers to provide showers and ensure that employees working in a regulated area shower at the end of the work shift. The standard for methylenedianiline (MDA) (29 CFR 1910.1050) requires employers to ensure that employees who may potentially be exposed to MDA above the action level shower at the end of the work shift.

Paragraph (i)(3)(ii) requires employers to ensure that employees use the showers at the end of the work activity or shift involving beryllium if the employees reasonably could have been exposed above the TWA PEL or STEL, and if beryllium could reasonably have contaminated the employees' body parts other than hands, face, and neck. This language is intended to convey that showers are required for employees who satisfy both paragraphs (i)(3)(ii)(A) and (B) when work activities involving beryllium exposure have been completed for the day. For example, if employees perform work activities involving beryllium exposure for the first two hours of a work shift, and then perform activities that do not involve exposure, they should shower after the exposure period to avoid increasing the duration of exposure, potential of accidental ingestion, and contamination of the work area from beryllium residue on their hair and body parts other than hands, face, and neck. If, however, employees are performing tasks involving exposure intermittently throughout the day, this provision is not intended to require them to shower before the completion of the last task involving exposure.

To minimize the possibility of food contamination and the likelihood of additional exposure to beryllium through inhalation or ingestion, paragraph (i)(4) would require that employers provide employees with a place to eat and drink where beryllium exposure is below the action level, and where the surfaces are maintained as free as practicable of beryllium. Eating and drinking areas must further comply with the Sanitation standard (29 CFR 1910.141(g)), which prohibits consuming food or beverages in a toilet area or in any area with exposures above an OSHA PEL.

The requirement to maintain surfaces as free as practicable of beryllium is included in other OSHA health standards such as those for lead in general industry (29 CFR 1910.1025), lead in construction (29 CFR 1926.62), chromium (IV) (29 CFR 1910.1026), and

asbestos (29 CFR 1910.1001). As OSHA explained in a January 13, 2003, letter of interpretation concerning the meaning of "as free as practicable" in OSHA's Lead in Construction standard (29 CFR 1926.62), OSHA evaluates whether a surface is "as free as practicable" of a contaminant by the rigor of the employer's program to keep surfaces clean (OSHA, 2003). A sufficient housekeeping program may be indicated by a routine cleaning schedule and the use of effective cleaning methods to minimize the possibility of exposure from accumulation of beryllium on surfaces. OSHA's compliance directive on Inspection Procedures for Chromium (IV) Standards provides additional detail on how OSHA interprets "as free as practicable" for enforcement purposes (OSHA, 2008a). As explained in the directive, if a wipe sample reveals a toxic substance on a surface, and the employer has not taken practicable measures to keep the surface clean, the employer has not kept the surface as free as practicable of the toxic substance.

The proposed standard does not require the employer to provide separate eating and drinking areas to employees at the worksite. Employees may consume food or beverages offsite. However, where the employer chooses to allow employees to consume food or beverages at a worksite where beryllium is present, the employer would be required to maintain the area in accordance with paragraph (i)(4) of this proposed standard.

Paragraph (i)(5)(i) would prohibit eating, drinking, smoking, chewing tobacco or gum, or applying cosmetics in regulated areas. Where exposures can reasonably be expected at levels above the proposed TWA PEL or STEL, there is a greater risk of beryllium contaminating the food, drink, tobacco, gum, or cosmetics. Prohibiting these activities would reduce the potential for this manner of exposure.

Under paragraph (i)(5)(ii), employers would also be required to ensure that employees do not enter eating or drinking areas wearing contaminated protective clothing or equipment. This is to further minimize the likelihood that employees will be exposed to beryllium in eating and drinking areas through inhalation, dermal contact, and ingestion.

The draft regulatory text presented during the SBREFA process would have required handwashing facilities and certain other hygiene provisions when exposures exceeded the TWA PEL, or when there was "anticipated skin exposure." Small Entity Representatives

(SERs) from OSHA's SBREFA panel expressed concern that the phrase "anticipated skin exposure" was vague and lacked definition (OSHA, 2007a). Commenters suggested that this could require employers at workplaces with low exposures to make significant modifications to the workplace, such as installing showers and change rooms. OSHA has evaluated the hygiene triggers and clarified that change rooms are only required when employees must remove their street clothes in order to wear protective clothing. Showers are only required when exposures exceed the TWA PEL or STEL, and beryllium could reasonably contaminate employees' hair or body parts other than hands, face, and neck. OSHA has removed the phrase "anticipated skin exposure" from the proposed standard. OSHA believes these changes address the commenters' concerns.

#### (j) Housekeeping

Paragraph (j) of the proposed standard requires employers to maintain surfaces in beryllium work areas as free as practicable of accumulations of beryllium; promptly clean spills and emergency releases; use appropriate cleaning methods; and properly dispose of beryllium-contaminated waste, debris, and materials. These provisions are especially important because they minimize additional sources of exposure that engineering controls are not designed to address. Good housekeeping measures are a cost-effective way to control employee exposures by removing settled beryllium that could otherwise become re-entrained into the surrounding atmosphere by physical disturbances or air currents and could enter an employee's breathing zone. Contact with contaminated surfaces may also result in dermal exposure to beryllium. As discussed in this preamble at section V, Health Effects, researchers have identified skin exposure to beryllium as a pathway to sensitization. The proposed provisions in this paragraph are consistent with housekeeping requirements in other OSHA standards for toxic metals including cadmium (29 CFR 1910.1027), chromium (VI) (29 CFR 1910.1026), and lead (29 CFR 1910.1025).

Paragraph (j)(1) requires the employer to ensure that all surfaces in beryllium work areas are maintained as free as practicable of accumulations of beryllium, and that spills and emergency releases are cleaned up promptly. Employers must follow the procedures that they have listed under their exposure control plan required by paragraph (f)(1) to clean beryllium-

contaminated surfaces, and use the cleaning methods required by paragraph (j)(2). Good housekeeping practices are essential in controlling beryllium exposure. Beryllium-containing material deposited on ledges, equipment, floors, and other surfaces must be promptly removed to prevent these deposits from becoming airborne and to minimize the likelihood of skin contact with beryllium.

Paragraph (j)(1) directs the employer to maintain surfaces where beryllium may accumulate "as free as practicable" of beryllium. In this context, the phrase "as free as practicable" sets forth the baseline goal in the development of an employer's housekeeping program to keep work areas free from surface contamination. For a detailed discussion of the meaning of the phrase "as free as practicable," see the discussion of proposed paragraph (i) earlier in this section of the preamble.

Employers must regularly clean surfaces in beryllium work areas to minimize re-entrainment of dust into the work environment, and to ensure that accumulations of beryllium do not become sources of exposure. Although OSHA does not define "surface" in the proposed standard, the term would include surfaces workers come into contact with such as working surfaces, floors, and storage facilities, as well as surfaces workers do not directly contact such as rafters. Because all surfaces in beryllium work areas could potentially accumulate beryllium that workers could later inhale, touch, or ingest, all surfaces in beryllium work areas must be kept as free as practicable of beryllium.

OSHA has preliminarily decided not to require employers to measure beryllium contamination on surfaces, because the Agency does not have the necessary data to understand the relationship between surface level of beryllium and risk of absorption through the skin. The use of wipe samples, however, remains a useful qualitative tool to detect the presence of beryllium on surfaces.

As mentioned above, when beryllium is released into the workplace as a result of a spill or emergency release, paragraph (j)(1)(ii) would require the employer to ensure prompt and proper cleanup in accordance with the written exposure control plan required by paragraph (f)(1) and to use the cleaning methods required by paragraph (j)(2) of this proposed standard. Spills or emergency releases not attended to promptly are likely to result in additional employee exposure or skin contact.

Paragraph (j)(2) provides that clean-up procedures for beryllium-containing material must minimize employee exposure. OSHA recognizes that each work environment is unique, so OSHA has established performance-oriented requirements for housekeeping to allow employers to determine how best to clean beryllium work areas while minimizing employee exposure. Paragraph (j)(2)(i) of the proposed standard would require that surfaces contaminated with beryllium be cleaned by high efficiency particulate air filter (HEPA) vacuuming or other methods that minimize the likelihood of beryllium exposure. OSHA believes HEPA vacuuming is a highly effective method of cleaning beryllium-contaminated surfaces. However, other cleaning methods equally effective at minimizing the likelihood of beryllium exposure may be used.

Paragraph (j)(2)(ii) would permit dry sweeping or brushing in certain cases only. The employer must demonstrate that it has tried cleaning with a HEPA-filter vacuum or another method that minimizes the likelihood of exposure, and that those methods were not effective under the particular circumstances found in the workplace. OSHA has included this provision in an attempt to provide employers flexibility when exposure-minimizing cleaning methods would not be effective, but OSHA is not aware of any circumstances in which dry sweeping or brushing would be necessary. OSHA requests comment on whether dry sweeping or brushing would ever be necessary, and if so, under what circumstances (see section I of this preamble, Issues and Alternatives).

Paragraph (j)(2)(iii) would prohibit the use of compressed air in cleaning beryllium-contaminated surfaces unless it is used in conjunction with a ventilation system designed to capture any resulting airborne beryllium. This provision is also intended to prevent the dispersal of beryllium into the air.

Proposed paragraph (j)(2)(iv) details further protections for those employees who are using certain cleaning methods. Under this provision, where employees use dry sweeping, brushing, or compressed air to clean beryllium-contaminated surfaces, the employer must provide respiratory protection and protective clothing and equipment and ensure that each employee uses this protection in accordance with paragraphs (g) and (h) of this standard. The failure to provide proper and adequate protection to those employees performing cleanup activities would defeat the purpose of the housekeeping

practices required to control beryllium exposure.

Paragraph (j)(2)(v) would require employers to ensure that equipment used to clean beryllium from surfaces is handled in a manner that minimizes employee exposure and the re-entrainment of beryllium into the workplace environment. For example, cleaning and maintenance of HEPA-filtered vacuum equipment must be done carefully to avoid exposure to beryllium. Similarly, filter changes and bag and waste disposal must be performed in a manner that minimizes the risk of employee exposure to airborne beryllium. This provision is consistent with the requirement in proposed paragraph (f)(1)(i)(F) for the written exposure control plan, under which employers must establish and implement procedures for minimizing the migration of beryllium. And of course, employees handling and maintaining cleaning equipment must be protected in accordance with the other paragraphs of this proposed standard as well, including the requirements for respiratory protection and PPE in paragraphs (g) and (h).

Proposed paragraph (j)(3)(i) would require that items visibly contaminated with beryllium and consigned for disposal be disposed of in sealed, impermeable bags or other closed impermeable containers. Proposed paragraph (j)(3)(ii) requires these containers to be marked with warning labels to inform individuals who handle these items of the potential hazards associated with beryllium exposure, and the labels must contain specific language in accordance with paragraph (m)(3) of the proposed standard. Alerting employers and employees who are involved in disposal to the potential hazards of beryllium exposure will better enable them to implement protective measures.

Proposed paragraph (j)(3)(iii) gives employers two options for materials designated for recycling that are visibly contaminated with beryllium: Sealing them in impermeable enclosures and labeling them in accordance with proposed paragraph (m)(3), or cleaning them to remove visible particulate. Proposed paragraph (j)(3)(iii) allows employers this flexibility to facilitate the recycling process, and ensures that employees handling these items for recycling purposes will not be exposed to visible particulate if the items are not sealed in impermeable enclosures and labeled with warnings about the dangers of beryllium exposure.

OSHA believes that the concept and importance of housekeeping programs in protecting workers from beryllium

exposure are generally well understood and acknowledged by the affected employer community. Small Entity Representatives (SERs) on the SBREFA Advisory Panel indicated that most of the responding small business entities engaged in regular and routine housekeeping activities in areas where beryllium-containing material has been used or processed (OSHA, 2008b). Housekeeping activities included wet mopping, vacuuming, and sweeping in and around machinery and other surfaces. In performing these tasks, respirator and PPE usage varied. In some cases, employers provided the protection, but did not require its usage. In other instances, no protection was available to workers performing housekeeping duties. (OSHA, 2007a).

Those companies that did have comprehensive housekeeping policies provided the Agency with a number of useful practices and examples in response to the RFI as well as during the SBREFA process. One company offered its 8-step housekeeping and control strategy into the record as a comprehensive model (Brush Wellman, 2003). Another company presented its facility housekeeping program specifying a number of containment measures such as tack mats, absorbent carpet, and damp disposable towels to collect any contamination from beryllium operations. Certain practices were expressly prohibited such as dry sweeping, brushing, wiping, and the use of compressed air systems to clean machinery (Honeywell, 2003). Researchers with the National Jewish Hospital and Research Center found that most of the beryllium facilities that they visited prohibited the use of compressed air in beryllium areas (NJMRC, 2003).

Several commenters also questioned the vagueness of the term "contaminated surfaces" (OSHA, 2008b). The proposed standard no longer uses this term. Rather, proposed paragraph (j) would require employers to maintain surfaces in beryllium work areas "as free as practicable of accumulations of beryllium," which is explained earlier in this section.

#### (k) Medical Surveillance

Under paragraph (k)(1) of the proposed standard, OSHA would require employers to make medical surveillance available at no cost, and at a reasonable time and place, for all employees who have worked in a regulated area for more than 30 days in the past 12 months; show signs and symptoms of CBD; are exposed to beryllium during an emergency; or were exposed to beryllium in concentrations above  $0.2 \mu\text{g}/\text{m}^3$  for more than 30 days

in a 12-month period for 5 years or more.

Under paragraph (k)(1)(ii), the required medical surveillance must be performed by or under the direction of a licensed physician. OSHA chose to require licensed physicians, as opposed to PLHCPs, to oversee medical surveillance in this standard, and to provide certain services required by this standard (see, e.g., paragraphs (k)(1)(ii) and (k)(5)). OSHA has in the past allowed a PLHCP to perform all aspects of medical surveillance, regardless of whether the PLHCP is a licensed physician (see OSHA's standards regulating chromium (VI) (29 CFR 1910.1026) and methylene chloride (29 CFR 1910.1052)). OSHA has proposed that a licensed physician perform some of the requirements of paragraph (k) in response to a multi-stakeholder coalition proposal to this effect. OSHA believes this requirement strikes an appropriate balance between ensuring that a licensed physician supervises the overall care of the employee, while giving the employer the flexibility to retain the services of a variety of qualified licensed health care professionals to perform certain other services required by paragraph (k). However, OSHA also believes it may be appropriate to allow a PLHCP who is not a licensed physician to perform all of the services required by proposed paragraph (k) (see also section I of this preamble, Issues and Alternatives). OSHA requests comment on this proposed requirement.

The purpose of medical surveillance for beryllium is, where reasonably possible, to identify beryllium-related adverse health effects so that appropriate intervention measures can be taken, and to determine the employee's fitness to use personal protective equipment such as respirators. The proposed standard is consistent with Section 6(b)(7) of the OSH Act (29 U.S.C. 655(b)(7)), which requires that, where appropriate, medical surveillance programs be included in OSHA health standards to aid in determining whether the health of employees is adversely affected by exposure to toxic substances. Other OSHA health standards, such as Chromium (VI) (29 CFR 1910.1026), Methylene Chloride (29 CFR 1910.1052), and Cadmium (29 CFR 1910.1027), also include medical surveillance requirements.

The proposed standard is intended to encourage participation in medical surveillance by requiring at paragraph (k)(1)(i) that the employer provide medical examinations without cost to employees (also required by section

6(b)(7) of the Act (29 U.S.C. 655(b)(7)), and at a reasonable time and place. If participation requires travel away from the worksite, the employer would be required to bear all travel costs. Employees must be paid for time away from work spent attending medical examinations, including travel time.

Paragraph (k)(1)(i)(A) proposes to require employers to make medical surveillance available to all employees who worked in a regulated area for more than 30 days in the past 12 months. This requirement attempts to ensure that those employees who are at most risk for developing beryllium-related adverse health effects have access to medical services so that such adverse health effects can be detected early.

In addition, paragraph (k)(1)(i)(B) would require that employers provide medical surveillance to any employee who shows signs or symptoms of CBD. It is expected that employees experiencing signs and symptoms of exposure will report them to their employers. If an employer becomes aware that an employee shows signs and symptoms of CBD either through employee self-reporting or from observation of the employee, the employer is required to provide medical surveillance to the employee. However, this provision is not intended to force employers to survey their workforce, make diagnoses, or determine causality.

Proposed paragraph (k)(1)(i)(B) recognizes that some employees may exhibit signs and symptoms of the adverse health effects associated with beryllium exposure even when not exposed above the TWA PEL or the STEL for more than 30 days per year. OSHA's preliminary risk assessment concludes that there is significant risk of adverse health effects from beryllium exposure below the proposed PEL (see this preamble at section VI, Preliminary Risk Assessment). In addition, beryllium sensitization and CBD could develop in employees who are especially sensitive to beryllium, may have been unknowingly exposed, or may have been exposed to greater amounts than the exposure assessment suggests.

Self-reporting by employees will be supported by the training required under proposed paragraph (m)(4)(ii) on the health hazards of beryllium exposure and the signs and symptoms of CBD, and the medical surveillance and medical removal requirements of the proposed standard in paragraphs (k) and (l). Employees have a right under section 11(c) of the OSH Act to report suspected work-related health effects to their employers without retaliation. Any employer program or practice that

discourages employees from reporting or penalizes workers who report work-related health effects would violate section 11(c). See Memorandum from Richard E. Fairfax to Regional Administrators (March 12, 2012), available at <http://www.osha.gov/as/opa/whistleblowermemo.html>.

As discussed in this preamble at section V, Health Effects, CBD causes fatigue, weakness, difficulty breathing, and a persistent dry cough, among other symptoms. In more advanced cases, CBD may also result in anorexia and weight loss, as well as right side heart enlargement (cor pulmonale) and heart disease. By requiring covered employers to make a medical exam available when an employee exhibits these types of symptoms, the proposed standard would protect all employees who may have developed CBD, whether or not these employees have been exposed to beryllium in an emergency or for more than 30 days in a regulated area.

Paragraph (k)(1)(i)(C) would require that appropriate surveillance also be made available for employees exposed to beryllium during an emergency, regardless of the airborne concentrations of beryllium to which these employees are routinely exposed in the workplace. Emergency situations involve uncontrolled releases of airborne beryllium, and the significant exposures that can occur in these situations justify a requirement for medical surveillance. The proposed requirement for medical examinations after exposure in an emergency is consistent with several other OSHA health standards, including the standards for chromium (VI) (29 CFR 1910.1026), methylenedianiline (29 CFR 1910.1050), butadiene (29 CFR 1910.1051), and methylene chloride (29 CFR 1910.1052).

Paragraph (k)(1)(i)(D) would require medical surveillance to be provided to employees who have been exposed to beryllium above  $0.2 \mu\text{g}/\text{m}^3$  for more than 30 days in a 12-month period for 5 years or more. The five-years of exposure would not need to be consecutive to satisfy this provision. OSHA included this provision to ensure that these employees receive the low-dose helical tomography (CT scan, low-dose computed tomography (LDCT), or CT screening) required by paragraph (k)(3)(ii)(F) of the proposed standard, even if these employees have not been exposed above  $0.2 \mu\text{g}/\text{m}^3$  in the previous 12-month period, are not exhibiting signs and symptoms of CBD, and have not been exposed in an emergency. The CT scan is a method of detecting tumors, and is commonly used to diagnose lung cancer.

Paragraph (k)(2) of the proposed standard specifies how frequently medical examinations are to be offered to those employees covered by the medical surveillance program. Under paragraph (k)(2)(i)(A), employers would be required to provide each employee with a medical examination within 30 days after the employee has worked in a regulated area for more than 30 days in the past 12 months, unless the employee has received a medical examination provided in accordance with this standard within the previous 12 months. Paragraph (k)(2)(i)(B) requires employers to provide medical examinations to employees exposed to beryllium during an emergency, and to those who are showing signs or symptoms of CBD, within 30 days of the employer becoming aware that these employees meet the criteria of paragraph (k)(1)(i)(B) or (C). Paragraph (k)(2)(i)(B) requires an examination without regard to whether these employees received an exam in the previous 12 months.

Paragraph (k)(2)(ii) of the proposed standard requires that employers provide an examination annually (after the first examination is made available) to employees who continue to meet the criteria of paragraph (k)(1)(i)(A) or (B). This includes employees who have worked in a regulated area for more than 30 days in the past 12 months and employees who continue to exhibit signs and symptoms of CBD. The requirement for annual examinations in paragraph (k)(2)(ii) means that an examination must be made available at least once every 12 months.

Employees exposed in an emergency, who are covered by paragraph (k)(1)(i)(C), are not included in the annual examination requirement unless they also meet the criteria of paragraph (k)(1)(i)(A) or (B), because OSHA expects that most effects of exposure will be detected during the medical examination provided within 30 days of the emergency, pursuant to paragraph (k)(2)(i)(A). An exception to this is beryllium sensitization, which OSHA believes may result from exposure in an emergency, but may not be detected within 30 days of the emergency. Thus, proposed paragraph (k)(3)(ii)(E) requires biennial testing for beryllium sensitization for employees exposed in emergencies. This paragraph is discussed in more detail later in this section of the preamble. Employees covered by paragraph (k)(1)(i)(D) are also not required to receive exams annually unless they also meet the criteria of paragraph (k)(1)(i)(A) or (B).

OSHA believes that the annual provision of medical surveillance, and

the biennial provision of beryllium sensitization testing and CT scans for certain employees, are appropriate frequencies for screening employees for beryllium-related diseases. The main goals of medical surveillance for employees are to detect beryllium sensitization before employees develop CBD, and to detect CBD, lung cancer, and other adverse health effects at an early stage. The proposed requirement for annual examinations is consistent with other OSHA health standards, including those for chromium (VI) (29 CFR 1910.1026) and formaldehyde (29 CFR 1910.1048). Based on the Agency's experience, OSHA believes that annual surveillance and biennial tests for beryllium sensitization and CT scans would strike a reasonable balance between the need to diagnose health effects at an early stage, while being sufficiently affordable for employers.

Finally, proposed paragraph (k)(2)(iii) would require the employer to offer a medical examination at the termination of employment, if the departing employee meets the criteria of paragraph (k)(1)(i)(A), (B), or (C) at the time the employee's employment is terminated. This would apply to employees who worked in a regulated area for more than 30 days during the previous 12 months, employees showing signs or symptoms of CBD, and employees who were exposed to beryllium in an emergency at any time during their employment. This proposed requirement is waived if the employer provided the departing employee with an exam during the six months prior to the date of termination. The provision of an exam at termination is intended to ensure that no employee terminates employment while carrying a detectable, but undiagnosed, health condition related to beryllium exposure.

Proposed paragraph (k)(3) details the contents of the examination. Paragraph (k)(3)(i) would require the employer to ensure that the PLHCP advises the employee of the risks and benefits of participating in the medical surveillance program and the employee's right to opt out of any or all parts of the medical examination. Benefits of participating in medical surveillance may include early detection of adverse health effects, and aiding intervention efforts to prevent or treat disease. However, there may also be risks associated with medical testing for some conditions, which the PLHCP should communicate to the employee.

Paragraph (k)(3)(ii) then specifies that the medical examination must consist of a medical and work history; a physical examination with emphasis on the respiratory tract, skin breaks, and wounds; and pulmonary function tests.

Special emphasis is placed on the portions of the medical and work history focusing on beryllium exposure, health effects associated with beryllium exposure, and smoking.

The physical exam focuses on organs and systems known to be susceptible to beryllium toxicity. For example, proposed paragraph (k)(3)(ii)(C) focuses on the skin, and paragraph (k)(3)(ii)(D) focuses on the lungs. The information obtained will allow the PLHCP and supervising physician to assess the employee's health status, identify adverse health effects related to beryllium exposure, and determine if limitations should be placed on the employee's exposure to beryllium. The proposed standard does not include a comprehensive list of specific tests that must be part of the medical examination. OSHA does not believe that any particular test—beyond those listed in paragraph (k)(3)(ii)(D)–(F)—is necessarily applicable to all employees covered by the medical surveillance requirements. The Agency proposes to give the PLHCP the flexibility to determine any other appropriate tests to be selected for a given employee, as provided in paragraph (k)(3)(ii)(G).

Under paragraph (k)(3)(ii)(E), an employee must be offered a BeLPT (or a more reliable and accurate test for identifying beryllium sensitization) at the employee's first examination, and then every two years after the first examination unless the employee is confirmed positive. The requirement to test for beryllium sensitization applies whether or not an employee is otherwise entitled to a medical examination in a given year. For example, for an employee exposed during an emergency who would normally be entitled to 1 exam within 30 days of the emergency but not annual exams thereafter, the employer must still provide this employee with a test for beryllium sensitization every 2 years. This biennial requirement applies until the employee is confirmed positive. OSHA believes that the biennial testing required under paragraph (k)(3)(ii)(E) is adequate to monitor employees that have the potential to develop sensitization while being sufficiently affordable for employers.

OSHA considers the BeLPT to be a reliable medical surveillance tool for the purposes of a medical surveillance program. However, OSHA considers two abnormal test results necessary to confirm a finding of beryllium sensitization when using the BeLPT ("confirmed positive"). Therefore, a BeLPT must also be offered within one month of an employee receiving a single

abnormal result. However, this requirement is waived if a more reliable and accurate test becomes available that could confirm beryllium sensitization based on one test result. OSHA requests comment on how to determine whether a test is more reliable and accurate than the BeLPT for identifying beryllium sensitization. OSHA has included a non-mandatory appendix that describes the BeLPT, discusses several studies of the BeLPT's validity and reliability, and states criteria OSHA believes are important to judge a new test's validity and reliability (Appendix A).

Under paragraph (k)(3)(ii)(F), a CT scan must be offered to employees who have been exposed to beryllium at concentrations above  $0.2 \mu\text{g}/\text{m}^3$  for more than 30 days in a 12-month period for 5 years or more. The five years of exposure do not need to be consecutive. As with the requirement for sensitization testing explained above, the CT scan must be offered to an employee who meets the criteria of paragraph (k)(1)(i)(D) without regard to whether the employee is otherwise required to receive a medical exam in a given year. The CT scan must be offered to employees who meet the criteria of paragraph (k)(1)(i)(D) for the first time beginning on the start-up date of this standard, or 15 years after the employee's first exposure to beryllium above  $0.2 \mu\text{g}/\text{m}^3$  for more than 30 days in a 12-month period, whichever is later. OSHA proposed the requirement for CT screening based in part on the Agency's consideration of the draft recommended standard submitted by industry and union stakeholders (Materion and USW, 2012).

The CT scan requirement may be triggered by exposures that occurred before or after the effective date of this standard, or a combination of exposures before and after the effective date. This requirement may also be triggered by exposures that occurred when the employee was working for a different employer. An employer is required to offer a CT scan to employees who meet the criteria of paragraph (k)(1)(i)(D) if the employer has exposure records demonstrating that the employee meets the criteria, regardless of whether the exposure records were generated by the employer or given to the employer by the employee or a third party.

In a recent systematic review of CT screening trials for lung cancer, Bach *et al.* found a significant (20 percent) mortality reduction in the population studied (26,309 men and women between ages 55 and 74, with at least 30 pack-years of smoking history) (National Lung Screening Trial, 2011). The benefits of screening for other

populations are less clear at this time. CT screening was not shown to offer significant reduction in mortality in two other, smaller trial populations with at least 20 pack-years of smoking history (DANTE, 2009; DLCST, 2012). In addition, there is yet to be agreement on how to properly compute and set the radiation dose for LDCT. Clarification on such procedural issues will help inform analyses of LDCT-associated radiation exposure and its risks as part of a screening protocol for employees exposed to occupational carcinogens (Christensen, 2014).

OSHA seeks comment on the proposed requirement and whether it is likely to benefit the beryllium-exposed employee population. As appropriate, please submit information, studies and data to support your comments.

OSHA notes that another form of CT scanning, High Resolution Computed Tomography (HRCT), is available and may be useful in screening for CBD. In patients with CBD, HRCT scanning of the chest is more sensitive than plain chest radiography in identifying abnormalities (NAS, 2008). However, HRCT scans showing no signs consistent with CBD have been reported in 25 percent of patients with biopsy-proven noncaseating granulomas (Newman *et al.*, 1994). OSHA seeks comment on whether HRCT should be included in the list of diagnostic procedures a CBD Diagnostic Center should be able to provide (see this Preamble at Section XVIII, paragraph (b), Definitions).

Other types of tests and examinations not mentioned in this standard, including X-ray, arterial blood gas, diffusing capacity, and oxygen desaturation during exercise, may also be useful in evaluating the effects of beryllium exposure. In addition, medical examinations that include more invasive testing, such as bronchoscopy, alveolar lavage, and transbronchial biopsy, have been demonstrated to provide additional valuable medical information. OSHA believes that the PLHCP is in the best position to decide which medical tests are necessary for each individual examined. Where specific tests are deemed appropriate by the PLHCP, the proposed standard, at paragraph (k)(3)(ii)(G), would require that they be provided.

Proposed paragraph (k)(4) details which information must be provided to the PLHCP. Specifically, the proposed standard would require the employer to ensure the examining PLHCP has a copy of the standard and all the appendices, and to provide to the examining PLHCP the following information, if known or reasonably available to the employer: a



description of the employee's former and current duties as they relate to beryllium exposure ((k)(4)(i)); the employee's former and current exposure levels ((k)(4)(ii)); a description of any personal protective clothing and equipment, including respirators, used or to be used by the employee, including when and for how long the employee has used that clothing and equipment ((k)(4)(iii)); and information the employer has obtained from previous medical examinations provided to the employee, that is currently within the employer's control ((k)(4)(iv)). OSHA believes making this information available to the PLHCP will aid in the PLHCP's evaluation of the employee's health as it relates to the employee's assigned duties and fitness to use personal protective equipment, including respirators, when necessary. In order to protect the employee's privacy, employee medical information may only be provided to the PLHCP by the employer after the employee has signed a medical release.

Providing the PLHCP with exposure monitoring results, as required under paragraph (k)(4)(ii), will assist the physician completing the written medical opinion in determining if an employee is likely to be at risk of adverse effects from beryllium exposure at work. A well-documented exposure history would also assist the PLHCP in determining if a condition (e.g., dermatitis, decrease in diffusing capacity, or gradual changes in arterial blood gases) may be related to beryllium exposure. See this preamble at section V, Health Effects, for a more detailed discussion of the health effects associated with beryllium exposure.

Proposed paragraph (k)(5) would require employers to obtain a written medical opinion from the licensed physician who performed or directed the exam within 30 days of the examination. The purpose of requiring the physician to supply a written opinion to the employer is to provide the employer with a documented medical basis for the employee's eligibility for medical removal, and to assess the employee's ability to use protective clothing and equipment, including respirators. In addition, provision of the written opinion to the employer may alert the employer to sources of beryllium exposure or problems with exposure controls at its worksite. OSHA believes the 30-day period will allow the licensed physician sufficient time to receive and consider the results of any tests included in the examination, and allow the employer to take any necessary protective measures in a timely manner. The proposed

requirement that the opinion be in written form is intended to ensure that employers and employees have the benefit of the same information and that no information gets lost in oral communications. OSHA requests comment on the relative merits of the proposed standard's requirement that employers obtain the PLHCP's written opinion or an alternative that would provide employees with greater discretion over the information that goes to employers (see this preamble at Section 1, Issues and Alternatives, Issue #26).

Paragraphs (k)(5)(i)(A)–(C) of the proposed standard specify what must be included in the licensed physician's written opinion. The first item for inclusion is the licensed physician's opinion as to whether the employee has any detected medical condition that would place the employee at increased risk of CBD from further exposure. The standard also proposes that the medical opinion include any recommended limitations on the employee's exposure, including recommended use of, and limitations on the use of, personal protective clothing or equipment such as respirators.

The licensed physician would also need to state in the written opinion that the PLHCP has explained the results of the medical examination to the employee, including the results of any tests conducted, any medical conditions related to exposure that require further evaluation or treatment, and any special provisions for use of protective clothing or equipment, including respirators. Under proposed paragraph (k)(5)(i)(C), OSHA anticipates that the employee will be informed directly by the PLHCP of all results of his or her medical examination, including conditions of non-occupational origin. Direct consultation between the PLHCP and employee ensures that the employee will receive all information about the employee's health status, including non-occupationally related conditions that are not communicated to the employer.

Proposed paragraph (k)(5)(ii) would require the employer to ensure that neither the licensed physician nor any other PLHCP reveals to the employer findings or diagnoses which are unrelated to beryllium exposure. OSHA has proposed this provision to reassure employees participating in medical surveillance that they will not be penalized or embarrassed as a result of the employer obtaining information about them not directly pertinent to beryllium exposure. Paragraph (k)(5)(iii) would also require the employer to provide a copy of the licensed physician's written opinion to the

employee within two weeks after receiving it to ensure that the employee has been informed of the results of the examination in a timely manner.

Proposed paragraph (k)(6)(i) provides for the referral to a CBD diagnostic center of any employee who is confirmed positive for beryllium sensitization. Within 30 days after the employer learns of the confirmed positive result, the employer must ensure that a licensed physician designated by the employer consults with the employee about referral to a CBD diagnostic center for further testing, to determine whether a sensitized employee has CBD. If the employee chooses to obtain a clinical evaluation at a CBD diagnostic center, the diagnostic center must be agreed upon by the employer and the employee. The employer and employee must make a good faith effort to agree on a CBD diagnostic center that is acceptable to them both. Under paragraph (k)(6)(ii), the employer is responsible for all costs associated with testing performed at the center. The term CBD diagnostic center is defined in proposed paragraph (b), and discussed in this section of the preamble regarding proposed paragraph (b).

Finally, under paragraph (k)(7), the employer would be required to convey the results of the medical tests to OSHA for evaluation and analysis at the request of the Assistant Secretary. The results of the tests may be used to evaluate the nature, variability, reliability, and relevance of the beryllium sensitization test results, to evaluate the effectiveness of the beryllium standard in reducing beryllium-related occupational disease, or for other scientific purposes. Results conveyed to OSHA must first be stripped of employees' names, social security numbers, and other identifying information.

Employees of beryllium vendors who qualify for benefits under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) (42 U.S.C. 7384–7385s–15) and its implementing regulations (20 CFR part 30) may also qualify for medical surveillance benefits under this proposed standard. Covered medical surveillance provided to eligible persons under the EEOICPA program is paid for by the federal government.

Employees covered by both the EEOICPA program and this proposed standard would not be required to attend separate medical examinations for the separate programs. Rather, these dual-coverage employees could attend consolidated medical examinations at which they would receive the services

required under both programs. These examinations would be paid for by the federal government under the EEOICPA program to the extent that the services provided are covered under the EEOICPA program. If this proposed standard requires services that are not covered by the EEOICPA program, the employer would be required to pay for these additional services.

As stated in the SBREFA Report, the medical surveillance section “was the most controversial part of the draft standard for most SERs and received the most comment” (OSHA, 2008b). SERs generally were concerned about the cost of medical surveillance, commenting that surveillance is unnecessary for employees with low beryllium exposures (OSHA, 2008b). The requirement of dermal triggers for medical surveillance was confusing for SERs and led to a number of comments (OSHA, 2008b). One SER suggested that the medical surveillance requirements should be performance-based, which would allow employers to determine which tests were appropriate for their employees (OSHA, 2008b). Use of the BeLPT was also controversial, given SERs’ concerns about its accuracy and costs (OSHA, 2008b). OSHA requests comment on the proposed requirements for beryllium sensitization testing, including issues raised in this preamble at section I, Issues and Alternatives, and on the regulatory alternatives presented later in this section.

In response to these concerns, OSHA notes several changes made to the regulatory text since the SBREFA panel was convened. In the proposed standard, medical surveillance is limited to those employees who have worked in a regulated area for more than 30 days per year in the previous 12-month period, employees showing signs and symptoms of CBD, employees exposed during emergencies, and employees who have been exposed above  $0.2 \mu\text{g}/\text{m}^3$  for more than 30 days in a 12-month period for five years or more. Requiring medical surveillance for employees with exposures in a regulated area (*i.e.*, with exposures above the TWA PEL or STEL for more than 30 days in a year) should alleviate some SERs’ concerns that surveillance is not necessary for employees with low exposures. Employees with exposures at or above the action level but below the PEL are no longer included in medical surveillance, unless they show signs or symptoms of CBD or were exposed during an emergency. Since the SBREFA panel was held, OSHA has also removed the requirement for medical surveillance based only on dermal exposure to beryllium, eliminating the

confusion caused by the dermal exposure provision.

These changes will result in fewer employees being eligible for medical surveillance than were covered in the draft standard presented to the SBREFA panel. The changes will thereby reduce costs to employers. However, OSHA has preliminarily determined that a significant risk of beryllium sensitization, CBD, and lung cancer exist at exposure levels below the proposed PEL, and there is evidence that beryllium sensitization can occur from short-term exposures (see this preamble at Section V, Health Effects, and Section VIII, Significance of Risk). The Agency therefore anticipates that some employees will develop adverse health effects and may not receive the benefits of early intervention in the disease process because they are not eligible for medical surveillance (see this preamble at Section V, Health Effects). Thus, OSHA is considering three regulatory alternatives that would expand eligibility for medical surveillance to a broader group of employees than those eligible in the proposed standard. Under Regulatory Alternative #14, medical surveillance would be available to employees who are exposed to beryllium above the proposed PEL, including employees exposed for fewer than 30 days per year. Regulatory Alternative #15 would expand eligibility for medical surveillance to employees who are exposed to beryllium above the proposed action level, including employees exposed for fewer than 30 days per year. Regulatory Alternative #21 would extend eligibility for medical surveillance as set forth in proposed paragraph (k) to all employees in shipyards, construction, and general industry who meet the criteria of proposed paragraph (k)(1). However, all other provisions of the standard would be in effect only for employers and employees that fall within the scope of the proposed rule. Most of these alternatives would provide surveillance to fewer employees (and cost less to employers) than the draft regulation presented to the SBREFA Panel, but would provide more surveillance (and cost more to employers) than the medical surveillance requirements in the current proposal.

The SER who suggested allowing performance-based surveillance stated that this would permit employers “to design and determine what tests were appropriate” (OSHA, 2008b). OSHA is considering two regulatory alternatives that would provide greater flexibility in the program of tests provided as part of an employer’s medical surveillance

program. Under Regulatory Alternative #16, employers would not be required to offer employees testing for beryllium sensitization. Regulatory Alternative #18 would eliminate the CT scan requirement from the proposed rule.

OSHA is evaluating these alternatives and has also included some performance-based elements in its medical surveillance requirements (*e.g.*, (k)(3)(G)). However, the Agency has preliminarily determined that the testing required by the proposed standard is necessary and appropriate for the employees who must be offered medical surveillance. OSHA believes it is important to detect cases of sensitization, CBD and other beryllium-related health effects early so that employees can quickly be removed from exposure, be provided appropriate protective clothing and equipment, benefit from medical removal, and receive treatment, as applicable. As discussed in this preamble at section VIII, Significance of Risk, early intervention in the disease process may slow or prevent progression to more advanced disease. Further, this surveillance is particularly necessary in a standard such as this one, where OSHA has preliminarily found a significant risk of material impairment of health at the proposed PEL. OSHA requests comments on the proposed requirements for sensitization testing, CT scans, and medical examinations, and on Regulatory Alternatives #14 and #15 discussed above.

Finally, at least one SER commented that providing annual BeLPTs would result in high costs with no added benefit to employees (OSHA, 2008b). As discussed previously, OSHA would also allow substitution of a more accurate and reliable test for the BeLPT should such a test become available. When this occurs, employers can choose to use whichever test is less expensive. OSHA has also, in its proposed standard, reduced the frequency of required BeLPTs (or other test substituted for the BeLPT) to every two years, with follow-up tests for employees who receive abnormal test results. This change would significantly reduce the cost of testing, but would also delay early detection of beryllium-related health effects and intervention to prevent disease progression among employees in medical surveillance. In addition, the longer the time interval between when an employee becomes sensitized and when the employee’s case is identified in the surveillance program, the more difficult it will be to identify and address the exposure conditions that led to the employee’s sensitization. Therefore, lengthening the time between

sensitization tests will diminish the usefulness of the surveillance information in identifying and correcting problem areas and reducing risks to other employees.

The benefits of regular medical surveillance for beryllium-related health effects and the costs of surveillance to employers are important and complex factors in the proposed standard, and OSHA requests feedback from the regulated and medical communities to help determine the most appropriate schedule for periodic testing. In particular, the Agency requests comments on several alternatives to the proposed frequency of sensitization testing, CT scans, and general medical examinations. Regulatory alternative #17 would require employers to offer annual testing for beryllium sensitization to eligible employees, as in the draft proposal presented to the SBREFA panel. Regulatory Alternative #19 would similarly increase the frequency of periodic CT scans from biennial to annual scans. Finally, under Regulatory Alternative #20, all periodic components of the medical surveillance exams would be available biennially to eligible employees. Instead of requiring employers to offer eligible employees a medical examination every year, employers would be required to offer eligible employees a medical examination every other year. The frequency of testing for beryllium sensitization and CT scans would also be biennial for eligible employees, as in the proposed standard. For all comments on the medical surveillance provisions of the proposed standard, please provide an explanation of your position, and supporting data or studies as appropriate.

#### (l) Medical Removal Protection

Paragraph (l) of the proposed rule contains the provisions related to medical removal protection (MRP). Proposed paragraph (l)(1) explains that employees in jobs with exposure at or above the action level become eligible for medical removal when they are diagnosed with CBD or confirmed positive for beryllium sensitization. These medical findings may be made pursuant to the surveillance requirements of proposed paragraph (k). The terms "CBD" and "confirmed positive" are defined in proposed paragraph (b).

Proposed paragraph (l)(1) is in keeping with OSHA's provisions for MRP in past standards, where the Agency has specified objective removal criteria. For example, the Lead standard (29 CFR 1910.1025) requires that an employee be removed from exposure at

or above the action level when an employee's blood lead concentration exceeds a certain value. Similarly, the Cadmium standard (29 CFR 1910.1027) includes objective biological monitoring criteria that trigger removal.

Paragraph (l)(2) lays out the options for employees who are eligible for MRP. Specifically, paragraph (l)(2)(i) would permit eligible employees to choose removal as described under proposed paragraph (l)(3), and proposed paragraph (l)(2)(ii) would permit them to remain in a job with exposure at or above the action level and wear a respirator in accordance with the Respiratory Protection standard (29 CFR 1910.134). Eligible employees must choose one of these two options. OSHA requests comment on whether the standard should establish a timeframe in which eligible employees must choose one of the options in paragraph (l)(3) (such as within 7 days, 14 days, or 30 days), and whether the standard should require the employee to wear a respirator if the employee fails to choose one of the options within the specified timeframe.

Proposed paragraph (l)(3) describes eligible employees' removal options. When an employee chooses removal, the employer is required to remove the employee to comparable work if such work is available. Comparable work is a position for which the employee is already qualified or can be trained within one month, in an environment where beryllium exposure is below the action level. Comparable work would not require the employee to use a respirator, although the employee may choose to use a respirator to minimize beryllium exposure. An employer is not required to place an employee on paid leave if the employee refuses comparable work offered under paragraph (l)(3)(i). An employee must be transferred to comparable work, trained for comparable work, or placed on paid leave immediately after choosing removal.

If comparable work is not immediately available, paragraph (l)(3)(ii) would require the employer to place the employee on paid leave for six months or until comparable work becomes available, whichever occurs first. If comparable work becomes available before the end of the six month paid leave period, the employer is obligated to offer the open position to the employee. Should the employee decline, the employer has no further obligation to continue the paid leave.

Proposed paragraph (l)(3)(iii) would continue a removed employee's rights and benefits for six months, regardless of whether the employee is removed to

comparable work or placed on paid leave. The six month period would begin when the employee is removed, which means either the day the employer transfers the employee to comparable work, or the day the employer places the employee on paid leave. For this period, the provision would require the employer to maintain the employee's base earnings, seniority, and other rights and benefits of employment as they existed at the time of removal. This provision is typical of medical removal provisions in other OSHA standards, such as Cadmium (29 CFR 1910.1027) and Benzene (29 CFR 1910.1028).

Paragraph (l)(4) would reduce an employer's obligation to provide MRP benefits to a removed employee if, and to the extent that, the employee receives compensation from a publicly or employer-funded compensation program for earnings lost during the removal period, or receives income from another employer made possible by virtue of the employee's removal. Benefits received under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) do not constitute wage replacement, and therefore would not offset the employee's medical removal benefits under this proposed standard.

By protecting an employee's rights and benefits during the first six months of removal, and by reducing in certain circumstances an employer's obligation to compensate employees for earnings lost, OSHA emphasizes that MRP is not intended to serve as a workers' compensation system. The primary reason MRP has been included in this standard is to provide eligible employees a six-month period to adjust to the comparable work arrangement or seek alternative employment, without any further exposure at or above the action level.

The prospect of a medical removal provision concerned some SERS. Some stated that there is no evidence that removing sensitized employees will change their health outcomes (OSHA 2008b). Others commented that they did not believe medical removal was appropriate because neither sensitization nor CBD is reversible (OSHA 2008b).

OSHA believes that medical removal is an important means of protecting employees who have become sensitized or developed CBD, and is an appropriate means to enable them to avoid further exposure. The scientific information on effects of exposure cessation is limited at this time, but the available evidence suggests that removal from exposure can be beneficial for individuals who are

sensitized or have early-stage CBD (see this preamble at section VIII, Significance of Risk). As discussed in the Health Effects section of this preamble, section V, only those who are sensitized can develop CBD. As CBD progresses, symptoms become serious and debilitating. Steroid treatment is less effective at later stages, once fibrosis has developed (see this preamble at section VIII, Significance of Risk). Given the progressive nature of the disease, OSHA believes it is reasonable to conclude that removal from exposure to beryllium will benefit sensitized employees and those with CBD.

There is widespread support for removal of individuals with sensitization or CBD from further beryllium exposure in the medical community and among other experts in beryllium disease prevention and treatment. Physicians at National Jewish, one of the main CBD research and treatment sites in the US, “consider it important and prudent for individuals with beryllium sensitization and CBD to minimize their exposure to airborne beryllium,” and “recommend individuals diagnosed with beryllium sensitization and CBD who continue to work in a beryllium industry to have exposure of no more than 0.01 micrograms per cubic meter of beryllium as an 8-hour time-weighted average” (National Jewish site on Chronic Beryllium Disease: Work Environment Management, accessed May 2013). The Department of Energy included MRP in its Chronic Beryllium Disease Prevention Program (10 CFR part 850), stating that without MRP, employers would be “free to maintain high-risk workers in their current jobs, which would not be sufficiently protective of their health” (64 FR 68894, December 8, 1999). MRP is included in the recommended beryllium standard that beryllium industry and union stakeholders submitted to OSHA in 2012 (Materion and United Steelworkers, 2012).

OSHA believes that MRP also improves the medical surveillance program described in proposed paragraph (k). Paragraph (k)(1)(i)(B) requires medical examinations for employees showing signs or symptoms of CBD. The success of that program will depend in part on employees’ willingness to report their symptoms, submit to examinations, respond to questions, and comply with instructions. Guaranteeing paid leave or comparable work can help allay an employee’s fear that a CBD diagnosis will negatively affect earnings or career prospects. MRP encourages employees

to report their symptoms and seek treatment, as OSHA has previously recognized when including medical removal in regulations governing the exposure to lead (43 FR 52973, November 14, 1978), benzene (52 FR 34557, September 11, 1987), and cadmium (57 FR 42367–68, September 14, 1992). This reasoning was also cited by the Department of Energy in support of the medical removal provisions of its Chronic Beryllium Disease Prevention Program, stating that the availability of medical removal benefits encourages worker participation and cooperation in medical surveillance (64 FR 68893, December 8, 1999).

MRP also provides an incentive for employers to keep employee exposures low. The risk of developing CBD or beryllium sensitization decreases at lower exposures (see this preamble at section VI, Preliminary Risk Assessment), meaning that employers can improve their chances of avoiding MRP costs by lowering employee exposure levels. OSHA previously noted this incentive when describing MRP provisions in the Lead standard (43 FR 52973, November 14, 1978) and the Cadmium standard (57 FR 42368, September 14, 1992).

Finally, OSHA’s preliminary risk assessment indicates that significant risk remains at the proposed TWA PEL (see this preamble at section VI, Preliminary Risk Assessment). MRP offers additional protection for situations in which workers develop CBD or beryllium sensitization despite exposures at or below the PEL. As discussed above regarding the definition of “action level” in paragraph (b), if OSHA finds a continuing exposure risk at the PEL, it has the authority to impose additional feasible requirements on employers to further reduce risk when those requirements will result in a greater than minimal incremental benefit to workers’ health (*Asbestos II*, 838 F.2d at 1274).

During the SBREFA process, SERs commented that small entities may lack the flexibility and resources to provide comparable positions for MRP-eligible employees (OSHA 2008b). The SBREFA Panel recommended that OSHA give careful consideration to the impacts that an MRP requirement could have on small businesses (OSHA, 2008b). In response to this recommendation, the Agency has provided flexibility in how employers may comply with MRP requirements. Where employers have no comparable positions in environments with exposures below the action level, the proposed standard permits an employer to place eligible employees on paid leave for six months, or until

comparable work becomes available. Under proposed paragraph (l)(4), if an employee is placed on paid leave and receives government or employer-provided compensation, or such paid leave allows the employee to secure other work, the original employer’s compensation obligations would be offset. Also in response to the Panel’s recommendations, OSHA analyzed Regulatory Alternative #22, which would eliminate the proposed requirement to offer MRP to employees with beryllium sensitization or CBD.

Finally, OSHA notes that there is considerable scientific uncertainty about the effects of exposure cessation on the development of CBD among sensitized individuals and the progression from early-stage to late-stage CBD. Members of the medical community support removal from beryllium exposure as a prudent step in the management of beryllium sensitization and disease. For example, physicians at National Jewish Medical Center, a leading organization in CBD research and treatment, recommend individuals diagnosed with beryllium sensitization and CBD who continue to work in a beryllium industry to have exposure of no more than 0.01 micrograms per cubic meter of beryllium as an 8-hour TWA (<http://www.nationaljewish.org/healthinfo/conditions/beryllium-disease/environment-management/>). However, the scientific literature on the effects of exposure cessation is limited. It suggests that removal from exposure can have beneficial effects for some individuals, but provides no conclusive evidence on whether exposure cessation will prevent CBD or CBD progression for most people (see this preamble at Section V, Health Effects, and Section VIII, Significance of Risk).

OSHA proposes to include MRP in the beryllium standard, providing workers with sensitization or CBD the opportunity and means to minimize their further exposure to beryllium via MRP in keeping with the recommendation of beryllium specialists in the medical community and with the draft recommended standard provided by union and industry stakeholders (Materion and Steelworkers, 2012).

OSHA solicits comments on the health effects of MRP and the proposed provisions for MRP. Is MRP an appropriate means of intervention in the disease process for workers with beryllium sensitization or CBD? Do the proposed MRP provisions appropriately balance SBREFA commenters’ concerns with the need to reduce beryllium exposure for employees with

sensitization or CBD? Please comment on whether MRP should be included in the standard (Regulatory Alternative #22). Please explain your positions on these issues and provide any relevant data or studies.

(m) Communication of Hazards to Employees

Paragraph (m) of this proposal sets forth the employer's obligations to comply with OSHA's Hazard Communication standard (HCS)(29 CFR 1910.1200), and to take additional steps to warn and train employees about the hazards of beryllium.

Paragraph (m)(1)(i) of this proposal requires chemical manufacturers, importers, distributors, and employers to comply with all applicable requirements of the HCS for beryllium. As described in this preamble at section V, Health Effects, and section VI, Preliminary Beryllium Risk Assessment, OSHA considers beryllium a hazardous chemical.

In classifying the hazards of beryllium, the employer must address at least the following: Cancer; lung effects (chronic beryllium disease and acute beryllium disease); beryllium sensitization; skin sensitization; and skin, eye, and respiratory tract irritation (paragraph (m)(1)(ii)). According to the HCS, employers must classify hazards if they do not rely on the classifications of chemical manufacturers, importers, and distributors (see 29 CFR 1910.1200(d)(1)).

Paragraph (m)(1)(iii) requires that employers include beryllium in the hazard communication program established to comply with the HCS, and ensure that each employee has access to labels on containers and safety data sheets for beryllium and is trained in accordance with the HCS and paragraph (m)(4) of this proposal.

According to paragraph (e)(1)(ii) of this proposal, employers must establish and maintain regulated areas wherever employees are or can reasonably be expected to be exposed to beryllium at levels above the TWA PEL or STEL, and each employee entering a regulated area must wear a respirator and protective clothing and equipment in accordance with paragraphs (g) and (h) of this standard. Under paragraph (m)(2) of this proposal, employers must provide and display warning signs at each approach to a regulated area so that each employee is able to read and understand the signs and take necessary protective steps before entering the area.

Employers must ensure that warning signs required by paragraph (m)(2) are legible and readily visible, and that they bear the following legend:

Danger; Beryllium; May Cause Cancer; Causes Damage to Lungs; Authorized Personnel Only; Wear respiratory protection and protective clothing and equipment in this area.

Some SERs objected to having cancer warnings displayed on the legends for warning signs and labels. They expressed the opinion that cancer warnings would unnecessarily scare customers and employees. Further, they alleged evidence for beryllium causation of cancer was not sufficient (OSHA, 2008b). OSHA disagrees with these comments. OSHA has thoroughly reviewed the literature for beryllium carcinogenicity, and has preliminarily concluded that beryllium is carcinogenic. OSHA's finding that inhaled beryllium causes lung cancer is based on the best available epidemiological data, reflects evidence from animal and mechanistic research, and is consistent with the conclusions of other government and public health organizations (see this preamble at section V, Health Effects). For example, the International Agency for Research on Cancer (IARC), National Toxicology Program (NTP), and American Conference of Governmental Industrial Hygienists (ACGIH) have all classified beryllium as a known human carcinogen (IARC, 2009). OSHA believes that the weight of evidence is sufficient to support the requirement for cancer warnings on signs and labels.

The signs required by paragraph (m)(2) of this proposal are intended to serve as a warning to employees and others who may not be aware that they are entering a regulated area, and to remind them of the hazards of beryllium so that they take necessary protective steps before entering the area. These signs are also intended to supplement the training that employees must receive regarding the hazards of beryllium, since even trained employees need to be reminded of the locations of regulated areas and of the precautions necessary before entering these dangerous areas (see paragraph (m)(4) of this proposal and 29 CFR 1910.1200(h) for training requirements).

The use of warning signs is important to make employees who are regularly scheduled to work at these sites aware of beryllium hazards, to alert employees who have limited access to these sites of beryllium hazards, and to warn those who do not have access to regulated areas to avoid the area. Access must be limited to authorized personnel to ensure that those entering the area are adequately trained and equipped, and to limit exposure to those whose presence is absolutely necessary. By limiting access to authorized persons, employers

can minimize employee exposure to beryllium in regulated areas and thereby minimize the number of employees that may require medical surveillance or be subject to the other requirements in this proposal associated with working in a regulated area.

Paragraph (m)(2) specifies the wording of the warning signs for regulated areas in order to ensure that the proper warning is consistently given to employees, and to notify employees that respirators and personal protective clothing and equipment are required in the regulated area. OSHA believes that the use of the word "Danger" is appropriate, based on the evidence of the toxicity of beryllium. "Danger" is used to attract the attention of employees to alert them to the fact that they are entering an area where the TWA PEL or STEL may be exceeded, and to emphasize the importance of the message that follows. The use of the word "Danger" is also consistent with other OSHA health standards dealing with toxins such as cadmium (29 CFR 1910.1027), methylenedianiline (29 CFR 1910.1050), asbestos (29 CFR 1910.1001), and benzene (29 CFR 1910.1028). In addition, use of the word "Danger" for this chemical is consistent with the Globally Harmonized System of Classification and Labeling of Chemical guidelines (GHS) (77 FR 17740-48, March 26, 2012). In the **Federal Register** notice for the revised HCS, which incorporates the GHS, OSHA explains that for substance-specific standards, warning signs must be as consistent as possible with label information for that substance (*Id.*).

Paragraph (m)(3) requires that labels be affixed to all bags and containers of clothing, equipment, and materials visibly contaminated with beryllium. The term "materials" includes waste, scrap, debris, and any other items visibly contaminated with beryllium that are consigned for disposal or recycling (see paragraphs (h)(2)(iv) and (v) and (j)(3)(i) through (iii)). The labels must state:

Danger; Contains Beryllium; May Cause Cancer; Causes Damage to Lungs; Avoid Creating Dust; Do Not Get on Skin.

The purpose of this labeling requirement is to ensure that all affected employees, not only the employees of a particular employer, are apprised of the presence of beryllium-containing materials and the hazardous nature of beryllium exposure. With this knowledge, employees can take steps to protect themselves through proper work practices established by their employers. Employees are also better able to alert their employers if they

believe exposures or skin contamination can occur.

As discussed previously, these labeling requirements are consistent with the HCS, which requires classification of hazardous chemicals and labeling appropriate for the classification (see 77 FR 17740–48, March 26, 2012). In addition, these requirements for labeling are consistent with the mandate of section (6)(b)(7) of the OSH Act, which requires that OSHA health standards prescribe the use of labels or other appropriate forms of warning to apprise employees of the hazards to which they are exposed.

Paragraph (m)(4) contains requirements for employee information and training, and applies to all employees who are or can reasonably be expected to be exposed to airborne beryllium. Employers must ensure that employees receive information and training in accordance with the requirements of the HCS (29 CFR 1910.1200(h)), including specific information on beryllium as well as any other hazards addressed in the workplace hazard communication program. Under the HCS, employers must provide their employees with information such as the location and availability of the written hazard communication program, including lists of hazardous chemicals and safety data sheets, and the location of operations in their work areas where hazardous chemicals are present. The HCS also requires employers to train their employees on ways to detect the presence or release of hazardous chemicals in the work area such as any monitoring conducted, the physical and health hazards of the chemicals in the work area, measures employees can take to protect themselves, and the details of the employer's hazard communication program (29 CFR 1910.1200(h)(3)).

Under paragraph (m)(4)(i)(B), training must be provided to each employee by the time of initial assignment, which means before the employee's first day of work in a job that could reasonably be expected to involve exposure to airborne beryllium. This training must be repeated at least annually thereafter ((m)(4)(i)(C)). OSHA believes that annual retraining is necessary due to the hazards of beryllium exposure, and for reinforcement of employees' knowledge of those hazards. The annual training requirement is consistent with other OSHA standards such as those for lead (29 CFR 1910.1025), cadmium (29 CFR 1910.1027), benzene (29 CFR 1910.1028), coke oven emissions (29 CFR 1910.1029), cotton dust (29 CFR 1910.1043), and butadiene (29 CFR 1910.1051).

Paragraph (m)(4)(ii) requires the employer to ensure that each employee who is or can reasonably be expected to be exposed to airborne beryllium can demonstrate knowledge of nine enumerated categories of information (see paragraph (m)(4)(ii)(A)—(I)). Providing information and training on these topics is essential to informing employees of current hazards and explaining how to minimize potential health hazards associated with beryllium exposure. As part of an overall hazard communication program, training serves to explain and reinforce the information presented on labels and safety data sheets. These written forms of communication will be most effective when employees understand the information presented and are aware of how to avoid or minimize exposures, thereby reducing the possibility of experiencing adverse health effects. Training should lead to better work practices and hazard avoidance.

The training requirements in paragraph (m)(4)(ii) are performance-oriented. This paragraph lists the topics that training must address, but does not prescribe specific training methods. OSHA believes that the employer is in the best position to determine how to conduct training that imparts knowledge and promotes retention. Appropriate training may include video, DVD or slide presentations; classroom instruction; hands-on training; informal discussions during safety meetings; written materials; or a combination of these methods. This performance-oriented approach is intended to encourage employers to tailor training to the needs of their workplaces, thereby resulting in the most effective training program in each individual workplace.

For training to be effective, the employer must ensure that it is provided in a manner that each employee is able to understand. OSHA recognizes that employees have varying education levels, literacy levels, and language skills, and is requiring that they receive training in a language and at a level of complexity that accounts for these differences. This may require, 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 well. The employer would not be required to provide training in the employee's preferred language if the employee understands both languages; as long as the employee is able to understand the language used, the intent of the proposed standard would be met.

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. When video presentations or computer-based programs are used, employers may meet this requirement 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.

In addition to being performance-oriented, these training requirements are also results-oriented. Paragraph (m)(4)(ii) requires employers to ensure that affected employees can demonstrate knowledge of the nine topics enumerated in paragraph (m)(4)(ii)(A) through (I). Accordingly, employers must ensure that employees participate in and comprehend the training, and are able to demonstrate knowledge of the specified topics. Some examples of methods to ensure knowledge are discussions of the required training subjects, written tests, or oral quizzes. Although the standard only requires annual retraining, employers must ensure that employees can demonstrate up-to-date knowledge of the listed topics at all times.

Paragraph (m)(4)(iii) requires employers to provide additional training, even if a year has not passed since the previous training, when workplace changes (such as modification of equipment, tasks, or procedures) result in new or increased employee exposure that exceeds or can reasonably be expected to exceed either the TWA PEL or the STEL. Some examples of changes in work conditions triggering the requirement for additional training include changes in work production operations or personnel that affect the way employees operate equipment. Additional training would also be required if employers introduce new production or personal protective equipment where employees do not yet know how to properly use the new equipment. Misuse of either the new production equipment or PPE could result in new exposures above the TWA PEL or STEL. As another example, employers must provide additional training before employees repair or upgrade engineering controls if exposures during these activities will exceed or can reasonably be expected to exceed either the TWA PEL or the STEL. OSHA believes the additional training requirement in this proposal is essential because it ensures that employees are able to actively participate in protecting themselves under the conditions found in the workplace, even if those conditions change.

Paragraph (m)(5) requires that employers make copies of the standard and its appendices readily available at no cost to each employee and designated employee representative. This requirement ensures that employees and their representatives have direct access to regulations affecting them, and knowledge of the protective measures employers must take on employees' behalf.

Commenters to both the RFI and SBREFA recognized the importance of educating and training their employees about the hazards of beryllium exposure. In commenting on an earlier OSHA draft standard for beryllium during the SBREFA process, several companies (*e.g.*, Morgan Bronze Products, Precision Stamping, and Mid Atlantic Coatings) supported training that was understandable to the employee. They agreed that employees should be able to demonstrate knowledge of health hazards associated with beryllium exposure, and the medical surveillance program as described in paragraph (k) of this section. They also supported additional training when exposures exceed the PEL (OSHA 2008b). Most SERs reported already training their employees about beryllium risks and how employees can protect themselves (OSHA, 2008b). OSHA agrees with comments supporting the necessity of training, and in order to assist in the development of training programs, intends to develop outreach materials and other guidance materials.

#### (n) Recordkeeping

Paragraph (n) of the proposed standard requires employers to maintain records of exposure measurements, historical monitoring data, objective data, medical surveillance, and training. The recordkeeping requirements are proposed in accordance with section 8(c) of the 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 Act or for developing information regarding the causes and prevention of occupational injuries and illnesses. The proposed recordkeeping provisions are also consistent with OSHA's standard addressing access to employee exposure and medical records (29 CFR 1910.1020).

Proposed paragraph (n)(1)(i) requires employers to keep records of all measurements taken to monitor employee exposure to beryllium as required by paragraph (d) of this standard. Paragraph (n)(1)(ii) would require that such records include the

following information: The date of measurement for each sample taken; the operation involving exposure to beryllium that was monitored; the sampling and analytical methods used and evidence of their accuracy; the number, duration, and results of samples taken; the types of respiratory protection and other personal protective equipment used; and the name, social security number, and job classification of each employee represented by the monitoring, indicating which employees were actually monitored.

These requirements are consistent with those found in other OSHA standards, such as those for methylene chloride (29 CFR 1910.1052) and chromium (VI) (29 CFR 1910.1026). These standards, like most of OSHA's substance-specific standards, require that exposure monitoring and medical surveillance records include the employee's social security number. OSHA has included this requirement in the past because social security numbers are particularly useful in identifying employees, since each number is unique to an individual for a lifetime and does not change when an employee changes employers. When employees have identical or similar names, identifying employees solely by name makes it difficult to determine to which employee a particular record pertains. However, based on privacy concerns, OSHA examined alternatives to requiring social security numbers for employee identification as part of its Standards Improvement Project-Phase II ("SIPs") Final Rule. The Agency analyzed public comment on the necessity, usefulness, and effectiveness of social security numbers as a means of identifying employee records. OSHA also analyzed comments regarding privacy concerns raised by this requirement, as well as the availability of other effective methods of identifying employees for OSHA recordkeeping purposes. Comments were divided regarding whether social security information should be retained for exposure and medical records. The Agency examined the comments and decided not to take any action in the SIPs final rule regarding the use of social security numbers because the conflicting comments all raised significant concerns, and OSHA wished to study the issue further. (See 70 FR 1112, 1126–27, March 7, 2005).

In this rulemaking, OSHA proposes to continue to require the use of social security numbers. OSHA emphatically recommends against distributing or posting employees' social security numbers with monitoring results. OSHA welcomes comment on this issue.

Proposed paragraph (n)(2) addresses historical monitoring data. Paragraph (n)(2)(i) would require employers to establish and maintain an accurate record of any historical monitoring data used to satisfy the initial monitoring requirements in paragraph (d)(2) of this standard. As explained earlier in this preamble, paragraph (d)(2) permits employers to substitute beryllium monitoring results obtained at an earlier time for the initial monitoring requirements, as long as employers abide by the criteria specified. Paragraph (n)(2)(ii) requires the employer to establish and maintain records or documents showing that the criteria discussed in paragraph (d)(2) are met. This would mean documenting the workplace conditions present when the historical data were collected, for purposes of showing that those conditions closely resemble the conditions present in the employer's current operations. Employers should also document the dates of reliance on the historical data as well as the dates on which the historical data were collected.

Proposed paragraph (n)(3) addresses objective data. Proposed paragraph (n)(3)(i) requires employers to establish and maintain accurate records of the objective data relied upon to satisfy the requirement for initial monitoring in proposed paragraph (d)(2). Under proposed paragraph (n)(3)(ii), the record must contain the following information: The data relied upon; the beryllium-containing material in question; the source of the data; a description of the operation exempted from initial monitoring and how the data support the exemption; and other information demonstrating that the data meet the requirements for objective data in accordance with paragraph (d)(2). Such other information may include reports of engineering controls, work area layout and dimensions, and natural air movements pertaining to the data and current conditions.

Since historical and objective data may be used to exempt the employer from certain types of monitoring, as specified in paragraph (d), it is critical that the use of these types of data be carefully documented. Historical and objective data are intended to provide the same degree of assurance that employee exposures have been correctly characterized as would exposure monitoring. The records must demonstrate a reasonable basis for conclusions drawn from the data.

Under proposed paragraph (n)(4)(i) employers must establish and maintain accurate medical surveillance records for each employee covered by the

medical surveillance requirements of the standard in paragraph (k). Paragraph (n)(4)(ii) lists the categories of information that an employer would be required to record: the employee's name, social security number, and job classification; a copy of all physicians' written opinions; and a copy of the information provided to the PLHCP as required by paragraph (k)(4) of this standard.

OSHA believes that medical records, like exposure records, are necessary and appropriate. Medical records document the results of medical surveillance and the screening of employees. Employers can use the information contained in the records to identify and adjust hazardous workplace conditions and mitigate exposures. Employees can use these records to make informed decisions regarding medical surveillance and medical removal. PLHCPs would have the records to use in any further employee consultations or in making recommendations at a later time. In sum, medical records play an important part in properly evaluating the effects of beryllium exposure on employees' health.

Paragraph (n)(5)(i) would require that employers prepare and maintain records of any training required by this standard. At the completion of training, the employer would be required to prepare a record that indicates the name, social security number, and job classification of each employee trained; the date the training was completed; and the topic of the training. This record maintenance requirement would also apply to records of annual retraining or additional training as described in paragraph (m)(4).

Proposed paragraphs (n)(1) through (4) require employers to maintain exposure measurements, historical monitoring data, and medical surveillance records, respectively, in accordance with OSHA's Records Access standard (29 CFR 1910.1020). That standard, specifically 29 CFR 1910.1020(d), requires employers to ensure the preservation and retention of exposure and medical records. Exposure measurements and historical monitoring data are considered employee exposure records that must be maintained for at least 30 years in accordance with 29 CFR 1910.1020(d)(1)(ii). Medical surveillance records must be maintained for at least the duration of employment plus 30 years in accordance with 29 CFR 1910.1020(d)(1)(i).

Proposed paragraph (n)(5)(ii) requires employers to retain training records, including records of annual retraining or additional training required under this standard, for a period of three years

after the completion of the training. OSHA believes that the retention period for training records is reasonable for documentation purposes. The three year period for the maintenance of training records is consistent with the Bloodborne Pathogens standard (29 CFR 1910.1030). Other OSHA standards require training records to be kept for one year beyond the last date of employment (*e.g.*, Asbestos (29 CFR 1910.1001), Methylenedianiline in construction (29 CFR 1926.60), and Asbestos in construction (29 CFR 1926.1101)).

These maintenance provisions, as well as the access requirements discussed below, ensure that records are available to employees so that they may examine the employer's exposure measurements, historical monitoring data, and objective data, as well as medical surveillance and training records, and evaluate whether employees are being adequately protected. Moreover, compliance with the requirement to maintain records of exposure data will enable the employer to show, at least for the duration of the retention-of-records period, that the requirements of this standard were carried out appropriately. For example, maintenance of these types of data could protect employers from allegations of violating paragraph (d)(2). The lengthy record retention period is necessitated by the long latency period commonly associated with diseases such as chronic beryllium disease and cancer (see this preamble at section V, Health Effects).

Paragraph (n)(6) requires that all records mandated by this standard must be made available for examination and copying to the Assistant Secretary, the Director of NIOSH, each employee, and each employee's designated representative as stipulated by OSHA's Records Access standard (29 CFR 1910.1020).

Paragraph (n)(7) requires that employers comply with the Records Access standard regarding the transfer of records. Specifically, the requirements for the transfer of records are explained in 29 CFR 1910.1020(h), which instructs employers either to transfer records to successor employers or, if there is no successor employer, to inform employees of their access rights at least three months before the cessation of the employer's business.

Commenters to the RFI fully endorsed the need for the collection and maintenance of health-related records dealing with beryllium exposure, as well as those for employee hazard training (Brush Wellman, 2003). No comments were received in opposition

to the need for such recordkeeping. However, one commenter suggested that most dental labs will not have any incentive to comply with the recordkeeping requirements because they have fewer than ten employees and therefore would not be subject to OSHA audits of their records. The commenter noted that OSHA will have difficulty measuring the effectiveness of the standard if small businesses do not keep accurate records (OSHA, 2007a). OSHA does not intend to exempt small businesses from the recordkeeping requirements in this proposal because the Agency believes the severity of disease resulting from beryllium exposure is great enough to justify requiring small businesses to maintain employee health records in accordance with this proposal. Also, recordkeeping for fewer employees should be less resource-intensive than for a larger organization. OSHA requests comment on the appropriateness of the proposed recordkeeping requirements.

#### (o) Dates

According to paragraph (o), this standard will become effective 60 days after the publication of the final rule in the **Federal Register**. OSHA intends for this period to allow affected employers the opportunity to familiarize themselves with the standard and to make preparations in order to be in compliance by the start-up dates. Under paragraph (o)(2), employer obligations to comply with most requirements of the final rule would begin 90 days after the effective date (150 days after publication of the final rule). This additional time period is designed to allow employers to complete initial exposure assessments or otherwise make exposure determinations by use of historical or objective data, to establish regulated areas, to obtain appropriate work clothing and equipment, and to comply with other provisions of the rule.

There are two exceptions to the normal start-up intervals—establishing change rooms and implementing engineering controls—that provide additional time for employers to comply. Change rooms are required no later than one year after the effective date of the standard, and engineering controls need to be in place within two years after the effective date. The delayed start-up dates allow affected employers sufficient time to design and construct change rooms where necessary, and to design, obtain, and install any required control equipment. In addition, the longer intervals for change rooms and engineering controls are consistent with other OSHA



substance-specific standards such as those for chromium (VI) (29 CFR 1910.1026) and cadmium (29 CFR 1910.1027). OSHA solicits comment on the appropriateness of these proposed start-up dates.

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## Authority and Signature

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, directed the preparation of this notice. OSHA is issuing this notice under Sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); section 41 of the Longshore and Harbor Worker's Compensation Act (33 U.S.C. 941); section 107 of the Contract Work Hours and Safety Standards Act (Construction Safety Act) (40 U.S.C. 3704); Secretary of Labor's Order 1–2012 (77 FR 3912, January 25, 2012); and 29 CFR part 1911.

Signed at Washington, DC, on July 14, 2015.

### David Michaels,

*Assistant Secretary of Labor for Occupational Safety and Health.*

## Proposed Standard

Chapter XVII of Title 29 of the Code of Federal Regulations is proposed to be amended as follows:

## PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

### Subpart Z—Toxic and Hazardous Substances

■ 1. The authority citation for subpart Z of part 1910 is revised to read as follows:

**Authority:** Sections 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. 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; 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.

## List of Subjects in 29 CFR Part 1910

Cancer, Chemicals, Hazardous substances, Health, Occupational safety and health, Reporting and recordkeeping requirements.

**§ 1910.1000 [Amended]**

■ 2. In § 1910.1000:  
 ■ a. Table Z-1 is amended by revising the entry for “Beryllium and beryllium

compounds (as Be)”; and by adding footnote “W”; and  
 ■ b. Table Z-2 is amended by adding footnote “Y”.

The revisions and additions read as follows:

**TABLE Z-1—LIMITS FOR AIR CONTAMINANTS**

Substance	CAS No. (c)	ppm (a) <sup>1</sup>	mg/m <sup>3</sup> (b) <sup>1</sup>	Skin designation
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *
Beryllium and beryllium compounds (as Be); see 1910.1024 <sup>w</sup> .				
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *

<sup>1</sup> 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 cotton 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.

<sup>w</sup> See Table Z-2 for the exposure limits for any operations or sectors for which the exposure limits in § 1910.1024 are not in effect.

**TABLE Z-2**

Substance	8-hour time weighted average	Acceptable ceiling concentration	Acceptable maximum peak above the acceptable ceiling average concentration for an 8-hr shift	
			Concentration	Maximum duration
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *
Beryllium and beryllium compounds (as Be) <sup>y</sup> .....	2 µg/m <sup>3</sup>	5 µg/m <sup>3</sup>	25µg/m <sup>3</sup>	30 minutes
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *
* * * * *	* * * * *	* * * * *	* * * * *	* * * * *

<sup>y</sup> This standard applies to any operations or sectors for which the Beryllium standard, 1910.1024, is not in effect.

■ 3. Section 1910.1024 is added to subpart Z to read as follows:

**§ 1910.1024 Beryllium**

(a) *Scope and application.* (1) This section applies to occupational exposures to beryllium in all forms, compounds, and mixtures in general industry, except those articles and materials exempted by paragraphs (a)(2) and (3) of this section.

(2) This section does not apply to articles, as defined in the Hazard Communication standard (HCS) (29 CFR 1910.1200(c)), that contain beryllium and that the employer does not process.

(3) This section does not apply to materials containing less than 0.1% beryllium by weight.

(b) *Definitions.*

*Action level* means a concentration of airborne beryllium of 0.1 micrograms

per cubic meter of air (µg/m<sup>3</sup>) calculated as an 8-hour time-weighted average (TWA).

*Assistant Secretary* means the Assistant Secretary of Labor for Occupational Safety and Health, United States Department of Labor, or designee.

*Beryllium lymphocyte proliferation test (BeLPT)* means the measurement of blood lymphocyte proliferation in a laboratory test when lymphocytes are challenged with a soluble beryllium salt. A confirmed positive test result indicates the person has beryllium sensitization.

*Beryllium work area* means any work area where employees are, or can reasonably be expected to be, exposed to airborne beryllium, regardless of the level of exposure.

*CBD Diagnostic Center* means a medical diagnostic center that has on-site facilities to perform a clinical evaluation for the presence of chronic beryllium disease (CBD) that includes bronchoalveolar lavage, transbronchial biopsy and interpretation of the biopsy pathology, and the beryllium bronchoalveolar lavage lymphocyte proliferation test (BeBALLPT).

*Chronic beryllium disease (CBD)* means a chronic lung disease associated with exposure to airborne beryllium.

*Confirmed Positive* means two abnormal test results from either consecutive BeLPTs or a second abnormal BeLPT result within a 2-year period of the first abnormal test result. It also means the result of a more reliable and accurate test indicating a

person has been identified as having beryllium sensitization.

*Director* means the Director of the National Institute for Occupational Safety and Health (NIOSH), U.S. Department of Health and Human Services, or designee.

*Emergency* means any uncontrolled release of airborne beryllium.

*Exposure and exposure to beryllium* mean the exposure to airborne beryllium 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 particles 0.3 micrometers in diameter.

*Physician or other licensed health care professional (PLHCP)* means an individual whose legally permitted scope of practice (*i.e.*, license, registration, or certification) allows the individual to independently provide or be delegated the responsibility to provide some or all of the health care services required by paragraph (k) of this standard.

*Regulated area* means an area that the employer must demarcate, including temporary work areas where maintenance or non-routine tasks are performed, where an employee's exposure exceeds, or can reasonably be expected to exceed, either of the permissible exposure limits (PELs).

*This standard* means this beryllium standard, 29 CFR 1910.1024.

(c) *Permissible Exposure Limits (PELs)*. (1) *Time-weighted average (TWA) PEL*. The employer shall ensure that each employee's exposure does not exceed 0.2  $\mu\text{g}/\text{m}^3$  calculated as an 8-hour TWA.

(2) *Short-term exposure limit (STEL)*. The employer shall ensure that each employee's exposure does not exceed 2.0  $\mu\text{g}/\text{m}^3$  as determined over a sampling period of 15 minutes.

(d) *Exposure monitoring*—(1) *General*.

(i) These exposure monitoring requirements apply when employees are, or may reasonably be expected to be, exposed to airborne beryllium.

(ii) Except as provided in paragraphs (d)(2)(i) and (ii) of this section, the employer shall determine the 8-hour TWA exposure for each employee based on one or more breathing zone samples that reflect the exposure of employees on each work shift, for each job classification, in each beryllium work area.

(iii) Except as provided in paragraph (d)(2)(i) and (ii) of this section, the employer shall determine short-term exposure from 15-minute breathing zone samples measured in operations that are likely to produce exposures above the STEL for each work shift, for each job

classification, and in each beryllium work area.

(iv) The employer may perform representative sampling to characterize exposure, provided that the employer:

(A) Performs representative sampling where several employees perform the same job tasks, in the same job classification, on the same work shift, and in the same work area, and have similar duration and frequency of exposure;

(B) Takes sufficient personal breathing zone air samples to accurately characterize exposure on each work shift, for each job classification, in each work area; and

(C) Samples those employee(s) who are expected to have the highest exposure.

(v) *Accuracy of measurement*. The employer shall use a method of exposure monitoring and analysis that can measure beryllium to an accuracy of plus or minus 25 percent within a statistical confidence level of 95 percent for airborne concentrations at or above the action level.

(2) *Initial exposure monitoring*. The employer shall conduct initial exposure monitoring to determine the 8-hour TWA exposure and 15-minute short-term exposure for each employee. The employer does not have to conduct initial exposure monitoring in the following situations:

(i) Where the employer has conducted exposure monitoring for beryllium and relies on these historical data, provided that:

(A) The work operations and workplace conditions that were in place when the historical monitoring data were obtained reflect workplace conditions closely resembling the processes, material, control methods, work practices, and environmental conditions used and prevailing in the employer's current operations;

(B) The characteristics of the beryllium-containing material being handled when the historical monitoring data were obtained closely resemble the characteristics of the beryllium-containing material used during the job for which initial monitoring will not be performed; and

(C) The exposure monitoring satisfied all other requirements of this section, including Accuracy of Measurement in paragraph (d)(1)(v).

(ii) Where the employer relies on objective data to satisfy initial monitoring requirements, provided that such data:

(A) Demonstrate that any material containing beryllium or any specific process, operation, or activity involving beryllium cannot release beryllium dust,

fumes, or mist in concentrations at or above the action level or above the STEL under any expected conditions of use; and

(B) Reflect workplace conditions closely resembling the processes, material, control methods, work practices, and environmental conditions used and prevailing in the employer's current operations.

(3) *Periodic exposure monitoring*. If initial exposure monitoring indicates that exposures are at or above the action level and at or below the TWA PEL, the employer shall conduct periodic exposure monitoring at least annually in accordance with paragraph (d)(1) of this section.

(4) *Additional monitoring*. The employer also shall conduct exposure monitoring within 30 days after any of the following situations occur:

(i) Any change in production processes, equipment, materials, personnel, work practices, or control methods that can reasonably be expected to result in new or additional exposure; or

(ii) The employer has any other reason to believe that new or additional exposure is occurring.

(5) *Employee notification of monitoring results*. (i) Within 15 working days after receiving the results of any exposure monitoring completed under this standard, the employer shall notify each employee whose exposure is measured or represented by the monitoring individually in writing of the monitoring results or shall post the monitoring results in an appropriate location that is accessible to each of these employees.

(ii) Where exposures exceed the TWA PEL or STEL, the written notification required by paragraph (d)(5)(i) of this section shall include suspected or known sources of exposure and the corrective action(s) the employer has taken or will take to reduce exposure to or below the PELs, where feasible corrective action exists but had not been implemented when the monitoring was conducted.

(6) *Observation of monitoring*. (i) The employer shall provide an opportunity to observe any exposure monitoring required by this standard to each employee whose exposures are measured or represented by the monitoring and each employee's representative(s).

(ii) When observation of monitoring requires entry into an area where the use of protective clothing or equipment (which may include respirators) is required, the employer shall provide each observer with appropriate protective clothing and equipment at no

cost to the observer and shall ensure that each observer uses such clothing and equipment.

(iii) The employer shall ensure that each observer complies with all applicable OSHA requirements and the employer's workplace safety and health procedures.

(e) *Beryllium work areas and regulated areas*—(1) *Establishment.* (i) The employer shall establish and maintain a beryllium work area wherever employees are, or can reasonably be expected to be, exposed to airborne beryllium, regardless of the level of exposure.

(ii) The employer shall establish and maintain a regulated area wherever employees are, or can reasonably be expected to be, exposed to airborne beryllium at levels above the TWA PEL or STEL.

(2) *Demarcation.* (i) The employer shall identify each beryllium work area through signs or any other methods that adequately establish and inform each employee of the boundaries of each beryllium work area.

(ii) The employer shall identify each regulated area in accordance with paragraph (m)(2) of this section.

(3) *Access.* The employer shall limit access to regulated areas to:

(i) Persons the employer authorizes or requires to be in a regulated area to perform work duties;

(ii) Persons entering a regulated area as designated representatives of employees for the purpose of exercising the right to observe exposure monitoring procedures under paragraph (d)(6) of this section; and

(iii) Persons authorized by law to be in a regulated area.

(4) *Provision of personal protective clothing and equipment, including respirators.* The employer shall provide and ensure that each employee entering a regulated area uses:

(i) Respiratory protection in accordance with paragraph (g) of this section; and

(ii) Personal protective clothing and equipment in accordance with paragraph (h) of this section.

(f) *Methods of compliance*—(1) *Written exposure control plan.*

(i) The employer shall establish, implement, and maintain a written exposure control plan for beryllium work areas, which shall contain:

(A) An inventory of operations and job titles reasonably expected to have exposure;

(B) An inventory of operations and job titles reasonably expected to have exposure at or above the action level;

(C) An inventory of operations and job titles reasonably expected to have exposure above the TWA PEL or STEL;

(D) Procedures for minimizing cross-contamination, including but not limited to preventing the transfer of beryllium between surfaces, equipment, clothing, materials, and articles within beryllium work areas;

(E) Procedures for keeping surfaces in the beryllium work area as free as practicable of beryllium;

(F) Procedures for minimizing the migration of beryllium from beryllium work areas to other locations within or outside the workplace;

(G) An inventory of engineering and work practice controls required by paragraph (f)(2) of this standard; and

(H) Procedures for removal, laundering, storage, cleaning, repairing, and disposal of beryllium-contaminated personal protective clothing and equipment, including respirators.

(ii) The employer shall update the exposure control plan when:

(A) Any change in production processes, materials, equipment, personnel, work practices, or control methods results or can reasonably be expected to result in new or additional exposures to beryllium;

(B) An employee is confirmed positive, is diagnosed with CBD, or shows signs or symptoms associated with exposure; or

(C) The employer has any reason to believe that new or additional exposures are occurring or will occur.

(iii) The employer shall make a copy of the exposure control plan accessible to each employee who is or can reasonably be expected to be exposed to airborne beryllium in accordance with OSHA's Access to Employee Exposure and Medical Records (Records Access) standard (29 CFR 1910.1020(e)).

(2) *Engineering and work practice controls.* (i) (A) For each operation in a beryllium work area, the employer shall ensure that at least one of the following engineering and work practice controls is in place to minimize employee exposure:

(1) Material and/or process substitution;

(2) Ventilated partial or full enclosures;

(3) Local exhaust ventilation at the points of operation, material handling, and transfer; or

(4) Process control, such as wet methods and automation.

(B) An employer is exempt from using the above controls to the extent that:

(1) The employer can establish that such controls are not feasible; or

(2) The employer can demonstrate that exposures are below the action level, using no fewer than two representative personal breathing zone samples taken 7 days apart, for each affected operation.

(ii) If after implementing the control(s) required by (f)(2)(i)(A) exposures exceed the TWA PEL or STEL, the employer shall implement additional or enhanced engineering and work practice controls to reduce exposures to or below the PELs.

(iii) Wherever the employer demonstrates that it is not feasible to reduce exposures to or below the PELs by the engineering and work practice controls required by paragraphs (f)(2)(i) and (ii) of this section, the employer shall implement and maintain engineering and work practice controls to reduce exposures to the lowest levels feasible and supplement these controls by using respiratory protection in accordance with paragraph (g) of this section.

(3) *Prohibition of rotation.* The employer shall not rotate employees to different jobs to achieve compliance with the PELs.

(g) *Respiratory protection*—(1) *General.* The employer shall provide at no cost and ensure that each employee uses respiratory protection during:

(i) Periods necessary to install or implement feasible engineering and work practice controls where exposures exceed or can reasonably be expected to exceed the TWA PEL or STEL;

(ii) Operations, including maintenance and repair activities and non-routine tasks, when engineering and work practice controls are not feasible and exposures exceed or can reasonably be expected to exceed the TWA PEL or STEL;

(iii) Work operations for which an employer has implemented all feasible engineering and work practice controls when such controls are not sufficient to reduce exposure to or below the TWA PEL or STEL;

(iv) Emergencies.

(2) *Respiratory protection program.*

Where this standard requires an employee to use respiratory protection, such use shall be in accordance with the Respiratory Protection Standard (29 CFR 1910.134).

(h) *Personal protective clothing and equipment*—(1) *Provision and use.* The employer shall provide at no cost and ensure that each employee uses appropriate personal protective clothing and equipment in accordance with the written exposure control plan required under paragraph (f)(1) of this section and OSHA's Personal Protective Equipment standards (29 CFR part 1910 subpart I):

(i) Where employee exposure exceeds or can reasonably be expected to exceed the TWA PEL or STEL;

(ii) Where employees' clothing or skin may become visibly contaminated with

beryllium including during maintenance and repair activities or during non-routine tasks; or

(iii) Where employees' skin can reasonably be expected to be exposed to soluble beryllium compounds.

(2) *Removal and storage.* (i) The employer shall ensure that each employee removes all beryllium-contaminated protective clothing and equipment:

(A) At the end of the work shift or at the completion of tasks involving beryllium, whichever comes first, or

(B) When protective clothing or equipment becomes visibly contaminated with beryllium.

(i) The employer shall ensure that each employee removes protective clothing visibly contaminated with beryllium as specified in the exposure control plan required by paragraph (f)(1) of this section.

(iii) The employer shall ensure that each employee stores and keeps required protective clothing separate from street clothing.

(iv) The employer shall ensure that no employee removes beryllium-contaminated protective clothing or equipment from the workplace, except for employees authorized to do so for the purposes of laundering, cleaning, maintaining or disposing of beryllium-contaminated protective clothing and equipment at an appropriate location or facility away from the workplace.

(v) When protective clothing or equipment required by this standard is removed from the workplace for laundering, cleaning, maintenance or disposal, the employer shall ensure that protective clothing and equipment are stored and transported in sealed bags or other closed containers that are impermeable and are labeled in accordance with paragraph (m)(3) of this section and the HCS (29 CFR 1910.1200).

(3) *Cleaning and replacement.* (i) The employer shall ensure that all reusable protective clothing and equipment required by this standard is cleaned, laundered, repaired, and replaced as needed to maintain its effectiveness.

(ii) The employer shall ensure that beryllium is not removed from protective clothing and equipment by blowing, shaking or any other means that disperses beryllium into the air.

(iii) The employer shall inform in writing the persons or the business entities who launder, clean or repair the protective clothing or equipment required by this standard of the potentially harmful effects of exposure to airborne beryllium and contact with soluble beryllium compounds and that the protective clothing and equipment

must be handled in accordance with this standard.

(i) *Hygiene areas and practices*—(1) *General.* For each employee working in a beryllium work area, the employer shall:

(i) Provide readily accessible washing facilities to remove beryllium from the hands, face, and neck; and

(ii) Ensure each employee exposed to beryllium to use these facilities when necessary.

(2) *Change rooms.* In addition to the requirements of paragraph (i)(1)(i) of this section, the employer shall provide affected employees with a designated change room and washing facilities in accordance with this standard and the Sanitation Standard (29 CFR 1910.141) where employees are required to remove their personal clothing.

(3) *Showers.* (i) The employer shall provide showers in accordance with the Sanitation standard (29 CFR 1910.141) where:

(A) Exposure exceeds or can reasonably be expected to exceed the TWA PEL or STEL; and

(B) Beryllium can reasonably be expected to contaminate employees' hair or body parts other than hands, face, and neck.

(ii) Employers required to provide showers under paragraph (i)(3)(i) of this section shall ensure that each employee showers at the end of the work shift or work activity if:

(A) The employee reasonably could have been exposed above the TWA PEL or STEL; and

(B) Beryllium could reasonably have contaminated the employee's hair or body parts other than hands, face, and neck.

(4) *Eating and drinking areas.* Whenever the employer allows employees to consume food or beverages in a beryllium work area, the employer shall ensure that:

(i) Surfaces in eating and drinking areas are as free as practicable of beryllium;

(ii) No employee in eating and drinking areas is exposed to airborne beryllium at or above the action level; and

(iii) Eating and drinking facilities provided by the employer are in accordance with the Sanitation standard (29 CFR 1910.141).

(5) *Prohibited activities.* (i) The employer shall ensure that no employees eat, drink, smoke, chew tobacco or gum, or apply cosmetics in regulated areas.

(ii) The employer shall ensure that no employees enter any eating or drinking area with protective work clothing or equipment unless surface beryllium has

been removed from the clothing or equipment by methods that do not disperse beryllium into the air or onto an employee's body.

(j) *Housekeeping*—(1) *General.* (i) The employer shall maintain all surfaces in beryllium work areas as free as practicable of accumulations of beryllium and in accordance with the exposure control plan required under paragraph (f)(1) of this section and the cleaning methods required under paragraph (j)(2) of this section; and

(ii) The employer shall ensure that all spills and emergency releases of beryllium are cleaned up promptly and in accordance with the exposure control plan required under paragraph (f)(1) of this section and the cleaning methods required under paragraph (j)(2) of this section.

(2) *Cleaning methods.* (i) The employer shall ensure that surfaces in beryllium work areas are cleaned by HEPA-filter vacuuming or other methods that minimize the likelihood and level of exposure.

(ii) The employer shall not allow dry sweeping or brushing for cleaning surfaces in beryllium work areas unless HEPA-filtered vacuuming or other methods that minimize the likelihood and level of exposure have been tried and were not effective.

(iii) The employer shall not allow the use of compressed air for cleaning beryllium-contaminated surfaces unless the compressed air is used in conjunction with a ventilation system designed to capture the particulates made airborne by the use of compressed air.

(iv) Where employees use dry sweeping, brushing, or compressed air to clean beryllium-contaminated surfaces, the employer shall provide and ensure that each employee uses respiratory protection and protective clothing and equipment in accordance with paragraphs (g) and (h) of this section.

(v) The employer shall ensure that cleaning equipment is handled and maintained in a manner that minimizes the likelihood and level of employee exposure and the re-entrainment of airborne beryllium in the workplace.

(3) *Disposal.* The employer shall ensure that:

(i) Waste, debris, and materials visibly contaminated with beryllium and consigned for disposal are disposed of in sealed, impermeable enclosures, such as bags or containers;

(ii) Bags or containers of waste, debris, and materials required by (j)(3)(i) of this section are labeled in accordance with paragraph (m)(3) of this section; and



(iii) Materials designated for recycling that are visibly contaminated with beryllium shall be cleaned to remove visible particulate, or placed in sealed, impermeable enclosures, such as bags or containers, that are labeled in accordance with paragraph (m)(3) of this section.

(k) *Medical surveillance*—(1) *General*. (i) The employer shall make medical surveillance as required by this paragraph available at no cost to the employee, and at a reasonable time and place, as follows:

(A) For each employee who has worked in a regulated area for more than 30 days in the last 12 months;

(B) For each employee showing signs or symptoms of CBD, such as shortness of breath after a short walk or climbing stairs, persistent dry cough, chest pain, or fatigue;

(C) For each employee exposed to beryllium during an emergency; and

(D) For each employee who was exposed to airborne beryllium above .2  $\mu\text{g}/\text{m}^3$  for more than 30 days in a 12-month period for 5 years or more, limited to the procedures described in paragraph (k)(3)(ii)(F) of this section unless the employee also qualifies for an examination under paragraph (k)(1)(i)(A), (B), or (C) of this section.

(ii) The employer shall ensure that all medical examinations and procedures required by this standard are performed by or under the direction of a licensed physician.

(2) *Frequency*. The employer shall provide a medical examination:

(i) Within 30 days after determining that:

(A) An employee meets the criteria of paragraph (k)(1)(i)(A) of this section, unless the employee has received a medical examination, provided in accordance with this standard, within the last 12 months; or

(B) An employee meets the criteria of paragraph (k)(1)(i)(B) or (C) of this section.

(ii) Annually thereafter for each employee who continues to meet the criteria of paragraph (k)(1)(i)(A) or (B) of this section; and

(iii) At the termination of employment for each employee who meets the criteria of paragraph (k)(1)(i)(A), (B), or (C) of this section at the time the employee's employment is terminated, unless an examination has been provided in accordance with this standard during the 6 months prior to the date of termination.

(3) *Contents of examination*. (i) The employer shall ensure that the PLHCP advises the employee of the risks and benefits of participating in the medical surveillance program and the

employee's right to opt out of any or all parts of the medical examination.

(ii) The employer shall ensure that the employee is offered a medical examination that includes:

(A) A medical and work history, with emphasis on past and present exposure, smoking history, and any history of respiratory system dysfunction;

(B) A physical examination with emphasis on the respiratory tract;

(C) A physical examination for skin breaks and wounds;

(D) Pulmonary function tests, performed in accordance with the guidelines established by the American Thoracic Society including forced vital capacity and forced expiratory volume at one (1) second (FEV<sub>1</sub>);

(E) (1) A standardized BeLPT upon the first examination and within every 2 years from the date of the first examination until the employee is confirmed positive. If a more reliable and accurate diagnostic test is developed after [EFFECTIVE DATE OF FINAL RULE] of this standard such that beryllium sensitization can be confirmed after one test, a second confirmation test need not be performed.

(2) If an employee who has not been confirmed positive receives an abnormal BeLPT result, a second BeLPT is to be performed within 1 month. This requirement for a second test is waived if a more reliable and accurate test for beryllium sensitization does not need to be repeated due to variability, repeatability and accuracy of the test methodology.

(F) Each employee who meets the criteria of paragraph (k)(1)(i)(D) shall be offered a low dose helical tomography (CT Scan). The CT Scan shall be offered every 2 years for the duration of the employee's employment. This obligation begins on the [EFFECTIVE DATE OF FINAL RULE], or on the 15th year after the employee's first exposure above .2  $\mu\text{g}/\text{m}^3$  for more than 30 days in a 12-month period, whichever is later; and

(G) Any other test deemed appropriate by the PLHCP.

(4) *Information provided to the PLHCP*. The employer shall ensure that the examining PLHCP has a copy of this standard and all appendices and shall provide the following information, if known:

(i) A description of the employee's former and current duties that relate to the employee's occupational exposure;

(ii) The employee's former and current levels of occupational exposure;

(iii) A description of any protective clothing and equipment, including respirators, used by the employee,

including when and for how long the employee has used that protective clothing and equipment; and

(iv) Information from records of employment-related medical examinations previously provided to the employee, currently within the control of the employer, after obtaining a medical release from the employee.

(5) *Licensed physician's written medical opinion*. (i) The employer shall obtain a written medical opinion from the licensed physician within 30 days of the examination, which contains:

(A) The licensed physician's opinion as to whether the employee has any detected medical condition that would place the employee at increased risk of CBD from further exposure;

(B) Any recommended limitations on the employee's exposure, including the use and limitations of protective clothing or equipment, including respirators; and

(C) A statement that the PLHCP has explained the results of the medical examination to the employee, including any tests conducted, any medical conditions related to exposure that require further evaluation or treatment, and any special provisions for use of protective clothing or equipment.

(ii) The employer shall ensure that neither the licensed physician nor any other PLHCP reveals to the employer specific findings or diagnoses unrelated to exposure to airborne beryllium or contact with soluble beryllium compounds.

(iii) The employer shall provide a copy of the licensed physician's written medical opinion to the employee within 2 weeks after receiving it.

(6) *Referral to a CBD diagnostic center*. (i) Within 30 days after an employer learns that an employee has been confirmed positive, the employer's designated licensed physician shall consult with the employee to discuss referral to a CBD diagnostic center that is mutually agreed upon by the employer and the employee.

(ii) If, after this consultation, the employee wishes to obtain a clinical evaluation at a CBD diagnostic center, the employer shall provide the evaluation at no cost to the employee.

(7) *Beryllium sensitization test results research*. Upon request by OSHA, employers must convey employees' beryllium sensitization test results to OSHA for evaluation and analysis. Employers must remove employees' names, social security numbers, and other personally identifying information from the test results before conveying them to OSHA.

(1) *Medical removal*. (1) If an employee works in a job with exposure

at or above the action level and is diagnosed with CBD or confirmed positive, the employee is eligible for medical removal.

(2) If an employee is eligible for medical removal, the employee must choose:

(i) Removal as described in paragraph (l)(3) of this section; or

(ii) To remain in a job with exposure at or above the action level, provided that the employee wears a respirator in accordance with the Respiratory Protection standard (29 CFR 1910.134).

(3) If the employee chooses removal:

(i) The employer shall remove the employee to comparable work for which the employee is qualified or can be trained within 1 month. In this standard, comparable work must be in a work environment where the exposure is below the action level. The employee must accept comparable work if such work is available;

(ii) If comparable work is not available, the employer shall place the employee on paid leave for 6 months or until such time as comparable work becomes available, whichever comes first; and

(iii) Whether the employee is removed to comparable work or placed on paid leave, the employer shall maintain for 6 months the employee's base earnings, seniority, and other rights and benefits that existed at the time of removal.

(4) The employer's obligation to provide medical removal protection benefits to a removed employee shall be reduced to the extent that the employee receives compensation for earnings lost during the period of removal from a publicly or employer-funded compensation program, or receives income from another employer made possible by virtue of the employee's removal.

(m) *Communication of hazards*—(1) *General*. (i) Chemical manufacturers, importers, distributors, and employers shall comply with all requirements of the HCS (29 CFR 1910.1200) for beryllium.

(ii) In classifying the hazards of beryllium, the employer shall address at least the following hazards: Cancer; lung effects (CBD and acute beryllium disease); beryllium sensitization; skin sensitization; and skin, eye, and respiratory tract irritation.

(iii) Employers shall include beryllium in the hazard communication program established to comply with the HCS. Employers shall ensure that each employee has access to labels on containers of beryllium and to safety data sheets, and is trained in accordance with the requirements of the HCS (29

CFR 1910.1200) and paragraph (m)(4) of this section.

(2) *Warning signs*—(i) *Posting*. The employer shall provide and display warning signs at each approach to a regulated area so that each employee is able to read and understand the signs and take necessary protective steps before entering the area.

(ii) *Sign specification*. (A) The employer shall ensure that the warning signs required by paragraph (m)(2)(i) of this section are legible and readily visible.

(B) The employer shall ensure each warning sign required by paragraph (m)(2)(i) of this section bears the following legend:

**DANGER  
BERYLLIUM  
MAY CAUSE CANCER  
CAUSES DAMAGE TO LUNGS  
AUTHORIZED PERSONNEL ONLY  
WEAR RESPIRATORY PROTECTION AND PRO-  
TECTIVE CLOTHING AND EQUIPMENT IN THIS  
AREA**

(3) *Warning labels*. The employer shall label each bag and container of clothing, equipment, and materials visibly contaminated with beryllium consistent with the HCS (29 CFR 1910.1200), and shall, at a minimum, include the following on the label:

**DANGER  
CONTAINS BERYLLIUM  
MAY CAUSE CANCER  
CAUSES DAMAGE TO LUNGS  
AVOID CREATING DUST  
DO NOT GET ON SKIN**

(4) *Employee information and training*. (i) For each employee who is or can reasonably be expected to be exposed to airborne beryllium:

(A) The employer shall provide information and training in accordance with the HCS (29 CFR 1910.1200(h));

(B) The employer shall provide initial training to each employee by the time of initial assignment; and

(C) The employer shall repeat the training required under this section annually for each employee.

(ii) The employer shall ensure that each employee who is or can reasonably be expected to be exposed to airborne beryllium can demonstrate knowledge of the following:

(A) The health hazards associated with exposure to beryllium and contact with soluble beryllium compounds, including the signs and symptoms of CBD;

(B) The written exposure control plan, with emphasis on the location(s) of beryllium work areas, including any regulated areas, and the specific nature of operations that could result in

employee exposure, especially employee exposure above the TWA PEL or STEL;

(C) The purpose, proper selection, fitting, proper use, and limitations of personal protective clothing and equipment, including respirators;

(D) Applicable emergency procedures;

(E) Measures employees can take to protect themselves from exposure to beryllium and contact with soluble beryllium compounds, including personal hygiene practices;

(F) The purpose and a description of the medical surveillance program required by paragraph (k) of this section including risks and benefits of each test to be offered;

(G) The purpose and a description of the medical removal protection provided under paragraph (l) of this section;

(H) The contents of the standard; and

(I) The employee's right of access to records under the Records Access standard (29 CFR 1910.1020).

(iii) When a workplace change (such as modification of equipment, tasks, or procedures) results in new or increased employee exposure that exceeds, or can reasonably be expected to exceed, either the TWA PEL or the STEL, the employer shall provide additional training to those employees affected by the change in exposure.

(iv) *Employee information*. The employer shall make a copy of this standard and its appendices readily available at no cost to each employee and designated employee representative(s).

(n) *Recordkeeping*—(1) *Exposure measurements*. (i) The employer shall maintain a record of all measurements taken to monitor employee exposure 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 operation that is being monitored;

(C) The sampling and analytical methods used and evidence of their accuracy;

(D) The number, duration, and results of samples taken;

(E) The type of personal protective clothing and equipment, including respirators, worn by monitored employees at the time of monitoring; and

(F) The name, social security number, and job classification of each employee represented by the monitoring, indicating which employees were actually monitored.

(iii) The employer shall maintain this record as required by the Records

Access standard (29 CFR 1910.1020(d)(1)(ii)).

(2) *Historical monitoring data.* (i) The employer shall establish and maintain an accurate record of any historical data used to satisfy the initial monitoring requirements of paragraph (d)(2) of this standard.

(ii) The record shall demonstrate that the data comply with the requirements of paragraph (d)(2) of this section.

(iii) The employer shall maintain this record as required by the Records Access standard (29 CFR 1910.1020).

(3) *Objective data.* (i) Where an employer uses objective data to satisfy the monitoring requirements under paragraph (d)(2) of this section, the employer shall establish and maintain a record of the objective data relied upon.

(ii) This record shall include at least the following information:

(A) The data relied upon;

(B) The beryllium-containing material in question;

(C) The source of the objective data;

(D) A description of the operation exempted from initial monitoring and how the data support the exemption; and

(E) Other information demonstrating that the data meet the requirements for objective data contained in paragraph (d)(2)(ii) of this section.

(iii) The employer shall maintain this record as required by the Records Access standard (29 CFR 1910.1020).

(4) *Medical surveillance.* (i) The employer shall establish and maintain a record for each employee covered by medical surveillance under paragraph (k) of this section.

(ii) The record shall include the following information about the employee:

(A) Name, social security number, and job classification;

(B) A copy of all licensed physicians' written opinions; and

(C) A copy of the information provided to the PLHCP as required by paragraph (k)(4) of this section.

(iii) The employer shall ensure that medical records are maintained in accordance with the Records Access standard (29 CFR 1910.1020).

(5) *Training.* (i) At the completion of any training required by this standard, the employer shall prepare a record that indicates the name, social security number, and job classification of each employee trained, the date the training was completed, and the topic of the training.

(ii) This record shall be maintained for 3 years after the completion of training.

(6) *Access to records.* Upon request, the employer shall make all records

maintained as a requirement of this standard available for examination and copying to the Assistant Secretary, the Director, each employee, and each employee's designated representative(s) in accordance with the Records Access standard (29 CFR 1910.1020).

(7) *Transfer of records.* The employer shall comply with the requirements involving transfer of records set forth in the Records Access standard (29 CFR 1910.1020).

(o) *Dates.* (1) *Effective date.* This standard shall become effective [DATE 60 DAYS AFTER PUBLICATION OF FINAL RULE IN THE **Federal Register**].

(2) *Start-up dates.* All obligations of this standard commence and become enforceable [DATE 90 DAYS AFTER EFFECTIVE DATE OF FINAL RULE] except:

(i) Change rooms required by paragraph (i) of this section shall be provided no later than 1 year after [EFFECTIVE DATE OF FINAL RULE]; and

(ii) Engineering controls required by paragraph (f) of this standard shall be implemented no later than 2 years after [EFFECTIVE DATE OF FINAL RULE].

(p) *Appendices.* Appendices A and B of this section are non-mandatory.

#### **Appendix A to § 1910.1024— Immunological Testing for the Determination of Beryllium Sensitization (Non-Mandatory)**

##### **I. Background**

Exposure to beryllium via inhalation or dermal contact has been determined to cause an immunological reaction (sensitization) in some individuals. Beryllium sensitization can progress to chronic beryllium disease (CBD). Identifying sensitized workers through an immunological screening program is an essential element in any monitoring and surveillance program designed to reduce the risk of developing CBD in the workplace (Kreiss, 1993b, Newman, 2005). Immunological testing for sensitization to beryllium serves to identify workers at risk for progression to CBD. The medical surveillance and medical removal provisions of the proposed standard provide for clinical evaluation of sensitized workers for early-stage CBD and intervention before progression to more debilitating health effects occurs.

2. This appendix provides an overview of the test currently used to detect beryllium sensitization, the peripheral blood Beryllium Lymphocyte Proliferation Test (BeLPT) as well as a description of the test procedure, the best available information on the accuracy of the test, and several repeat-testing algorithms designed to improve the predictive value of the test. It is important that this information be made available to employers, employees, physicians and other medical personnel to ensure their understanding of the test and the meaning of test results, and to provide a basis to compare

the reliability and validity (utility) of any other sensitization tests that may be developed with the utility of the BeLPT.

##### **II. The Peripheral Blood Beryllium Lymphocyte Proliferation Test (BeLPT)**

1. The BeLPT is an in-vitro blood test that measures the beryllium antigen-specific T-cell mediated immune response. Currently, the BeLPT is the most commonly available diagnostic tool for identifying beryllium sensitization.

2. To perform the BeLPT, venous blood is collected in heparinized tubes. Lymphocytes are isolated from the blood using centrifugation and washed in salt solution. The lymphocytes are counted and evaluated for cell viability. These cells are then cultured in quadruplicate in the presence or absence of beryllium sulfate at 1, 10, and 100  $\mu$ M concentrations for 3–7 days. During the last 4 hours of the culture, cells are pulsed with a radiolabeled DNA precursor (tritiated thymidine deoxyriboside), harvested onto filters and counted in a liquid scintillation counter. The counts per minute (cpm) from each set of quadruplicates are averaged and expressed as a ratio of the cpm of the beryllium stimulated cells to the unstimulated cells. This ratio is called the stimulation index (SI) (Maier, 2003).

3. The BeLPT is interpreted based on the proportion of SIs that exceeds a cut-off value, the expected SI for non-sensitized individuals. Each laboratory sets its own cut-off for the test (Newman 1996). Traditionally, this cut-off value is determined by testing cells from control/non-exposed individuals, and must be determined with each new serum lot that will be used for culturing the peripheral blood lymphocytes. The cut-off is based on the mean value of the peak stimulation index among controls plus 2 or 3 standard deviations. This methodology was modeled into a statistical method known as the "least absolute values" (an adaptation of the "statistical-biological positive" method) and relies on natural log modeling of the median stimulation index values (DOE 2001, Frome 2003). This methodology is recommended by the Department of Energy in guidance (DOE-SPEC-1142-2001) developed by DOE to optimize and standardize beryllium sensitivity testing. It is recommended, but not mandated, to be used in all DOE contracts with laboratories for the purchase of BeLPT services. Other labs have used a standard ratio of 3.0 (stimulated to unstimulated) as the cut-off for an abnormal result (Stange 2004, Deubner 2001).

4. BeLPT results are reported as "normal," "abnormal," or "borderline abnormal." According to the DOE a BeLPT result is considered "abnormal" if at least two of the six stimulation indices are elevated (DOE 2001). If only one of the six stimulation indices is elevated, the test is considered "borderline abnormal" (DOE 2001). If no stimulation index is elevated, the test is normal. A BeLPT may be considered uninterpretable if there are problems with the viability of the cells or lack of response to mitogen, or other problems with the test procedure. (DOE 2001).

5. Due to the nature of the test, issues with variability and reproducibility of a test can

arise between and within labs. Potential sources of variability include: technical problems such as bacterial contamination, cell death, omission of tritiated thymidine pulse, technician skill, degree of automation, use of flat- or round-bottom culture plates, serum concentration, use of beryllium sulfate versus beryllium fluoride, concentration of the culture serum, and the handling of outlier SIs (Mroz 1991).

6. *Test characteristics and testing algorithms.* The utility of any diagnostic, screening or surveillance test relies on the capacity of the test to predict whether or not an individual indeed has the condition intended to be reflected by the test. In the discussion below, sensitivity refers to the proportion of sensitized persons who test positive for sensitization using the BeLPT. Specificity refers to the proportion of non-sensitized persons who test negative. Positive predictive value (PPV) refers to the proportion of persons who test positive, who are actually sensitized. The PPV is related not only to the utility of the test, but also to the prevalence of the condition in the tested population. In the remainder of this discussion, we will refer to the results of a single BeLPT as “abnormal,” “normal,” and “borderline,” and will refer to the outcome of a testing algorithm as “positive” for sensitization or “negative.”

7. Stange et al. (2004) investigated the utility of BeLPT testing in a population of employees of 18 United States Department of Energy (DOE) sites. At these sites, 12,194

current and former employees were tested for beryllium sensitization at four laboratories with BeLPT expertise. Stange et al. reported that 68.3 percent of beryllium-sensitized workers tested positive based on a single abnormal BeLPT result (sensitivity). Thus, the rate of false negatives (undetected cases of beryllium sensitization) based on one normal result was 31.7 percent. Stange et al. reported a false positive rate of 1.09 percent for one abnormal BeLPT result and a PPV of 0.253, which they found comparable to other widely accepted medical tests. Middleton et al. (2006) adjusted Stange’s parameters to consider borderline test results and estimated that 59.7 percent of sensitized persons would test abnormal, 27.7 percent would test normal, and 12.6 percent would have borderline results. They estimated that among non-sensitized persons, 97.37 percent would test normal, 1.09 percent would test abnormal, and 1.58 percent would have borderline results. Stange et al. recommended repeat testing to confirm an abnormal BeLPT result to assure appropriate referral for CBD medical evaluation (Stange et al., 2004).

8. Middleton et al. (2006) studied the characteristics of two testing algorithms. The more basic algorithm used a single initial test plus subsequent split specimen confirmation tests. In the second, enhanced algorithm, an initial test was split and sent to different laboratories for analysis. The sensitivity, specificity, and PPV reported by Middleton were 65.7 percent, 99.9 percent, and 93

percent respectively for the basic algorithm, and 86 percent, 99.8 percent, and 90 percent respectively for the enhanced algorithm. The authors concluded that an algorithm for BeLPT testing and interpretation is best selected or designed after considering the (1) likelihood and level of exposure; (2) purpose of testing (i.e., screening versus medical testing of patients); (3) opportunity for one-time testing versus serial testing; (4) importance of getting the right answer the first time; and (5) number of persons to be tested and the funds available.

9. In April 2006, the Agency for Toxic Substances and Disease Registry (ATSDR) convened an expert panel of seven physicians and scientists to discuss the BeLPT and to consider what algorithm should be used to interpret BeLPT results to establish beryllium sensitization (Middleton et al., 2008). The three criteria proposed by panel members were Criteria A (one abnormal BeLPT result establishes sensitization); Criteria B (one abnormal and one borderline result establish sensitization); and Criteria C (two abnormal results establish sensitization).

10. Using the single-test outcome probabilities developed by Stange et al., the panel convened by ATSDR calculated and compared the sensitivity, specificity, and positive predictive values (PPVs) for each algorithm. The characteristics for each algorithm were as follows:

TABLE A.1—CHARACTERISTICS OF BeLPT ALGORITHMS  
[Adapted from Middleton et al., 2008]

	Criteria A (1 abnormal)	Criteria B (1 abnormal + 1 borderline)	Criteria C (2 abnormal)
Sensitivity .....	68.2%	65.7%	61.2%
Specificity .....	98.89%	99.92%	99.98%
PPV at 1% prevalence .....	38.3%	89.3%	96.8%
PPV at 10% prevalence .....	87.2%	98.9%	99.7%
False positives per 10,000 .....	111	8	2

11. The study demonstrated that confirmation of BeLPT results, whether as one abnormal and one borderline abnormal or as two abnormals, enhances the test’s PPV and protects the persons tested from unnecessary and invasive medical procedures. In populations with a high prevalence of beryllium sensitization (i.e., 10 percent or more), however, a single test may be adequate to predict sensitization (Middleton et al., 2008).

12. In a later analysis, Middleton et al. (2011) conducted an evaluation using borderline results from BeLPT testing. Utilizing the common clinical algorithm with a criterion that accepted 1 abnormal and 1 borderline as establishing beryllium sensitization resulted in a PPV of 94.4 percent. This study also found that 3 borderline results resulted in a PPV of 91 percent. Both of these PPVs were based on a population prevalence of 2 percent. This

study further demonstrates borderline results’ value in predicting beryllium sensitization using the BeLPT.

**III. New Beryllium-Specific Immunological Test Protocols**

1. In the medical surveillance provisions of this standard, OSHA requires the use of a standardized BeLPT, but states that a “more reliable and accurate diagnostic test” for beryllium sensitization may be used in lieu of the BeLPT if such a test is developed. The Agency considers the following criteria to be important in judging a new test’s validity and reliability:

a. A test report prepared by an independent<sup>1</sup> research laboratory stating that the laboratory has tested the protocol and has found it to be valid and reliable; and

b. An article that has been published in a peer-reviewed journal describing the protocol

and explaining how test data support the protocol’s validity and reliability.

c. Sensitivity and specificity that meet or exceed those reported for the BeLPT in peer-reviewed publications.

**Appendix B to § 1910.1024: Control Strategies To Minimize Beryllium Exposure (Non-Mandatory)**

Paragraph (f)(2)(i) of § 1910.1024 requires employers to use one or more of the control methods listed in paragraph (f)(2)(i)(A) of § 1910.1024 to minimize worker exposure in each operation in a beryllium work area, unless the operation is exempt under paragraph (f)(2)(i)(B) of § 1910.1024. This appendix sets forth a non-exhaustive list of control options that employers could use to comply with paragraph (f)(2)(i)(A) of § 1910.1024 for a number of specific beryllium operations.

<sup>1</sup> An example of an “independent” research laboratory would be a laboratory with no financial

interest in the protocol, and no affiliation with the manufacture or supply of beryllium.

TABLE B.1—EXPOSURE CONTROL RECOMMENDATIONS

Operation	Minimal control strategy*	Application group
Beryllium Oxide Forming (e.g., pressing, extruding).	For pressing operations: ..... (1) Install local exhaust ventilation (LEV) on oxide press tables, oxide feed drum breaks, press tumblers, powder rollers, and die set disassembly stations; (2) Enclose the oxide presses; and (3) Install mechanical ventilation (make-up air) in processing areas. For extruding operations: ..... (1) Install LEV on extruder powder loading hoods, oxide supply bottles, rod breaking operations, centerless grinders, rod laydown tables, dicing operations, surface grinders, discharge end of extrusion presses; (2) Enclose the centerless grinders; and (3) Install mechanical ventilation (make-up air) in processing areas.	Primary Beryllium Production; Beryllium Oxide Ceramics and Composites.
Chemical Processing Operations (e.g., leaching, pickling, degreasing, etching, plating).	For medium and high gassing operations ..... (1) Perform operation with a hood having a maximum of one open side; and (2) Design process so as to minimize spills; if accidental spills occur, perform immediate cleanup.	Primary Beryllium Production; Beryllium Oxide Ceramics and Composites; Copper Rolling, Drawing and Extruding.
Finishing (e.g., grinding, sanding, polishing, deburring).	(1) Perform portable finishing operations in a ventilated hood. The hood should include both downdraft and backdraft ventilation, and have at least two sides and a top. (2) Perform stationary finishing operations using a ventilated and enclosed hood at the point of operation. The grinding wheel of the stationary unit should be enclosed and ventilated.	Secondary Smelting; Fabrication of Beryllium Alloy Products; Dental Labs.
Furnace Operations (e.g., Melting and Casting).	(1) Use LEV on furnaces, pelletizer; arc furnace ingot machine discharge; pellet sampling; arc furnace bins and conveyors; beryllium hydroxide drum dumper and dryer; furnace rebuilding; furnace tool holders; arc furnace tundish and tundish skimming, tundish preheat hood, and tundish cleaning hoods; dross handling equipment and drums; dross recycling; and tool repair station, charge make-up station, oxide screener, product sampling locations, drum changing stations, and drum cleaning stations. (2) Use mechanical ventilation (make-up air) in furnace building.	Primary Beryllium Production; Beryllium Oxide Ceramics and Composites; Nonferrous Foundries; Secondary Smelting.
Machining .....	Use (1) LEV consistent with ACGIH® ventilation guidelines on deburring hoods, wet surface grinder enclosures, belt sanding hoods, and electrical discharge machines (for operations such as polishing, lapping, and buffing); (2) high velocity low volume hoods or ventilated enclosures on lathes, vertical mills, CNC mills, and tool grinding operations; (3) for beryllium oxide ceramics, LEV on lapping, dicing, and laser cutting; and (4) wet methods (e.g., coolants).	Primary Beryllium Production; Beryllium Oxide Ceramics and Composites; Copper Rolling, Drawing, and Extruding; Precision Turned Products.
Mechanical Processing (e.g., material handling (including scrap), sorting, crushing, screening, pulverizing, shredding, pouring, mixing, blending).	(1) Enclose and ventilate sources of emission; (2) Prohibit open handling of materials; and (3) Use mechanical ventilation (make-up air) in processing areas.	Primary Beryllium Production; Beryllium Oxide Ceramics and Composites; Aluminum and Copper Foundries; Secondary Smelting.
Metal Forming (e.g., rolling, drawing, straightening, annealing, extruding).	(1) For rolling operations, install LEV on mill stands and reels such that a hood extends the length of the mill; (2) For point and chamfer operations, install LEV hoods at both ends of the rod; (3) For annealing operations, provide an inert atmosphere for annealing furnaces, and LEV hoods at entry and exit points; (4) For swaging operations, install LEV on the cutting head; (5) For drawing, straightening, and extruding operations, install LEV at entry and exit points; and (6) For all metal forming operations, install mechanical ventilation (make-up air) for processing areas.	Primary Beryllium Production; Copper Rolling, Drawing, and Extruding; Fabrication of Beryllium Alloy Products.
Welding .....	For fixed welding operations: (1) Enclose work locations around the source of fume generation and use local exhaust ventilation; and (2) Install close capture hood enclosure designed so as to minimize fume emission from the enclosure welding operation. For manual operations: (1) Use portable local exhaust and general ventilation.	Primary Beryllium Production; Fabrication of Beryllium Alloy Products; Welding.

\* All LEV specifications should be in accordance with the ACGIH® Publication No. 2094, "Industrial Ventilation—A Manual of Recommended Practice" wherever applicable.

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