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DEPARTMENT OF AGRICULTURE

Commodity Credit Corporation

7 CFR Part 1450

RIN 0560-AI27

Biomass Crop Assistance Program

AGENCY: Commodity Credit Corporation and Farm Service Agency, USDA.

ACTION: Final rule; reopening of comment period.

SUMMARY: The Commodity Credit Corporation (CCC) and the Farm Service Agency (FSA) published a final rule on February 27, 2015, amending the Biomass Crop Assistance Program (BCAP) regulations to implement changes required by the Agricultural Act of 2014 (the 2014 Farm Bill). We are extending the comment period for the final rule to give the public more time to provide input and recommendations on the final rule.

DATES: The comment period for the final rule published February 27, 2015 (80 FR 10569), effective May 28, 2015, is reopened. We will consider comments that we receive by May 27, 2015.

ADDRESSES: We invite you to submit comments on the final rule. In your comment, please specify RIN 0560-AI27, February 27, 2015, and 80 FR 10569-10575. You may submit comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the online instructions for submitting comments; or
- *Mail, Hand Delivery, or Courier:* Kelly Novak, FSA CEPD, USDA, STOP 0513, 1400 Independence Ave. SW., Washington, DC, 20250-0512.

All written comments will be available for inspection online at www.regulations.gov and at the mail address above during business hours from 8 a.m. to 5 p.m., Monday through

Friday, except holidays. A copy of this extension and the published final rule are available through the FSA home page at <http://www.fsa.usda.gov/>.

FOR FURTHER INFORMATION CONTACT:

Kelly Novak, telephone (202) 720-4053. Persons with disabilities who require alternative means for communication should contact the USDA Target Center at (202) 720-2600 (voice).

SUPPLEMENTARY INFORMATION:

Background

On February 27, 2015, CCC and FSA published a final rule titled "Biomass Crop Assistance Program." The final rule implements all the required 2014 Farm Bill changes to BCAP and seeks comment on FSA's implementation of BCAP, given the required changes and changes to funding.

BCAP is administered by FSA using Commodity Credit Corporation (CCC) funds. Section 9010 of the 2014 Farm Bill (Pub. L. 113-79) amends 7 U.S.C. 8111 and reauthorizes BCAP with certain changes. BCAP provides assistance to biomass producers and owners in two payment categories:

- Matching payments to eligible material owners for the delivery of eligible material to qualified Biomass Conversion Facilities (BCFs). Qualified BCFs use biomass feedstocks to produce heat, power, biobased products, research, or advanced biofuels. The 2014 Farm Bill adds research as an authorized use of material by BCFs.

- Establishment and annual payments to producers who enter into contracts with CCC to produce eligible biomass crops on contract acres within BCAP project areas.

The final rule requested comments on how BCAP should be implemented in future years. FSA is, in particular, requesting public comments on the following questions:

- What information could FSA reasonably collect that would provide assurance that the biomass conversion facility has sufficient equity to be in operation by the date on which project area eligible crops are ready for harvest?
- How could FSA best determine if expansion of a project area would advance the maturity of that project area?
- What credible risk tools and sources should FSA consider in determining whether proposed crops are potentially invasive?

- With a new cost share cap of 50 percent for establishment costs for perennial crops in project areas, what establishment practices should FSA consider as most important to support?

- With the new limits to the BCAP budget, what priorities should FSA consider in implementing the program?

FSA received several comments requesting an extension of the comment period. We have determined that providing an extension of the original comment period will give the public more time to provide input and to make recommendations on the final rule. With this extension, the public may submit comments through May 27, 2015. This extension of comment period does not change the effective date of the final rule, which is May 28, 2015, so as not to delay the implementation of the changes to BCAP required by the 2014 Farm Bill.

Signed on May 15, 2015.

Joy Harwood,

Acting Executive Vice President, Commodity Credit Corporation, and Administrator, Farm Service Agency.

[FR Doc. 2015-12220 Filed 5-19-15; 8:45 am]

BILLING CODE 3410-05-P

DEPARTMENT OF AGRICULTURE

Rural Business-Cooperative Service

Rural Housing Service

Rural Utilities Service

Farm Service Agency

7 CFR Part 1980

RIN 0570-AA94

Strategic Economic and Community Development

AGENCY: Rural Business-Cooperative Service, Rural Housing Service, Rural Utilities Service, Farm Service Agency, U.S. Department of Agriculture (USDA).

ACTION: Interim rule with public comment.

SUMMARY: This interim rule implements Section 6025, Strategic Economic and Community Development, under the Agricultural Act of 2014 (2014 Farm Bill). Unless the Agency provides otherwise, the Agency will reserve up to 10 percent of the funds appropriated to

certain Rural Development (RD) programs each fiscal year to fund projects that support the implementation of strategic economic and community development plans across multi-jurisdictional areas. The programs from which funds will be reserved are community facility programs, water and waste disposal programs, and rural business and cooperative development programs. To be eligible for the reserved funds, projects must be first eligible for funding under the programs from which the funds are reserved. In addition, projects must be carried out solely in rural areas. Any reserved funding that is not obligated by June 30 of the fiscal year in which the funds were reserved will be returned to the programs' regular funding accounts.

DATES: Effective June 19, 2015. Written comments must be received on or before August 18, 2015. The comment period for the information collection under the Paperwork Reduction Act of 1995 ends July 20, 2015.

ADDRESSES: Submit your comments on this rule by any of the following methods:

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

- *Mail:* Submit written comments via the U.S. Postal Service to the Branch Chief, Regulations and Paperwork Management Branch, U.S. Department of Agriculture, STOP 0742, 1400 Independence Avenue SW., Washington, DC 20250-0742.

- *Hand Delivery/Courier:* Submit written comments via Federal Express Mail, or other courier service requiring a street address, to the Branch Chief, Regulations and Paperwork Management Branch, U.S. Department of Agriculture, 300 7th Street SW., 7th Floor, Washington, DC 20024.

All written comments will be available for public inspection during regular work hours at the 300 7th Street SW., 7th Floor address listed above.

FOR FURTHER INFORMATION CONTACT: Aaron Morris, Rural Housing Service, Community Facilities, U.S. Department of Agriculture, STOP 0787, 1400 Independence Avenue SW., Washington, DC 20250-3225; email: aaron.morris@wdc.usda.gov; telephone (202) 720-1500.

SUPPLEMENTARY INFORMATION:

Executive Summary

I. Purpose of the Regulatory Action

This action is needed in order to implement Section 6025 of the Agricultural Act of 2014 (2014 Farm Bill) (7 U.S.C. 2008v). Section 6025

provides the Secretary of Agriculture the authority to give priority to projects that support strategic economic development or community development plans. Section 6025 enables the Secretary to reserve up to 10 percent of program funds from certain Rural Development programs, as identified in the section. This action implements this priority.

II. Summary of the Major Provisions

1. *Programs.* Based on the authorizing statute, funds will be reserved from one or more of eight RD programs. These programs, which are referred to as the "underlying programs," are:

- Community Facility Loans
- Fire and Rescue and Other Small Community Facilities Projects
- Community Facilities Grant Program
- Community Programs Guaranteed Loans
- Water and Waste Disposal Programs Guaranteed Loans
- Water and Waste Loans and Grants
- Business and Industry Guaranteed Loanmaking and Servicing
- Rural Business Development Grants

2. *Funding.* RD will reserve up to 10 percent of an underlying program's program level to fund projects under this priority. The authorizing statute sets the upper limit on the amount of funding that can be reserved for this priority. Based on a program's budget and demand for reserved funding, RD may set lower percentages for a specific fiscal year.

Any funding that is not expended by June 30, as specified by the authorizing statute, will be returned to the applicable underlying program's account for obligation for all eligible projects in that program.

3. *Applications.* To be considered for funding under this priority, applicants and their projects must be eligible for one of the underlying program and must submit a specific form. The information in this form, which will accompany the application material for the applicable underlying program, will enable RD to determine whether the proposed project is eligible to receive reserved funds and, if so, to score the application in order to determine which projects will receive reserved funds.

4. *Scoring applications.* RD will score these applications based on:

- The underlying program's criteria.
- The proposed project's direct support of the objectives found in the strategic economic development or community development plan that it supports.
- Certain characteristics (as specified in the authorizing statute) of strategic

economic development or community plan that the proposed project support.

The scores from these three areas will be summed, with higher scoring applications receiving priority for reserved funding.

5. *Applications that do not received reserved funds.* If an application does not receive reserved funds, it will be automatically competed with all other applications for remaining funds in that program's account. Reserved funding applications will compete based on only the score they receive on the underlying program's scoring criteria.

6. *Awardees.* Applicants who receive reserved funds for this priority will submit information on the project's measures, metrics, and outcomes to the appropriate entity(ies) monitoring the implementation of the plan.

7. *Analysis.* Because the objectives for a particular plan are driven by applicants and the multiple jurisdictions involved, RD has not yet identified a single set of metrics that would allow for parsing, or attributing, marginal benefits or impacts of the underlying program that would be achieved because of association with a multi-jurisdictional plan. However, RD is committed to the continual improvement of its collection and analysis of administrative and programmatic data to better understand the impact and benefit of support for projects associated with multi-jurisdictional plans.

III. Costs and Benefits

The cost to the individual applicant to apply for reserved funding is nominal. RD estimates the cost to complete the specific form to be no more than \$300 assuming on average approximately 9 hours per form. The primary benefit of this action is to foster an environment of increased collaboration between project applicants and rural communities as they consider how to best use RD resources to address multi-jurisdictional needs, by leveraging federal, state, local or private funding, or otherwise capitalize upon the unique strengths of the rural area to support successful community and economic development.

Classification

This action has been reviewed under Executive Order (EO) 12866 and has been determined to be "economically significant" by the Office of Management and Budget. The EO defines a "economically significant regulatory action" as one that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect, in

a material way, the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this EO.

The Agency conducted a benefit-cost analysis to fulfill the requirements of EO 12866. In this analysis, the Agency identifies alternatives considered, the distributional effects of the reserved funding, the estimated costs of applying for and the potential benefits of receiving reserved funding to the various applicants under the eight programs included and to the Agency, the effect on the underlying programs, and the present value of the reserved funding.

Alternatives considered. The Agency did not identify meaningful alternatives to the proposed action.

Distributional effects. The proposed action will result in a distributional effect via "transfer payments" by directing Agency funds from projects that do not support a strategic economic development or community development plan to projects that do support such plans. (Transfer payments are monetary payments from one group to another that do not affect total resources available to society.) In general, the Agency does not expect the distributional effect to be large because many projects funded by the underlying programs already are found in areas covered by plans that would qualify for Section 6025 reserved funding. It is unknown as to how many such projects would apply for the reserved funding.

To the extent that there is an increase in Agency funding of projects that support such plans, the Agency expects areas within the region covered by a plan to be "better off" than if the project was not funded. The extent of this transfer, however, cannot be calculated at this time. In contrast, the proposed action may result in a negative impact by not funding a project that does not support such a plan.

Costs. In this analysis, the Agency estimates the cost to the public for applying for and receiving reserved funding is approximately \$106,000 per year. With an estimated 374 applicants and 317 awardees per year, this equates to approximately \$285 per applicant.

The number of applicants was determined by first estimating the most recent estimate of the number of applicants (e.g., from Paperwork Reduction Act packages) for each of the individual programs included and then determining the percentage of those applicants that are in an area covered by an Economic Development Administration (EDA) approved plan. Next, the number of underlying program applicants was multiplied by the percentage of applicants in an EDA-approved plan area and this result was then multiplied by an estimate of how many such potential applicants would actually apply for Section 6025 reserved funds. For Rural Business Development Grants (RBDG), the same steps were used with one additional adjustment factor taking into account difference in funding levels between the "old" Rural Business Enterprise Grant (RBEG) and Rural Business Opportunity Grant (RBOG) programs and the new RBDG program.

The number of awardees was estimated in a similar fashion. For each included program, the number of awardees over the last few years was determined and then the percentage of those awardees that are in an area covered by an EDA approved plan was determined. Next, the number of underlying program awardees was multiplied by the percentage of awardees in an EDA-approved plan area and this result was multiplied by the percentage of potential applicants that would likely apply for Section 6025 reserved funds (as determined earlier for estimating the number of applicants). For RBDG, the same steps were used with two additional modifications—(1) using the same adjustment as for determining applicants to take into account difference in funding levels between the "old" RBEG and RBOG programs and the new RBDG program and (2) taking into account the requirement that no more than 10 percent of the RBDG funding could be used to support projects that support "RBOG" purposes.

In terms of costs to the Government for administering and implementing this project, the Agency estimated a cost of approximately \$121,200 for reviewing and scoring the Section 6025 applications assuming 12 hours per application.

Benefits. The priority provided by Section 6025 is directed at only those eligible applications that are carried out solely in a rural area and that also support development plans on a multi-jurisdictional basis. As a result of this priority, the Agency expects that rural entities will access Rural Development

programs in a manner that supports projects and initiatives that develop long-term community and economic growth strategies. The Agency will work with rural communities to consider how they might use Rural Development resources to address multi-jurisdictional needs, by leveraging federal, state, local or private funding, or otherwise capitalize upon the unique strengths of the rural area to support successful community and economic development. This priority will help to maximize the impact of resources available at all levels of government and ultimately help rural communities reach their full potential. Such projects will be more effective than "one-off" projects (i.e., those that meet an immediate need) in contributing to the larger strategic vision because they will be based on a strategy that takes into account the region's strengths and weaknesses, leveraging the area's assets in the most effective way possible.

Aligning projects with regional economic and community development plans helps engage individuals, organizations, local governments, institutes of learning, and the private sector in a meaningful conversation about what capacity building efforts would best serve the community in terms of creating jobs, creating investments, and generating regional wealth. In addition, the alignment helps take into account and, where possible, leverage other regional planning efforts, including the use of other federal funds and resources that support a region's goals and objectives. This helps prevent duplication, while better harnessing and directing limited federal resources for implementation efforts.

In sum, the Agency expects that the reservation of funds under this provision will result in an increased share of existing program funding going to projects that support strategic economic development or community development plans, thereby helping to address regional specific needs more directly and more generally strengthening the Agency's ability to help ensure a thriving rural economy.

Underlying Programs. The proposed action will not change the underlying provisions of the included programs (e.g., eligibility, applications, award decisions, scoring, and servicing provisions).

Present Values. Net present values were calculated using a 3 percent and a 7 percent discount rate for program levels covering Fiscal Years 2015 through 2019. The values were calculated for a baseline scenario (i.e., without the Section 6025 priority) and for a "with Section 6025 priority"

scenario. For the Section 6025 priority scenario, 10 percent of each of the underlying programs' program level funds is assumed to be used to fund Section 6025 applications and the remaining 90 percent of each of the underlying programs' program level funds is used to fund "regular program" applications.

The results show that the net present value associated with funding Section 6025 priority applications ranges from \$448 million to \$466 million, but that there is no net difference between the baseline scenario and the "with Section 6025 priority" scenario. This occurs because Section 6025 neither increases nor decreases the program level fund allocation for any of the underlying programs.

Catalog of Federal Domestic Assistance

RD programs affected by this rulemaking are shown in the Catalog of Federal Domestic Assistance (CFDA) with numbers as indicated:

- 10.760—Water and Waste Disposal Systems for Rural Communities
- 10.766—Community Facilities Loans and Grants
- 10.768—Business and Industry Guaranteed Loan Program
- 10.351—Rural Business Development Grants

All active CFDA programs can be found at www.cfda.gov.

Executive Order 12372, Intergovernmental Review of Federal Programs

This action is not subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials.

Executive Order 12988, Civil Justice Reform

This interim rule has been reviewed under Executive Order 12988, Civil Justice Reform. RD has determined that this rule meets the applicable standards provided in section 3 of the Executive Order. Additionally, (1) all State and local laws and regulations that are in conflict with this rule will be preempted; (2) no retroactive effect will be given to the rule; and (3) administrative appeal procedures, if any, must be exhausted before litigation against the Department or its agencies may be initiated, in accordance with the regulations of the National Appeals Division of USDA at 7 CFR part 11.

National Environmental Policy Act

This document has been reviewed in accordance with 7 CFR part 1940,

subpart G, "Environmental Program" and 7 CFR 1794 "Environmental Policies and Procedures." To be eligible for the set-aside funds, a project must meet all of the requirements of the applicable underlying program, including its National Environmental Policy Act (NEPA) requirements. Any project eligible for the set-aside funding is already an action included the underlying programs and such actions are covered by NEPA, and therefore categorically excluded. Therefore, RD has determined that this action does not constitute a major Federal action significantly affecting the quality of the human environment and, in accordance with the NEPA of 1969, 42 U.S.C. 4321 *et seq.*, an Environmental Impact Statement is not required.

Unfunded Mandates Reform Act

This rule contains no Federal mandates (under the regulatory provisions of Title II of the Unfunded Mandates Reform Act of 1995) for State, local, and Tribal governments or the private sector. Thus, this rule is not subject to the requirements of sections 202 and 205 of the Unfunded Mandates Reform Act of 1995.

Regulatory Flexibility Act

Under section 605(b) of the Regulatory Flexibility Act, 5 U.S.C. 605(b), RD certifies that this rule will not have a significant economic impact on a substantial number of small entities. The rule affects applicants across eight RD programs. Many of these applicants are small businesses. For example, with the Business and Industry (B&I) Guaranteed Loan program alone, RD estimates that approximately 50 percent of the 1,117 active lenders in the current B&I portfolio are small entities as defined by the Regulatory Flexibility Act. Therefore, RD has determined that this rule will affect a substantial number of small entities.

However, RD has determined that the economic impact of the rule on these small entities will not be significant. The rule does not make any changes to the programs from which funds will be reserved. The rule will require applicants to submit an additional form if seeking funding that is reserved for projects that support strategic economic development or community development plans. Based on the data in the Paperwork Reduction Act (PRA) burden package, RD estimates that the cost to complete this form will, on average, be no more than \$300. Therefore, this rule will not have a significant impact on small entities.

Executive Order 13132, Federalism

The policies contained in this rule do not have any 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. Nor does this interim rule impose substantial direct compliance costs on state and local governments. Therefore, consultation with states is not required.

Executive Order 13175, Consultation and Coordination With Indian Tribal Governments

This rule has been reviewed in accordance with the requirements of Executive Order 13175, "Consultation and Coordination with Indian Tribal Governments." Executive Order 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that 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.

Rural Development has assessed the impact of this rule on Indian tribes and determined that the interim rule does not, to our knowledge, have tribal implications that require tribal consultation under EO 13175. On August 21, 2014, however, Rural Development opened consultation on Farm Bill section 6025 pertaining to this regulation. Twenty one (21) Tribes participated in this consultation, and Rural Development received zero (0) formal and actionable comments. Primary Tribal concerns included definitions within the rule regarding "plans" and "multi-jurisdictional" strategies.

Rural Development plans to use an inclusive definition of "plans" so that a wide range of plans that Tribes currently have adopted and implemented may be used, as long as certain minimum standards are met. For instance the plan must be multi-jurisdictional and include:

- Economic conditions of the region;
- economic and community strengths, weaknesses, opportunities, and threats for the region;
- consideration of such aspects as the environmental and social conditions;
- strategies and implementation plan that build upon the region's strengths and opportunities ;=and resolve the

weaknesses and threats facing the region;

- performance measures to evaluate the successful implementation of the plan;
- support of key community stakeholders.

These minimum criteria do not pose any unique or additional implications or challenges for Tribes. The rule incentivizes additional planning, partnering and strategies between Tribes and other units of government/jurisdictions, such as other Indian Tribes, States, Counties, Cities, Townships, Towns, Boroughs, etc. These details of the rule, along with many others, were explained, contextualized and clarified during the consultation event on August 21, to provide a deeper understanding of the agency's underlying rationale in implementing this program in this manner.

If a Tribe requests additional consultation, Rural Development will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions and modifications identified herein are not expressly mandated by Congress.

Paperwork Reduction Act

The information collection requirements contained in this interim rule have been submitted to the Office of Management and Budget (OMB). However, in accordance with the Paperwork Reduction Act of 1995, USDA RD will seek OMB approval of the reporting and recordkeeping requirements contained in this rule and hereby opens a 60-day public comment period.

Title: Strategic Economic and Community Development.

OMB Number: 0570-NEW.

Type of Request: New collection.

Abstract: This rule enables RD to reserve funds from eight RD programs for the specific purpose of funding projects that support strategic economic and community development plans.

In order to ensure a project qualifies for these reserved funds, RD must collect information on the proposed project, including how the project supports the implementation of a strategic community or economic development plan, and information on the plan itself in order to allow RD to prioritize projects if the reserved funding is insufficient to fund all eligible projects. The information required does not depend on the specific program whose reserved funding the applicant is seeking.

The following estimates are based on the average over the first 3 years the program will be in place.

Estimate of Burden: Public reporting burden for this collection of information is estimated to average 4.8 hours per response.

Respondents: Rural businesses; units of State, tribal, or local government; instrumentalities of a State, tribal, or local government; non-profit organizations; associations; academic institutions; public bodies; banks, credit unions, and other commercial lenders.

Estimated Number of Respondents: 374.

Estimated Number of Responses per Respondent: 1.85.

Estimated Number of Responses: 692.

Estimated Total Annual Burden (hours) on Respondents: 3,348.

E-Government Act Compliance

RD is committed to complying with the E-Government Act, to promote the use of the Internet and other information technologies, to provide increased opportunities for citizens to access Government information and services electronically.

USDA Non-Discrimination Statement

The U.S. Department of Agriculture (USDA) prohibits discrimination against its customers, employees, and applicants for employment on the bases of race, color, national origin, age, disability, sex, gender identity, religion, reprisal and, where applicable, political beliefs, marital status, familial or parental status, sexual orientation, or all or part of an individual's income is derived from any public assistance program, or protected genetic information in employment or in any program or activity conducted or funded by the Department. (Not all prohibited bases will apply to all programs and/or employment activities.)

If you wish to file an employment complaint, you must contact your agency's EEO Counselor (PDF) within 45 days of the date of the alleged discriminatory act, event, or in the case of a personnel action. Additional information can be found online at http://www.ascr.usda.gov/complaint_filing_file.html.

If you wish to file a Civil Rights program complaint of discrimination, complete the USDA Program Discrimination Complaint Form (PDF), found online at http://www.ascr.usda.gov/complaint_filing_cust.html, or at any USDA office, or call (866) 632-9992 to request the form. You may also write a letter containing all of the information requested in the form. Send your completed complaint form or

letter to us by mail at U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250-9410, by fax (202) 690-7442 or email at program.intake@usda.gov.

Individuals who are deaf, hard of hearing, or have speech disabilities and you wish to file either an EEO or program complaint please contact USDA through the Federal Relay Service at (800) 877-8339 or (800) 845-6136 (in Spanish).

Persons with disabilities who wish to file a program complaint, please see information above on how to contact us by mail directly or by email. If you require alternative means of communication for program information (e.g., Braille, large print, audiotope, etc.) please contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

I. Background and Discussion

RD administers a multitude of Federal programs for the benefit of rural America, ranging from housing and community facilities to infrastructure and business development. Its mission is to increase economic opportunity and improve the quality of life in rural communities by providing the leadership, infrastructure, capital, and technical support that enables rural communities to prosper. To achieve its mission, RD provides financial support (including direct loans, grants, and loan guarantees) and technical assistance.

Section 6025 of the 2014 Farm Bill amends the Consolidated Farm and Rural Development Act by adding a new section—Section 379H, Strategic Economic and Community Development. This section provides RD the ability to prioritize projects that are part of multi-jurisdictional strategic economic development or community development plans. This provides RD an important mechanism to further our mission by leveraging projects that spur regional economic and community development. In addition, this will reward communities that demonstrate best practices for furthering sustainable regional and community prosperity by bringing together key local and regional stakeholders and using long-term planning that integrates targeted investments across communities and regions.

II. Discussion of the Rule

The following paragraphs discuss each section of the interim rule and provide additional information on RD's intent in implementing each.

Purpose (§ 1980.1001)

This section summarizes the purpose of this subpart, which is to prioritize funding of projects that specifically further the implementation of strategic economic development and community development plans.

Programs (§ 1980.1002)

This section of the rule identifies the RD programs that the Secretary may elect to include for reserving funds for projects that support strategic economic development or community development plans. These programs are:

- Rural Community Facilities—community facility grants, guaranteed loans, and direct loans;
- Rural Utilities—water and waste disposal grants, guaranteed loans, and direct loans; and
- Rural Business and Cooperative Development—business and industry direct and guaranteed loans; and rural business development grants.

Applicability of Programs (§ 1980.1003)

One of the requirements for a project to be eligible for Section 6025 funds is that it meets the “applicable eligibility requirements of this title;” that is, the project must meet the applicable eligibility requirements for at least one of the programs identified within Section 6025 (referred to hereafter as the “underlying program(s)”) and from which the funding is reserved. For example, if a project is seeking Section 6025 funds from Community Facility grants, the project must meet the applicant and project eligibility requirements of the underlying Community Facility program.

It is also the intent of RD that all of the provisions of the underlying programs apply to applicants and their projects seeking funding under this subpart. These provisions include, but are not limited to, definitions, application requirements, and reporting, recordkeeping, and servicing requirements.

Of particular note is the incorporation by reference of the definitions of “rural area” for the underlying programs. Section 6025 requires a project seeking funding under this subpart to, in part, be “carried out solely in a rural area.” In addition, Section 6025 requires using the definitions of rural area for the underlying programs as defined in the applicable provisions of the Consolidated Farm and Rural Development Act, as amended. Rather than including a definition of “rural area” in this subpart, the applicable rural area definitions are incorporated by reference.

Finally, in order to implement Section 6025, RD found it necessary to supplement certain provisions of the underlying programs. This section thus also indicates where certain provisions of the underlying programs have been supplemented.

Funding (§ 1980.1004)

Section 6025 allows RD to reserve “an amount that does not exceed 10 percent of the funds made available for a fiscal year” for the three “functional categories”—Rural Community Facilities Category, Rural Utilities Category, and Rural Business and Cooperative Development Category. This section of the rule identifies how RD will implement the reservation of funds. Highlights of this section are:

- RD will reserve 10 percent of the funds appropriated each year to each underlying program, unless RD announces otherwise; and
- Any reserved funding not obligated by June 30 (or earlier if specified by RD) will be returned to the underlying program’s regular funding account.

The following paragraphs discuss these and other provisions associated with funding.

Individual program reservation of funds. RD has determined that the language in Section 6025 allows it the flexibility to reserve funds on either a functional category basis or on an individual program basis. Specifically, Section 6025 refers to “all amounts made available for” and then lists two or more programs using the conjunction “or” to link them. For example, for the Rural Business and Cooperative Development Category, Section 6025 states (emphasis added), in part, made available for business and industry direct and guaranteed loans under section 310(B)a)(2)(A); or rural business development grants under section 310(B)(c).

For ease of implementation at both the program level and the administration level, RD will reserve funds on an individual program basis. The rule allows RD to reserve funds on a basis other than an individual program basis. If RD elects to do so, RD will notify the public by publishing a notice.

Which programs will participate each year? Unless RD decides otherwise, RD will reserve funds from each of the programs identified in Section 6025 each year. Section 6025 provides RD the flexibility to not reserve funds from a specific program in a given year. RD may decide not to reserve funding from a particular program for a variety of reasons, including, but not limited to, the amount of funds appropriated to an individual program in a given year. If

RD makes such a decision, RD will announce in a notice which program(s) will not be included for that fiscal year.

Percentage of funding reserved. Unless RD decides to set a lower percentage, RD will reserve each fiscal year 10 percent of the program level funding appropriated to the underlying programs. Section 6025 states that RD may reserve “an amount that does not exceed 10 percent of the funds made available for a fiscal year for a functional category,” but the section does not prevent RD from reserving funds at a lower percentage.

The primary factors that RD will take into account for determining whether to set a lower percentage for a program are (1) the funding level for that program for the upcoming fiscal year and (2) based on past experience, the level of demand for reserved funding for the program. For example, if the demand for reserved funding for a program is consistently less than 10 percent, RD would likely reduce the percentage it reserves for this priority funding.

If RD decides to set a lower percentage, RD will announce in a notice the lower percentage(s) and for which program(s). Once the percentage to be used for a given fiscal year is determined, RD will not change that percentage so that the amount of funding reserved for each program will remain the same for the fiscal year.

Unobligated reserved funds. Per Section 6025, the reservation of funds may only extend through June 30th of the fiscal year in which the funds were first made available. Therefore, the rule sets for each of the underlying programs June 30th as the “default” date by which a program’s unobligated reserved funds will be returned to the underlying program’s regular funding account. (Funds would go unobligated in instances where the funding requests for a program’s reserved funds are less than the amount reserved for that program.)

Section 6025, however, does not prohibit RD from establishing a date earlier than June 30th after which unobligated reserved funds are returned to the underlying program’s account. RD may decide that an earlier date for a program is appropriate, for example, in order to coordinate the award of reserved funds with awards made for the underlying program. If RD elects to establish an earlier date, RD will announce in a notice the earlier date(s) and for which programs. This provision may result in programs having different dates for when unobligated reserved funds are returned to their respective underlying program’s regular funding account. For example, the date for one

program may be June 30th while the date for another program is March 31st.

Definitions (§ 1980.1005)

This section identifies the definitions that apply to this subpart. It also incorporates by reference definitions from the underlying regulations, including as discussed earlier the definitions of “rural area.” Lastly, if a term is defined in this subpart and in one of the underlying subparts, it has the meaning as defined in this subpart for purposes of receiving funding under this subpart. Terms specific to this subpart are discussed below.

Adopted. The statute requires “applications involving State, county, municipal, or tribal governments shall include an indication of consistency with an adopted regional economic or community development plan.” The primary consideration in defining “adopted” is that the appropriate entity has, or entities have, officially approved the plan for implementation. The appropriate entity or entities will vary among plans and may be, for example, a governing body or planning board.

Carried out solely in a rural area. To be eligible for reserved funding, the statute requires that the project be “carried out solely in a rural area.” RD projects funded under programs included in this subpart already require some degree of “rurality” to the project or the services provided by the project. To ensure that a rural area project supporting a regional economic development or community development plan contributes to such a plan, RD is focusing on the phrase “carried out solely” to mean either one of the following:

- The entire project is physically located in a rural area or
- The beneficiaries of the service(s) provided through the project must either reside in a rural area (in the case of individuals) or be located in a rural area (in the case of entities).

The first metric focuses on the physical location of the project and without regard as to who would benefit from the project. For example, a hospital built entirely in a rural area would be an eligible project regardless if it provides health care services to non-rural residents.

The second metric focuses on where the beneficiaries of the services provided are located. For example, consider a project designed to provide water to residents of a rural area, but part of the project is located in a non-rural area and part of the project is located in a rural area. This project would not be an eligible project under the first metric (because part of the

project is located in a non-rural area), but would be an eligible project under the second metric because the beneficiaries of the services (the individuals) reside entirely in a rural area. If, however, some of the beneficiaries reside in a non-rural area, then this project would not be an eligible project under either metric.

RD notes that projects must first be eligible under the appropriate underlying program in order to be considered eligible under this subpart. Then, the project must meet one of the two metrics established under this subpart. In most instances, meeting the underlying program’s eligibility requirement will mean that the project already meets one or the other of these two metrics.

Investment. Two criteria that the statute requires RD to take into consideration when evaluating a plan (see discussion on Scoring below) are investments from other Federal agencies and investments from philanthropic organizations. For purposes of this subpart, RD is defining investment to mean either monetary or non-monetary contributions because both types of contributions can be important components to implementing the plan, especially in communities with limited resources.

Jurisdiction and multi-jurisdictional. The statute requires that a project support a community or economic development plan on a “multi-jurisdictional” basis. To clarify how RD will consider this requirement, RD is first defining “jurisdiction” and then “multi-jurisdictional.”

The principal component of “jurisdiction” is a unit of government, such as a State, Indian tribe, county, city, township, town, borough, etc. However, a plan is not always developed by, nor necessarily targeted at, such units of governments. For example, there are regional authorities, such as regional planning organizations, that may assist with developing and implementing regional economic development or community development plans. Thus, RD intends the definition of jurisdiction to be broad enough to take into account such entities.

Using the definition of jurisdiction, RD is defining “multi-jurisdictional” to mean more than one jurisdiction. This provides the broadest concept.

Philanthropic organization. As noted earlier under Investment, one of the criteria for prioritizing plans is investment from philanthropic organizations. RD is seeking to implement a definition that is sufficient to include any entity whose mission is

to provide monetary, technical assistance, or other items of value for religious; charitable; scientific; literary; or educational purposes. Such entities include, but are not limited to, private trusts, foundations, churches, and charitable organizations.

Plan. As noted earlier in this preamble, the purpose of Section 6025 is to fund projects that support the implementation of strategic economic development or community development plans.

RD intends the definition of “plan” be inclusive rather than exclusive, but at the same time require the plan to address certain minimum elements in order to be effective in improving the economies of the region(s) addressed by the plan. RD examined plan requirements associated with other Federal agencies.

For the purposes of this subpart, a plan is a comprehensive economic development or community development strategy that outlines a region’s vision for shaping its economy. This strategy would cover, as appropriate and necessary, a wide range of aspects such as natural resources, land use, transportation, and housing. Such plans bring together key community stakeholders to create a roadmap to diversify and strengthen their communities and to build a foundation to create the environment for regional economic prosperity.

To be an acceptable plan for the purposes of the subpart, the plan must be supported by the jurisdictions affected by the plan and must address each of the following elements:

- The economic conditions of the region;
- the economic and community strengths, weaknesses, opportunities, and threats for the region, to include consideration of such aspects as the environmental and social conditions;
- strategies and implementation plan that build upon the region’s strengths and opportunities and resolve the weaknesses and threats facing the region;
- performance measures to evaluate the successful implementation of the plan; and
- support of key community stakeholders.

RD notes that inclusion of each of the five elements does not speak to the quality of the plan (as discussed below under Scoring) or to whether the plan has been adopted (as discussed earlier under Adopted in the Definitions section of the preamble).

Project. One of the eligibility criteria under this statute for projects seeking reserved funding under this subpart is

that the project meets the eligibility requirements of the underlying program. While the programs identify such eligibility requirements, they do not all contain a definition of a “project.” For this subpart, RD is providing a definition of project in broad terms to be “the eligible proposed use(s) for which funds are requested as described in the application material submitted to the Agency for funding under the underlying program.” “Eligible proposed uses(s)” refers to those proposed uses that are eligible for funding under the underlying program. The intent of this definition is to cover the various types of projects eligible under the underlying programs.

Project Eligibility (§ 1980.1010)

The statute identifies three criteria that a project must meet in order to be eligible for reserved funding. These criteria, which RD is implementing directly from the statute, are:

- The project must meet the project eligibility criteria of the applicable program identified in § 1980.1002;
- The project must be carried out solely in a rural area; and
- The project must support the implementation of a strategic economic development or community development plan on a multi-jurisdictional basis.

The first criterion simply means that a project must meet the project eligibility criteria of the underlying program. For example, if a project is applying for reserved funds from the Community Facility Grant program, the project must meet the eligibility criteria for that program.

For implementing the second criterion, RD is defining “carried out solely in a rural area.” See discussion under Definitions for more information.

For the third criterion, RD is shortening the criterion to read “supports a plan on a multi-jurisdictional basis” and is using the definition of “plan” to address the statute’s “strategic community and economic development plan.”

Applications (§ 1980.1015)

The section of the rule identifies two main components as follows:

1. *Underlying Program Applications.* Applicants must submit all of the application materials associated with the underlying program from which they are seeking reserved funding.
2. *Section 6025 Specific Application Information.* Applicants must submit information that addresses several items specific to being eligible to apply under this subpart and to allow RD to score the project and the plan it supports (see

Scoring section below). The following paragraphs identify what information an applicant must provide when seeking funding under this subpart. If the application for the underlying program already requests the same information, the applicant is not required to repeat that information.

The applicant (§ 1980.1015(a)). In addition to basic information on the applicant (*i.e.*, name, telephone, number, email address), this section also requires identification of whether the applicant includes a State, county, municipal, or tribal government. It is necessary to obtain this identification because there is a statutory requirement that applications involving such governmental entities must include an indication of consistency with an adopted regional economic or community development plan.

The plan (§ 1980.1015(b)). An applicant is required to identify by name the plan being supported by the project, the date the plan became effective, and the dates the plan is to remain in effect. The applicant is also required to provide contact information for the appropriate entity(ies) who prepared the plan.

As noted below in scoring, applications will be scored, in part, on the number of a plan’s objectives that a project will directly support for implementing the plan. To enable RD to score an application in this regard, the applicant must provide from the most current version of the plan a list and description of each objective that the project will directly support. To provide this information, the applicant may submit copies of the relevant pages from the plan or their own list and descriptions.

Applications will be also scored on the quality of the plan based on five criteria, as established in Section 6025—(1) collaboration, (2) regional resources, (3) investment from other Federal agencies, (4) investment from philanthropic organizations, and (5) clear objectives and the ability to establish measurable performance measures and track progress toward meeting the objectives. The Agency will evaluate each plan based on information provided by the applicant on each of these five criteria. Applicants may provide this information by submitting copies of the relevant pages from the plan or providing their own descriptions. In either case, failure to provide sufficient detail may result in a lower score for the application.

Because the criterion for collaboration is based, in part, on the collaboration of stakeholders within the service area of the plan, the applicant is also required

to describe the service area of the plan. Lastly, the applicant may provide, if available, a Web site address to the plan.

While the applicant is not required to submit a copy of the entire plan, RD encourages the applicant to provide a copy of relevant portions of the plan to facilitate RD review and scoring of the project and the plan.

The project (§ 1980.1015(c)). With regard to the project itself, the applicant is required to provide sufficient information on the project to enable RD to determine whether the project is “carried out solely in a rural area” as defined in this subpart. If the application material for the underlying program is sufficient to allow RD to make this determination, the applicant does not need to submit additional information. However, if it is not sufficient, the applicant must provide the necessary information showing that either the project will be physically located in a rural area or that the beneficiaries of the project’s services either reside in (if an individual) or are located in (if an entity) a rural area.

The applicant is also required to provide a detailed description of how the project directly supports one or more of the plan’s objectives (which are identified by the applicant under the information being requested on the plan, see above). Failure to provide sufficient information to demonstrate direct support may result in a lower score for the application.

Lastly, applicants that include a State, county, municipal, or tribal government must submit a letter from the appropriate entity(ies) who approved the plan (such as an elected or appointed official) certifying that the applicant’s project is consistent with the plan and that the plan has been adopted.

Agency Coordination (§ 1980.1015(d)). Applicants are required to submit certain information that will assist RD to coordinate the programs that provide funding to this subpart.

1. *Program areas.* The applicant is required to identify the program area for which the applicant is seeking funds—community facility program area, the water and waste disposal program area, or the rural business and cooperative development program area. If an applicant submits an application seeking funds from more than one of these program areas, the applicant would identify each program area.

2. *Multiple applications.* An applicant may submit more than one application in a fiscal year for funding under this subpart. For example, an applicant may submit three applications, one for each

of the three program areas. In this case, the applicant would identify in each application information on the other two applications. The information to be submitted is: The name(s) of the project(s), the program area(s) for which funds are being sought, and the dates that each application was submitted.

An applicant may submit applications at different times of the fiscal year. For example, an applicant may submit an application in November of a fiscal year and then another application in March of that same fiscal year. In such instances, the applicant would only need to identify the November application when submitting the March application.

3. *Previous applications.* If an applicant previously submitted one or more applications for funding under this subpart, the applicant is required to submit certain information in the current application concerning each of the previously submitted applications as follows:

- The date the previous application was submitted;
- The name of the project;
- The specific program area(s) from which funds were sought;
- Whether or not the project was selected for funding; and
- If the applicant received an award under this subpart, the specific program(s) that provided the funding; the date and amount of the award; and whether any of the funding came from funds reserved under this subpart.

Approved applications. Section 6025(e)(1) includes provisions that allow applicants who submitted applications prior to the effective date of this subpart that were approved, but not funded, to revise their applications to apply for reserved funding. RD will issue guidance on how these applications are to be resubmitted under a notice published in the **Federal Register** at the appropriate time.

Scoring (§ 1980.1020)

It is possible that the total amount of funds being requested by applicants for a particular program under this subpart may exceed the total reserved funds available for that program. To address this issue, RD will score projects on the basis of both the underlying program's scoring criteria, including discretionary points, and the scoring criteria, as described below, specific to this subpart.

To rank applications competing for the reserved funding under this subpart, RD will score an application considering two sets of scoring criteria (in addition to the scoring criteria of the applicable underlying program): (1) The

number of a plan's objectives that the project supports (maximum of 10 points) and (2) the plan itself based on the five criteria identified in Section 6025 (maximum of 10 points). The maximum number of "Section 6025" points that a project can receive is 20 points.

Scoring how the project supports a plan (maximum score of 10 points). RD will score a project's support for implementing the plan as follows:

- If the project directly supports implementation of three or more of the plan's objectives, the application will receive 10 points.
- If the project directly supports implementation of two of the plan's objectives, the application will receive 5 points.
- If the project directly supports implementation of less than two of the plan's objectives, the application will receive no points.

Scoring the plan supported by the project (maximum score of 10 points). RD will also score the plan that the project supports. RD will use the five criteria identified in Section 6025 and as discussed below. RD will award two points for each criterion that a plan demonstrates. The Agency will award these points on the basis of what is contained in the application. Applicants are encouraged to submit the relevant pages of the most current version of the Plan to provide documentation of these criteria.

- *Collaboration.* If the plan was developed through the collaboration of multiple stakeholders in the service area of the plan, including the participation of combinations of stakeholders, such as State, local, and tribal governments, nonprofit institutions, institutions of higher education, and private entities, RD will award two points.

- *Regional resources.* If the plan demonstrates an understanding of the region's assets (including natural resources, human resources, infrastructure, and financial resources) that could support the plan, RD will award two points.

- *Investment—other Federal agencies.* If the development of the plan or the activities and actions taken to implement the plan include monetary or non-monetary contributions from Federal agencies other than USDA, RD will award two points.

- *Investment—philanthropic organizations.* If the plan includes monetary or non-monetary contributions from philanthropic organizations, RD will award two points.

- *Objectives, measures, tracking.* If the plan contains clear objectives, the

ability to establish measurable performance measures, and the ability to track progress towards meeting the plan's objectives, RD will award two points.

Calculating an Application's Total Score

RD will calculate an application's total score by summing the application's scores received from (1) the underlying program, (2) the two sets of scoring criteria under this subpart, and (3) any discretionary points that may awarded by the State Director or the Administrator under the provisions of the applicable underlying program. RD will give higher priority for the reserved funding to higher scoring applications, based on the combined score.

Award Process (§ 1980.1025)

Unless RD indicates otherwise in a notice, the award process for the underlying program will be used to determine which projects receive funding under this subpart.

In years where funding is made available under this subpart, if a project is not awarded funds under this subpart, it is still eligible to compete for funds through the underlying program. Such projects will be scored only according to the criteria in the underlying program including any discretionary points. Any points awarded through the Section 6025 scoring criteria will not be included when competing with other projects in the underlying program. However, in years where funding is not made available under this subpart, projects are still eligible to compete for funding under the applicable underlying program. The scores for such projects when competing for underlying program funding will include the score assigned to the application under § 1980.1020(b) as described in a notice published in the **Federal Register**. The Agency intends to prioritize such applications in this manner even if it chooses not to reserve funds in a particular year as permitted by statute.

Evaluation of Project Information (§ 1980.1026)

An applicant that receives funding under this subpart is required to submit to the Agency information on the project's measures, metrics, and outcomes to the appropriate entity(ies) monitoring the implementation of the plan. Applicants would submit this information to the Agency for as long as the plan is in effect.

III. Invitation To Comment

RD encourages interested persons and organizations to submit written

comments, which may include data, suggestions, or opinions. Commenters should include their name, address, and other appropriate contact information. If persons with disabilities (e.g., deaf, hard of hearing, or have speech difficulties) require an alternative means of receiving this notice (e.g., Braille, large print, audiotape) in order to submit comments, please contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Comments may be submitted by any of the means identified in the **ADDRESSES** section. If comments are submitted by mail or hand delivery, they should be submitted in an unbound format, no larger than letter-size, suitable for copying and electronic filing. If confirmation of receipt is requested, a stamped, self-addressed, postcard or envelope should be enclosed. RD will consider all comments received during the comment period and will address comments in the preamble to the final regulation.

List of Subjects in 7 CFR Part 1980

Agriculture, Business and industry, Community facilities, Credit, Disaster assistance, Livestock, Loan programs—agriculture, Loan programs—business, Loan programs—housing and community development, Low and moderate income housing, Reporting and recordkeeping requirements, Rural areas.

For the reasons set forth in the preamble, 7 CFR part 1980 is amended as follows:

PART 1980—GENERAL

■ 1. The authority citation for part 1980 continues to read as follows:

Authority: 5 U.S.C. 301, 7 U.S.C. 1989

■ 2. Subpart K is added to read as follows:

Subpart K—Strategic Economic and Community Development

GENERAL

Sec.	
1980.1001	Purpose.
1980.1002	Programs.
1980.1003	Applicability of Program Regulations.
1980.1004	Funding.
1980.1005	Definitions.
1980.1006–1980.1009	[Reserved]
1980.1010	Project eligibility.
1980.1011–1980.1014	[Reserved]
1980.1015	Applications.
1980.1016–1980.1019	[Reserved]
1980.1020	Scoring.
1980.1021–1980.1024	[Reserved]
1980.1025	Award process.
1980.1026	Evaluation of Project information.
1980.1027–1980.1100	[Reserved]

§ 1980.1001 Purpose.

The purpose of this subpart is to give priority to Projects that support implementation of strategic economic development and community development plans on a Multi-jurisdictional basis for applications submitted for the programs identified in § 1980.1002.

§ 1980.1002 Programs.

The Agency may elect to reserve funds from one or more of the programs listed in paragraphs (a) through (h) of this section.

(a) Community Facility Loans (7 CFR part 1942, subpart A).

(b) Fire and Rescue and Other Small Community Facilities Projects (7 CFR part 1942, subpart C).

(c) Community Facilities Grant Program (7 CFR part 3570, subpart B).

(d) Community Programs Guaranteed Loans (7 CFR part 3575, subpart A).

(e) Water and Waste Disposal Programs Guaranteed Loans (7 CFR part 1779).

(f) Water and Waste Loans and Grants (7 CFR part 1780, subparts A, B, C, and D).

(g) Business and Industry Guaranteed Loanmaking and Servicing (7 CFR part 4279, subparts A and B; 7 CFR part 4287, subpart B).

(h) Rural Business Development Grants (7 CFR part 4280, subpart E).

§ 1980.1003 Applicability of Program Regulations.

Except as supplemented by this subpart, the provisions of the programs identified in § 1980.1002 are incorporated into this subpart.

§ 1980.1004 Funding.

Unless the Agency publishes a notice that indicates otherwise, the Agency will reserve funds according to the procedures specified in paragraphs (a) through (c) of this section for each of the programs identified in § 1980.1002 each fiscal year.

(a) *Individual program basis.* The Agency will reserve funds on an individual program basis.

(b) *Percentage of funds.* The Agency will reserve 10 percent of the funds made available in a fiscal year to each program identified in § 1980.1002 unless the Agency specifies a different percentage. If the Agency specifies a different percentage, the Agency will publish a notice indicating the percentage. The Agency may reserve the same or different percentages for each program in a single fiscal year.

(c) *Unobligated funds.* If a program's funds reserved under this subpart remain unobligated as of June 30 of the

fiscal year in which the funds are reserved, the Agency will return such remaining funds to that program's regular funding account for obligation for all eligible Projects in that program.

§ 1980.1005 Definitions.

In addition to the definitions found in the regulations for the programs identified in § 1980.1002, the following definitions apply to this subpart. If the same term is defined in any of the regulations for the programs identified in § 1980.1002, for purposes of this subpart, that term will have the meaning identified in this subpart.

Adopted means that a Plan has been officially approved for implementation by the appropriate entity or entities in the Jurisdiction(s) affected by the Plan (for example, a State, Indian Tribe, county, city, township, town, borough, etc.).

Agency means the Rural Business-Cooperative Service, the Rural Housing Service, or the Rural Utilities Service, or their successor agencies.

Carried Out Solely in a rural area means either:

(1) The Project is physically located in a rural area; or

(2) All of the beneficiaries of the services provided by the Project either reside in a rural area (for individuals) or are located in a rural area (for businesses).

Investment means either monetary or non-monetary contributions to the implementation of the Plan's objectives.

Jurisdiction means a unit of government or other entity with similar powers. Examples include, but are not limited to: City, county, district, special purpose district, township, town, borough, parish, village, State, and Indian tribe.

Multi-Jurisdictional means at least two Jurisdictions.

Philanthropic organization means an entity whose mission is to provide monetary, technical assistance, or other items of value for religious, charitable, scientific, literary, or educational purposes.

Plan means a comprehensive economic development or community development strategy that outlines a region's vision for shaping its economy, and includes, as appropriate and necessary, consideration of such aspects as natural resources, land use, transportation, and housing. Such Plans bring together key community stakeholders to create a roadmap to diversify and strengthen their communities and to build a foundation to create the environment for regional economic prosperity. To be acceptable under this subpart, the Plan must be

vetted and supported by the Jurisdictions affected by the Plan and must contain at a minimum the following:

- (1) A summary of the economic conditions of the region;
- (2) An in-depth analysis of the economic and community strengths, weaknesses, opportunities, and threats for the region, to include consideration of such aspects as the environmental and social conditions;
- (3) Strategies and implementation Plan to build upon the region's strengths and opportunities and to resolve the weaknesses and threats facing the region;
- (4) Performance measures that evaluate the successful implementation of the Plan's objectives; and
- (5) Support of key community stakeholders.

Project means the eligible proposed use(s) for which funds are requested as described in the application material submitted to the Agency for funding under the underlying program.

§§ 1980.1006–1980.1009 [Reserved]

§ 1980.1010 Project eligibility.

In order to be eligible to receive funds under this subpart, the Project must meet the following:

- (a) The Project must meet the Project eligibility criteria of the applicable program identified in § 1980.1002;
- (b) The Project must be Carried Out Solely in a rural area; and
- (c) The Project must support the implementation of a Plan on a Multi-Jurisdictional basis.

§§ 1980.1011–1980.1014 [Reserved]

§ 1980.1015 Applications.

In addition to the application material specific to the applicable program identified in § 1980.1002, each applicant seeking funding under this subpart must provide the information specified in paragraphs (a) through (d) of this section.

- (a) *Applicant*. The applicant must submit:
 - (1) Name of the applicant;
 - (2) Telephone number of the applicant;
 - (3) Email address of the applicant; and
 - (4) A statement indicating whether or not the applicant is or includes one of the following:
 - (i) State government;
 - (ii) County government;
 - (iii) Municipal government; or
 - (iv) Tribal government.
- (b) *Plan*. Each application must include the following information:
 - (1) The name of the Plan the Project

(2) The date the Plan became effective;

(3) The dates the Plan is to remain in effect;

(4) Contact information for the entity(ies) approving the Plan, including name(s), telephone number(s), and email address(es);

(5) As found in the most current version of the Plan, the name and description of each objective that the Project will directly support;

(6) A description of the service area of the Plan;

(7) Documentation that the Plan was developed through the collaboration of multiple stakeholders in the service area of the Plan, including the participation of combinations of stakeholders;

(8) Documentation that the Plan demonstrates an understanding of the applicable region's assets that could support the Plan;

(9) Documentation indicating whether or not the Plan includes monetary or non-monetary contributions from Federal agencies other than the U.S. Department of Agriculture;

(10) Documentation indicating whether or not the Plan includes monetary or non-monetary contributions from one or more Philanthropic organizations.

(11) Documentation that the Plan contains:

- (i) Clear objectives and
- (ii) The ability to establish measurable performance measures and to track progress towards meeting the Plan's objectives; and

(12) If available, a Web site address link to the Plan.

(c) *Project*. Each application must include the following information:

- (1) The name of the Project;
- (2) Sufficient detail to allow the Agency to determine that the Project has been Carried Out Solely in a rural area as defined in § 1980.1005;

(3) A detailed description of how the Project directly supports each objective identified under paragraph (b)(5) of this section; and

(4) If the application is from an applicant that includes a State, county, municipal, or tribal government, a letter from the appropriate entity(ies) indicating that:

(i) The Project is consistent with the Plan and

(ii) The Plan has been Adopted.

(d) *Agency coordination*. To help ensure coordination among the programs included in this subpart, the Agency is requiring applicants provide the Agency the information in paragraphs (d)(1) through (3) of this section.

(1) *Program areas*. Identify the program area(s) (*i.e.*, Community

Facilities, Water and Waste, Rural Business and Cooperative Development) from which funds are being sought.

(2) *Multiple applications*. If the applicant is submitting in the same fiscal year more than one application for funding under this subpart, identify in each application the other application(s) by providing:

- (i) The name(s) of the Project(s);
- (ii) The program area(s) for which funds are being sought; and
- (iii) The date that each application was submitted to the Agency.

(3) *Previous applicants*. If the applicant has previously submitted one or more applications for funding under this subpart, the applicant must provide in the current application the following information for each previous application:

- (i) The date the application was submitted;
- (ii) The name of the Project;
- (iii) The program area(s) from which funds were sought;
- (iv) Whether or not the Project was selected for funding; and
- (v) If the Project was selected for funding,

(A) The name(s) of the specific program(s) that provided the funding;

(B) The date and amount of the award; and

(C) Whether any of the funding came from the funds reserved under this subpart.

§§ 1980.1016–1980.1019 [Reserved]

§ 1980.1020 Scoring.

The Agency will score each eligible application seeking funding under this subpart as described in this section.

(a) *Underlying program scoring*. The Agency will score each application using the criteria for the applicable program identified in § 1980.1002. The maximum number of points an application can receive under this paragraph is based on the scoring criteria for the applicable underlying program, including any discretionary points that may be awarded.

(b) *Section 6025 scoring*. The Agency will score each application using the criteria identified in paragraphs (b)(1) and (2) of this section. The maximum number of points an application can receive under this paragraph is 20 points.

(1) *Project's direct support of a Plan's objectives*. The Agency will score each application on the basis of the number of a Plan's objectives the Project directly supports. The maximum score under this paragraph is 10 points.

(i) If the Project directly supports implementation of 3 of the Plan's objectives, 10 points will be awarded.

(ii) If the Project directly supports implementation of 2 of the Plan's objectives, 5 points will be awarded.

(iii) If the Project directly supports implementation of less than 2 of the Plan's objectives, no points will be awarded.

(2) *Characteristics of a Plan.* The Agency will score the Plan associated with a project based upon the characteristics of the Plan, which are identified in paragraphs (b)(2)(i) through (v) of this section. Applicants must supply sufficient documentation that demonstrates to the Agency the criteria identified in paragraphs (b)(2)(i) through (v) of this section. The maximum score under this paragraph is 10 points.

(i) *Collaboration.* If the Plan was developed through the collaboration of multiple stakeholders in the service area of the Plan, including the participation of combinations of stakeholders, such as State, local, and tribal governments, nonprofit institutions, institutions of higher education, and private entities, two points will be awarded.

(ii) *Resources.* If the Plan demonstrates an understanding of the applicable regional assets that could support the Plan, including natural resources, human resources, infrastructure, and financial resources, two points will be awarded.

(iii) *Other Federal Agency Investments.* If the Plan includes Investments from Federal agencies other than the U.S. Department of Agriculture, two points will be awarded.

(iv) *Philanthropic organization Investments.* If the Plan includes Investments from Philanthropic organizations, two points will be awarded.

(v) *Objectives and performance measures.* If the Plan contains clear objectives and the ability to establish measurable performance measures and to track progress toward meeting the objectives, two points will be awarded.

(c) *Total score.* The Agency will sum the scores each application receives under paragraphs (a) and (b) of this section in order to rank applications.

§§ 1980.1021–1980.1024 [Reserved]

§ 1980.1025 Award process.

(a) Unless RD indicates otherwise in a notice, the award process for the applicable underlying program will be used to determine which Projects receive funding under this subpart.

(b) In years when funding is made available under this subpart, Projects not receiving funding under this subpart are eligible to compete for funding under the applicable underlying program. The scores for such Projects

when competing for underlying program funding will not include the score assigned to the application under § 1980.1020(b).

(c) In years when funding is not made available under this subpart, Projects are eligible to compete for funding for the applicable underlying program. The scores for such Projects when competing for underlying program funding will include the score assigned the application § 1980.1020(b) as described in a notice published in the **Federal Register**.

§ 1980.1026 Evaluation of Project information.

To assist the Agency in evaluating the effectiveness of this subpart, each applicant that receives funding under this subpart must submit to the Agency all measures, metrics, and outcomes of the Project that are reported to the entity(ies) who are monitoring Plan implementation. This information will be submitted for as long as the Plan is in effect.

§§ 1980.1027–1980.1100 [Reserved]

Dated: May 12, 2015.

Lisa Mensah,

Under Secretary, Rural Development.

Dated: May 15, 2015.

Michael Scuse,

Under Secretary, Farm and Foreign Agricultural Services.

[FR Doc. 2015–12163 Filed 5–19–15; 8:45 am]

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DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

15 CFR Part 801

[Docket No. 150108021–5409–01]

RIN 0691–AA84

International Services Surveys: BE–180, Benchmark Survey of Financial Services Transactions Between U.S. Financial Services Providers and Foreign Persons

AGENCY: Bureau of Economic Analysis, Department of Commerce.

ACTION: Final rule.

SUMMARY: This final rule amends regulations of the Bureau of Economic Analysis (BEA), Department of Commerce, to reinstate reporting requirements for the BE–180, Benchmark Survey of Financial Services Transactions between U.S. Financial Services Providers and Foreign Persons. Benchmark surveys are conducted every five years; the prior survey covered

2009. For the 2014 benchmark survey, BEA is making one change in the survey data items to collect data on equity- and debt-related underwriting transactions separately. This mandatory survey is conducted under the authority of the International Investment and Trade in Services Survey Act (the Act). Unlike most other BEA surveys conducted pursuant to the Act, a response is required from persons subject to the reporting requirements of the BE–180, Benchmark Survey of Financial Services Transactions between U.S. Financial Services Providers and Foreign Persons, whether or not they are contacted by BEA, to ensure Complete coverage of financial services transactions between U.S. financial services providers and foreign persons.

DATES: This final rule is effective June 19, 2015.

FOR FURTHER INFORMATION CONTACT:

Christopher Stein, Chief, Services Surveys Branch (BE–50), Balance of Payments Division, Bureau of Economic Analysis, U.S. Department of Commerce, Washington, DC 20230; phone (202) 606–9850.

SUPPLEMENTARY INFORMATION: On

January 27, 2015, BEA published a notice of proposed rulemaking that set forth revised reporting criteria for the BE–180, Benchmark Survey of Financial Services Transactions between U.S. Financial Services Providers and Foreign Persons (80 FR 4228–4231). BEA received four comments on the proposed rule.

One comment was written on behalf of hedge fund managers who are subject to BE–180 reporting requirements. The letter stated that the BE–180 survey is not well suited to hedge funds and that, for these respondents, the burden of reporting is significant. The commenter made two recommendations: (1) Entities that are not contacted by BEA should have no reporting responsibilities (similar to other BEA surveys); and (2) BEA should not extend reporting by U.S. investment managers to other BEA surveys. BEA is very concerned about respondent burden and has employed several approaches to reduce the burden where possible. However, BEA does not adopt the above two recommendations because of the statistical needs that govern how the data are collected and tabulated. If BEA does not require responses from all persons subject to the reporting requirements of the BE–180, we could not ensure that a complete and accurate sample frame is maintained in the non-benchmark years. Thus, lack of this information in a benchmark year would result in incomplete data in our tabulated information in non-

benchmark years. To aid in communicating filing requirements, BEA will consider what additional guidance it can offer to hedge fund filers, possibly by providing expanded form instructions and Frequently Asked Questions (FAQs).

Another comment was written on behalf of the international banking community in the United States. The letter requested that BEA adopt an accommodating approach to allow impacted companies adequate time to complete the BE-180 survey. As the BE-180 applies to a broader audience and has reporting requirements that differ from the related BE-185 Quarterly Survey of Financial Services Transactions between U.S. Financial Services Providers and Foreign Persons, the commenter stated that additional time to comply was necessary to help alleviate the filing burden. To provide ample time for respondents to complete and file the BE-180 survey, BEA will accept filing extension requests through the October 1, 2015 due date.

Respondents can request extensions of 30 days or less over the phone or in writing; requests of greater than 30 days must be provided in writing. Additionally, any respondent that chooses to file electronically through BEA's eFile system will automatically receive a 30 day extension.

The third comment was written on behalf of the commercial energy industry and was concerned with the BE-180 definition of financial services provider. The commenter requested that BEA provide clarification with regard to what information should be reported by principals to commodity contracts. The commenter recommended that if BEA is unable to provide this clarification, the obligation to file the BE-180 should be limited only to those entities that are contacted by BEA. We will consider what additional guidance it can offer to clarify how commodity-related activities are to be reported, including expanded form instructions and FAQs.

The final comment was written on behalf of asset management firms that are subject to BE-180 reporting requirements. The letter stated that the impact of the BE-180 survey and the reporting burden for entities in this industry are significant. The commenter made three recommendations: (1) Entities that are not contacted by BEA should have no reporting responsibilities (similar to other BEA surveys); (2) BEA should raise the \$3 million monetary threshold for mandatory reporting on the BE-180 of financial services transactions; and (3) BEA should provide additional guidance to asset managers in order to

collect meaningful Survey data. BEA does not adopt the first recommendation because of the statistical needs that govern data collection and tabulation. As previously stated, BEA could not ensure that a complete and accurate sample frame is maintained in the non-benchmark years if we did not require responses from all persons subject to the reporting requirements of the BE-180, which is a benchmark survey. BEA does not adopt the second recommendation because the \$3 million threshold for mandatory reporting on the BE-180 survey is necessary to ensure an accurate sample frame for the quarterly BE-185 survey. Therefore, this threshold is unchanged from the previous benchmark survey. Regarding the third recommendation, BEA will consider what additional guidance it can offer to asset managers, possibly in the form of expanded instructions and FAQs, to aid in communicating the filing requirements.

The change in data items collected (described in the Description of Changes section below) will be reflected in the final version of the BE-180 survey form.

This final rule adds 15 CFR part 801.9 to set forth the reporting requirements for the BE-180, Benchmark Survey of Financial Services Transactions between U.S. Financial Services Providers and Foreign Persons. BEA conducts the BE-180 under the authority provided by the International Investment and Trade in Services Survey Act (22 U.S.C. 3101-3108) and by Section 5408 of the Omnibus Trade and Competitiveness Act of 1988.

By rule issued in 2012 (77 FR 24373), BEA established guidelines for collecting data on international trade in services and direct investment through notices, rather than through rulemaking. This final rule amends the regulations to require a response from persons subject to the reporting requirements of the BE-180, whether or not they are contacted by BEA, to ensure complete coverage of financial services transactions between U.S. financial services providers and foreign persons.

The BE-180 survey covers financial services transactions with foreign persons. In non-benchmark years, the universe estimates covering these transactions are derived from the sample data reported on BEA's BE-185, Quarterly Survey of Financial Services Transactions between U.S. Financial Services Providers and Foreign Persons.

The data are used by BEA to estimate the financial services component of the U.S. International Transactions Accounts and other economic accounts compiled by BEA. The data are needed to monitor U.S. exports and imports of

financial services; analyze their impact on the U.S. and foreign economies; support U.S. international trade policy on financial services; and assess and promote U.S. competitiveness in international trade in services. In addition, these data will improve the ability of U.S. businesses to identify and evaluate market opportunities.

The services covered by the BE-180 include the following transactions: (1) Brokerage services related to equity transactions; (2) other brokerage services; (3) underwriting and private placement services; (4) financial management services; (5) credit-related services, except credit card services; (6) credit card services; (7) financial advisory and custody services; (8) securities lending services; (9) electronic funds transfer services; and (10) other financial services.

Description of Changes From the 2009 BE-180 Survey

The changes amend the regulations and the survey form for the BE-180 Benchmark Survey of Financial Services Transactions between U.S. Financial Services Providers and Foreign Persons. These amendments include changes in the data items collected and questionnaire design. Under this final rule and unlike many other BEA surveys conducted pursuant to the Act, persons subject to the reporting requirements of the BE-180 are required to respond whether or not they are contacted by BEA. Also, we are adding one item to the 2014 BE-180 survey form to collect data on equity- and debt-related underwriting transactions separately. The 2009 BE-180 survey collected these transactions as a combined amount. Separate reporting of these transactions is needed to accurately remove equity- and debt-related underwriting fees from purchases and sales of equity and debt security transactions, which are reported inclusive of underwriting and brokerage fees. A number of reporters include language in their financial statements that suggests equity- and debt-related underwriting transactions are readily obtainable from their accounting records. In addition, BEA is redesigning the format and wording of the survey form. The new design incorporates cognitive design improvements made to other BEA surveys that improve the flow of the survey form and eliminate redundancies in the survey questions. Survey instructions and data item descriptions are being changed to improve clarity and to make the benchmark survey form more consistent with those of other BEA surveys.

Executive Order 12866

This final rule has been determined to be not significant for purposes of E.O. 12866.

Executive Order 13132

This final rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under E.O. 13132.

Paperwork Reduction Act

The collection of information in this final rule has been submitted to the Office of Management and Budget (OMB) under the Paperwork Reduction Act (PRA). OMB has pre-approved the information collection under OMB control number 0608-0062. Notwithstanding any other provisions of 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 PRA unless that collection displays a currently valid OMB control number.

The BE-180 survey is expected to result in the filing of reports from approximately 8,750 respondents. Approximately 1,250 respondents would report mandatory or voluntary data on the survey and approximately 7,500 would file exemption claims. The respondent burden for this collection of information will vary from one respondent to another, but is estimated to average ten hours for the respondents that file mandatory or voluntary data-including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information and two hours for other responses. Thus the total respondent burden for this survey is estimated at 27,500 hours, compared to 24,000 hours for the 2009 BE-180 survey. The increase in burden hours is due to an increase in the size of the respondent universe. Written comments regarding the burden-hour estimates or other aspects of the collection-of-information requirements contained in the final rule should be sent to both BEA via email at *Christopher.Stein@bea.gov*, and to OMB, via email at *pbugg@omb.eop.gov* or by FAX at (202) 395-7245.

Regulatory Flexibility Act

The Chief Counsel for Regulation, Department of Commerce, certified at the proposed rule stage to the Chief Counsel for Advocacy, Small Business Administration, under the provisions of the Regulatory Flexibility Act, 5 U.S.C. 605(b), that this final rule will not have

a significant economic impact on a substantial number of small entities. The factual basis for the certification was published in the proposed rule and is not repeated here.

BEA received one comment on the impact on small entities. The commenter, writing on behalf of asset management firms, stated that the broad scope of the financial services collected on the BE-180 survey, and the fact that the \$3 million mandatory reporting level applies separately to sales or purchases, will impact a larger number of small businesses than indicated by BEA. BEA is very concerned about respondent burden and only collects data from the broader group of filers on benchmark surveys that are conducted once every five years. BEA acknowledges that a larger number of asset managers may be required to complete the BE-180 survey as a result of the \$3 million threshold. However, even with a larger number of entities being required to report, preparing and submitting the required data will not have a significant economic impact on any entity, large or small. While the resources required to respond to the survey will vary from one respondent to another, BEA estimates that it will take, on average, ten hours for the respondents that file mandatory or voluntary data, and two hours for other responses. These estimates include time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing, reviewing, and submitting the appropriate form. This rule has no other impact or regulatory burden beyond the one-time reporting of the required information. Therefore, even businesses required to provide mandatory data on the survey will only expend a minimal number of hours of staff time to comply, which does not constitute a significant economic impact. Because this rule will not have a significant economic impact on a substantial number of small entities, no FRFA is required and none has been prepared.

List of Subjects in 15 CFR Part 801

International transactions, Economic statistics, Foreign trade, Penalties, Reporting and record keeping requirements, International Services.

Dated May 12, 2015.

Brian C. Moyer,

Director, Bureau of Economic Analysis.

For reasons set forth in the preamble, BEA amends 15 CFR part 801 as follows:

PART 801—SURVEY OF INTERNATIONAL TRADE IN SERVICES BETWEEN U.S. AND FOREIGN PERSONS AND SURVEYS OF DIRECT INVESTMENT

■ 1. The authority citation for 15 CFR part 801 continues to read as follows:

Authority: 5 U.S.C. 301; 15 U.S.C. 4908; 22 U.S.C. 3101–3108; E.O. 11961 (3 CFR, 1977 Comp., p. 86), as amended by E.O. 12318 (3 CFR, 1981 Comp. p. 173); and E.O. 12518 (3 CFR, 1985 Comp. p. 348).

■ 2. Revise § 801.3 to read as follows:

§ 801.3 Reporting requirements.

Except for surveys subject to rulemaking in §§ 801.7, 801.8 and 801.9, reporting requirements for all other surveys conducted by the Bureau of Economic Analysis shall be as follows:

(a) Notice of specific reporting requirements, including who is required to report, the information to be reported, the manner of reporting, and the time and place of filing reports, will be published by the Director of the Bureau of Economic Analysis in the **Federal Register** prior to the implementation of a survey;

(b) In accordance with section 3104(6)(2) of title 22 of the United States Code, persons notified of these surveys and subject to the jurisdiction of the United States shall furnish, under oath, any report containing information which is determined to be necessary to carry out the surveys and studies provided for by the Act; and

(c) Persons not notified in writing of their filing obligation by the Bureau of Economic Analysis are not required to complete the survey.

■ 3. Add § 801.9 to read as follows:

§ 801.9 Rules and regulations for the BE-180, Benchmark Survey of Financial Services Transactions between U.S. Financial Services Providers and Foreign Persons—2014.

A BE-180, Benchmark Survey of Financial Services Transactions between U.S. Financial Services Providers and Foreign Persons will be conducted covering 2014. All legal authorities, provisions, definitions, and requirements contained in §§ 801.1 through 801.2 and 801.4 through 801.6 are applicable to this survey. Specific additional rules and regulations for the BE-180 survey are given in paragraphs (a) through (e) of this section. More detailed instructions are given on the report forms and in instructions accompanying the report forms.

(a) *Response required.* A response is required from persons subject to the reporting requirements of the BE-180, Benchmark Survey of Financial Services

Transactions between U.S. Financial Services Providers and Foreign Persons—2014, contained herein, whether or not they are contacted by BEA to ensure complete coverage of financial services transactions between U.S. financial services providers and foreign persons. Also, a person, or its agent, that is contacted by BEA about reporting in this survey, either by sending a report form or by written inquiry, must respond in writing pursuant to this section. This may be accomplished by:

(1) Completing and returning the BE-180 survey by the due date; or,

(2) If exempt, by completing pages one through five of the BE-180 survey and returning them to BEA.

(b) *Who must report.* (1) A BE-180 report is required of each U.S. person that is a financial services provider or intermediary, or whose consolidated U.S. enterprise includes a separately organized subsidiary, or part, that is a financial services provider or intermediary, and that had transactions (either sales or purchases) directly with foreign persons in all financial services combined in excess of \$3,000,000 during its fiscal year covered by the survey on an accrual basis. The \$3,000,000 threshold should be applied to financial services transactions with foreign persons by all parts of the consolidated U.S. enterprise combined that are financial services providers or intermediaries. Because the \$3,000,000 threshold applies separately to sales and purchases, the mandatory reporting requirement may apply only to sales, only to purchases, or to both.

(i) The determination of whether a U.S. financial services provider or intermediary is subject to this mandatory reporting requirement may be based on the judgment of knowledgeable persons in a company who can identify reportable transactions on a recall basis, with a reasonable degree of certainty, without conducting a detailed manual records search.

(ii) Reporters that file pursuant to this mandatory reporting requirement must provide data on total sales and/or purchases of each of the covered types of financial services transactions and must disaggregate the totals by country and by relationship to the foreign transactor (foreign affiliate, foreign parent group, or unaffiliated).

(2) *Voluntary reporting.* If, during the fiscal year covered, sales or purchases of financial services by a firm that is a financial services provider or intermediary, or by a firm's subsidiaries, or parts, combined that are financial services providers or intermediaries, are \$3,000,000 or less, the U.S. person is

requested to provide an estimate of the total for each type of service. Provision of this information is voluntary. The estimates may be judgmental, that is, based on recall, without conducting a detailed records search. Because the \$3,000,000 threshold applies separately to sales and purchases, this voluntary reporting option may apply only to sales, only to purchases, or to both.

(3) *Exemption claims.* Any U.S. person that receives the BE-180 survey form from BEA, but is not subject to the mandatory reporting requirements and chooses not to report voluntarily, must file an exemption claim by completing pages one through five of the BE-180 survey and returning it to BEA. This requirement is necessary to ensure compliance with reporting requirements and efficient administration of the Act by eliminating unnecessary follow-up contact.

(c) *BE-180 definition of financial services provider.* The definition of financial services provider used for this survey is identical to the definition of the term as used in the North American Industry Classification System, United States, 2012, Sector 52—Finance and Insurance, and holding companies that own or influence, and are principally engaged in making management decisions for these firms (part of Sector 55—Management of Companies and Enterprises). For example, companies and/or subsidiaries and other separable parts of companies in the following industries are defined as financial services providers: Depository credit intermediation and related activities (including commercial banking, savings institutions, credit unions, and other depository credit intermediation); non-depository credit intermediation (including credit card issuing, sales financing, and other non-depository credit intermediation); activities related to credit intermediation (including mortgage and nonmortgage loan brokers, financial transactions processing, reserve, and clearinghouse activities, and other activities related to credit intermediation); securities and commodity contracts intermediation and brokerage (including investment banking and securities dealing, securities brokerage, commodity contracts and dealing, and commodity contracts brokerage); securities and commodity exchanges; other financial investment activities (including miscellaneous intermediation, portfolio management, investment advice, and all other financial investment activities); insurance carriers; insurance agencies, brokerages, and other insurance related activities; insurance and employee benefit funds (including pension funds,

health and welfare funds, and other insurance funds); other investment pools and funds (including open-end investment funds, trusts, estates, and agency accounts, real estate investment trusts, and other financial vehicles); and holding companies that own, or influence the management decisions of, firms principally engaged in the aforementioned activities.

(d) *Covered types of services.* The BE-180 survey covers the following types of financial services transactions (sales or purchases) between U.S. financial services companies and foreign persons: brokerage services related to equity transactions; other brokerage services; underwriting and private placement services; financial management service (including fees for mutual funds, pension funds, exchange-traded funds, private equity funds, corporate portfolio, individual portfolio, hedge funds, trusts, and other); credit related services, except credit card services; credit card services; financial advisory and custody services; securities lending services; electronic funds transfer services; and other financial services.

(e) *Due date.* A fully completed and certified BE-180 report, or qualifying exemption claim with pages one through five completed, is due to be filed with BEA not later than October 1, 2015.

[FR Doc. 2015-11996 Filed 5-19-15; 8:45 am]

BILLING CODE 3510-06-M

SOCIAL SECURITY ADMINISTRATION

20 CFR Part 404

[Docket No. SSA-2011-0098]

RIN 0960-AH43

Revised Medical Criteria for Evaluating Cancer (Malignant Neoplastic Diseases)

AGENCY: Social Security Administration.
ACTION: Final rule.

SUMMARY: We are revising the criteria in parts A and B of the Listing of Impairments (listings) that we use to evaluate claims involving cancer (malignant neoplastic diseases) under titles II and XVI of the Social Security Act (Act). These revisions reflect our adjudicative experience, advances in medical knowledge, recommendations from medical experts we consulted, and public comments we received in response to a Notice of Proposed Rulemaking (NPRM).

DATES: This rule is effective July 20, 2015.

FOR FURTHER INFORMATION CONTACT:

Cheryl A. Williams, Office of Medical Policy, Social Security Administration, 6401 Security Boulevard, Baltimore, Maryland 21235-6401, (410) 965-1020. 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:**Background**

We are revising and making final the regulations for evaluating cancer (malignant neoplastic diseases) that we proposed in an NPRM published in the *Federal Register* on December 17, 2013, at 78 FR 76508. Even though this rule will not go into effect until 60 days after publication of this document, for clarity we refer to it in this preamble as the “final” rule. We refer to the rule in effect prior to that time as the “prior” rule.

In the preamble to the NPRM, we discussed our proposed changes and our reasons for making them. Since we are mostly adopting those revisions as we proposed them, we are not repeating that information here. Interested readers may refer to the preamble in the NPRM, available at <http://www.regulations.gov>.

We are making some changes in this final rule based on the public comments we received on the NPRM. We explain these changes in the “Summary of Public Comments” below.

Why are we revising the cancer listings?

We developed this final rule as part of our ongoing review of the cancer body system. When we last revised the listings for this body system in a final rule published on October 6, 2009, we indicated that we would monitor and update the listings as needed.¹

How long will this final rule stay in effect?

We are extending the effective date of the cancer body system in parts A and B of the listings until 5 years after the effective date of this final rule. The rule will remain in effect only until that date unless we extend the expiration date. We will continue to monitor the rule and may revise it, as needed, before the end of the 5-year period.

Summary of Public Comments

In the NPRM, we gave the public a 60-day comment period that ended on February 18, 2014. We received 15 comments. The commenters included

national cancer advocacy groups, State agencies, a national group representing disability examiners in State agencies that make disability determinations for us, medical professionals, and individual members of the public.

We carefully considered all of the significant comments relevant to this rulemaking. We have condensed and summarized the comments below. We believe we have presented the commenters’ concerns and suggestions accurately and completely and responded to all significant issues that were within the scope of this rule. We provide our reasons for adopting or not adopting the recommendations in our responses below.

General Comments

Comment: Many commenters supported our proposal to change the name of this body system from “Malignant Neoplastic Diseases” to “Cancer” to make the name more recognizable to the lay public. However, some commenters believed this change was not necessary or appropriate. These commenters believed the lay public is sufficiently aware of the meaning of the term “malignant neoplastic diseases” and that we should continue using it as the body system’s name. One commenter thought “malignant neoplastic diseases” is a more encompassing name for the body system than “cancer.” The commenter contended the term “cancer” has traditionally meant only carcinoma, and does not include sarcoma, leukemia, or malignancies in other cell types.

Response: We disagree with the commenters’ view that the lay public is sufficiently aware of the term “malignant neoplastic diseases,” and have adopted our proposal to change the name of this body system to “Cancer.” We believe the lay public understands that the term “cancer” means not only carcinoma but also the wide array of malignancies. The National Cancer Institute (NCI), National Cancer Society (NCS), and other recognized experts use the term “cancer” when referring to carcinoma, sarcoma, leukemia, lymphoma, and malignancies of the central nervous system in their publications.²

Comment: A commenter, who supported the proposed name change, recommended that we use the term “anticancer therapy” instead of “antineoplastic therapy” in this final rule.

² For example, see “NCI Home” at <http://www.cancer.gov>, and “American Cancer Society Home” at <http://www.cancer.org/index>.

Response: We agree with the commenter and have modified the listings accordingly.

Comment: One commenter suggested we have only one listing for evaluating small-cell carcinomas rather than adopt our proposal to provide a criterion for small-cell carcinoma under several, specific listings.³

Response: We did not adopt the comment. Some small-cell carcinomas might be included under the single listing the commenter proposed, but may have favorable prognoses and not be of listing-level severity. These small-cell carcinomas have a favorable prognosis because physicians can detect them in their early stages when it is still possible to remove the cancer. The final listings cover small-cell carcinomas that occur in certain organs and tissues where physicians are unlikely to detect them in their early stages, and treatment is mainly palliative.

Comment: One commenter suggested that we include the stage of the cancer in the final listings for evaluating central nervous system and cervical cancers, and lymphomas.

Response: We did not adopt the comment for two reasons. First, the cancers mentioned by the commenter may have different staging systems that are inconsistent with each other. Second, staging systems could change, potentially resulting in an inability to find people with listing-level impairments disabled at the listing step of the sequential evaluation process.

Comment: A commenter proposed we provide more guidance in part B for evaluating conditions in children, resulting from cancer or its treatment, that do not meet the listings. The commenter said such conditions might include organ dysfunction resulting from small-cell carcinomas, or secondary lymphedema resulting from breast cancer treatment. The commenter believed the additional guidance would make the final listings more comprehensive.

Response: We did not adopt the comment because we believe final sections 113.00F and 113.00G already

³ We retained prior listing 13.14B for evaluating small-cell carcinoma in the lungs and added a criterion for small-cell carcinoma under the following specific listings: 13.02D for soft tissue cancers of the head and neck; 13.10D for cancer of the breast; 13.15C for cancer of the pleura and mediastinum; 13.16C for cancer of the esophagus or stomach; 13.17C for cancer of the small intestine; 13.18D for cancer of the large intestine; 13.22E for cancer of the urinary bladder; 13.23F for cancers of the female genital tract; and 13.24C for cancer of the prostate gland. We include a listing for small-cell carcinoma of the small intestine, even though it is a very rare cancer, to maintain internal consistency among the regulations, and because of the cancer’s unfavorable prognosis.

¹ See 74 FR 51229.

provide the type of guidance the commenter recommended. In these sections, we explain that if a child has a medically determinable impairment that does not meet the listings, we will determine whether the impairment medically equals the listings. This determination would include impairments caused by the cancer or treatment side effects. If the impairment does not medically equal a listing, section 113.00F further explains that we will also determine whether the impairment functionally equals the listings. Again, this determination would include impairments caused by the cancer or treatment side effects.

Comment: One commenter recommended we provide more guidance for evaluating treatment failure in bone marrow and stem cell transplantation, and proposed specific language for making this change.

Response: We believe the change, and the specific language the commenter proposed, is not necessary because listings for bone marrow and stem cell transplantation have a criterion for evaluating any residual impairments following treatment. These residual impairments would include the evaluation of those associated with treatment failure.

Section 13.00E—When do we need longitudinal evidence?

Comment: One commenter asked us to specify which sources can provide the evidence required in final section 13.00E3c to document that the treating source has started multimodal therapy under final listings 13.02E, 13.11D, and 13.14C. The commenter indicated that we should accept this evidence only from an acceptable medical source such as a medical or osteopathic doctor.

Response: We did not adopt the comment because it may limit our ability to obtain evidence to determine if multimodal therapy has started and, thus, establish listing-level severity. While an acceptable medical source may provide this evidence, our existing policy allows us to accept evidence from other medical sources to establish the impairment's severity.⁴ For example, this evidence may come from sources we do not consider acceptable medical sources, such as oncology nurse practitioners who administer chemotherapy and radiation therapists who deliver radiation treatments.

Sections 13.00I and 113.00I—What do we mean by the following terms?

Comment: One commenter expressed concern over proposed sections 13.00I6

and 113.00I5, in which we clarified that we consider a cancer to be “progressive” if it is still growing after the person has completed at least half of his or her planned initial anticancer therapy. The commenter believed this criterion might delay adjudication if the adjudicator must contact the treating source to ask how much of planned treatment the person has completed.

Response: We did not adopt this comment. We disagree with the commenter because we do not expect adjudicators to obtain more information than we required under the prior regulations. The proposed and final sections express our intent to decide as quickly as possible that a person is disabled.

Comment: The same commenter thought that the definition of the term “progressive” could result in a finding that the claimant has a condition medically equivalent to cancer listings that do not require the malignancy to be progressive.

Response: We do not share the commenter's concern because, as we explain in sections 13.00C and 113.00C, we will only apply the criteria in a specific listing to a cancer originating from that specific site.

Comment: One commenter recommended that we revise the definition of “persistent” cancer in final section 13.00I5. The commenter also provided language for the suggested revision.

Response: We did not adopt the comment for two reasons. First, the language the commenter proposed could be misinterpreted to require that all of a person's anticancer therapy must fail to achieve a complete remission, including any second- or third-line therapies after initial anticancer therapy.⁵ This interpretation would be contrary to our intent in listings that require only the planned initial anticancer therapy to fail. Second, the language the commenter proposed would not explain the meaning of the phrase “failed to achieve a complete remission.” By defining this phrase, the final section clarifies that the cancer is “persistent” if any of it remains after treatment is completed, even if the cancer responded to the initial therapy and became smaller.

Comment: One commenter recommended that the definition of the term “unresectable” in final section 13.00I8 address the presence of micrometastases. The commenter

contended that “unresectable” should not include situations in which the surgeon removed the tumor and then used adjuvant therapy to eliminate any micrometastases.

Response: We did not adopt the comment. We believe the commenter's proposed change is unnecessary. Final section 13.00I8 defines “adjuvant therapy” as anticancer therapy given after surgery “to eliminate any remaining cancer cells or lessen the chance of recurrence.” These “remaining cancer cells” include micrometastases.

Sections 13.00K and 113.00K—How do we evaluate specific cancers?

Comment: A commenter recommended that we add examples of common indolent lymphomas in final section 13.00K1a. The commenter also recommended that we add examples of common solid tumors in final section 113.00K3.

Response: We did not adopt the comment. These recommendations appear to be administrative concerns better handled through training and operating instructions for our adjudicators.

Comment: A commenter recommended that we create a listing for primary peritoneal carcinoma. The commenter argued that having a listing would be better than the guidance in section 13.00K7, in which we explained that we can evaluate this cancer in women under final 13.23E for ovarian cancer, and evaluate it in men under 13.15A for malignant mesothelioma.

Response: We did not adopt the commenter's recommendation that we create a listing for primary peritoneal carcinoma. Primary peritoneal carcinoma is very rare, and we do not usually provide listings for rare cancers. Instead, we believe the better practice is to clarify in the introductory text which listings to use to evaluate certain rare cancers, as we did in final section 13.00K7 for primary peritoneal carcinoma.

Comment: A few commenters expressed concern about the clarification in proposed section 13.00K8 that excludes “biochemical recurrence” for evaluating recurrent cancer of the prostate gland in listing 13.24A. In this section, we defined “biochemical recurrence” as an increase in the serum prostate-specific antigen (PSA) level following the completion of anticancer therapy. Section 13.24A requires corroborating evidence to document recurrence, such as radiological studies or findings on physical exam. Commenters believed this requirement might delay a finding

⁵ We may consider follow-up surgery to be a part of initial anticancer treatment if the intent of the follow-up surgery is to obtain clear margins and the complete eradication of any residual cancer left behind.

⁴ See 20 CFR 404.1513(d) and 416.913(d).

of disability and unfairly penalize people with prostate cancer. They noted that doctors frequently use PSA values to determine recurrence and may initiate anticancer treatment for recurrent cancer upon this evidence alone.

Response: We agree that in some cases, an isolated PSA reading may support a diagnosis of recurrent prostate cancer, especially if this diagnosis is from an acceptable medical source and is consistent with the prevailing state of medical knowledge and clinical practice. However, we did not adopt the comments because we believe it is reasonable to require corroborating evidence to confirm the diagnosis. A rising PSA level alone does not necessarily mean prostate cancer has returned. Additional factors, such as the cancer's TNM⁶ characteristics, PSA kinetics, timing of the biochemical recurrence, treatment modality, and Gleason score, should be considered.^{7 8} The American Joint Committee on Cancer notes that the natural progression from biochemical recurrence to clinical disease recurrence is highly variable and may depend on these additional factors.⁹ In light of this variability and the other factors that should be considered, we continue to believe that we should exclude "biochemical recurrence" in listing 13.24A.

Comment: One commenter recommended that we delete the parenthetical reference to "benign melanocytic tumor" in final sections 13.00K9 and 113.00K6. The commenter claimed that citing a benign disease in the cancer listings may be confusing for adjudicators.

Response: We did not adopt the comment because we believe the reference to benign melanocytic tumor can direct adjudicators to the appropriate body systems for evaluating this condition, Skin Disorders (8.00 and 108.00). This reference is similar to how final sections 13.00K6c and 113.00K4c direct adjudicators to the appropriate body systems for evaluating benign brain tumors.

⁶ The acronym "TNM" relates to the Tumor size, lymph Node involvement, and presence of Metastases.

⁷ PSA kinetics involves assessing the PSA level over time, such as measuring of its rate of change (velocity) and how long it takes it to double.

⁸ The National Cancer Institute defines "Gleason score" as a system of grading prostate cancer tissue based on how it looks under the microscope (available at: <http://www.cancer.gov/dictionary/CdrID=45696>).

⁹ See Carolyn C. Compton et al. eds., *Cancer Staging Atlas: A Companion to the Seventh Editions of the AJCC Cancer Staging Manual and Handbook*, New York: Springer, 2012, page 535–545.

Listing 13.02—Soft Tissue Cancers of the Head and Neck (Except Salivary Glands—13.08—and Thyroid Gland—13.09)

Comment: A commenter recommended revisions to 13.02E to condense the final listing significantly.

Response: We did not adopt the comment because the proposed change might be misinterpreted to include any metastases in the head or neck from cancers originating elsewhere under listing 13.02E. Our intent in this listing is to evaluate cancers that receive multimodal therapy and originate in the head and neck only.

Listing 113.05—Lymphoma (Excluding All Types of Lymphoblastic Lymphomas—113.06)

Comment: A commenter recommended that we include cerebrospinal fluid (CSF) findings as evidence for determining listing-level lymphoma under final listings 113.05A1 and 113.05B1.

Response: We did not adopt the comment. It is not a standard clinical practice in lymphoma to conduct cerebrospinal fluid examination for analysis; therefore, we do not believe it is appropriate to require this evidence to establish severity. However, we will inform adjudicators, through training and operating instructions, that they can accept CSF findings if this evidence is available.

Listing 13.10—Breast (Except Sarcoma—13.04)

Comment: One commenter asked how long adjudicators should defer adjudication of cases for evaluating breast cancer with secondary lymphedema resulting from anticancer therapy and treated by surgery to salvage or restore the functioning of an upper extremity under proposed listing 13.10E.

Response: We disagree with the commenter's premise that adjudicators need to defer adjudication of these cases. Adjudicators can adjudicate a case at the listing step if the surgery is performed. The need for this surgery to salvage or restore functioning of an upper extremity demonstrates listing-level severity of the secondary lymphedema without the need to make a determination about the effectiveness of the surgery.

Comment: A commenter recommended we add a listing that prescribes a period of disability of at least 18 months for people receiving multimodal therapy for breast cancer. The commenter noted that multimodal therapy could last 6 or more months and

produce very serious adverse effects. The commenter also noted that it is common for us to find these people disabled after the listing step in the sequential evaluation process by taking into consideration the adverse effects of treatment and that the length of treatment nearly satisfies the 12-month duration requirement. The commenter believed it would be better for us to make the determination of disability at the listing step.

Similarly, a commenter recommended we add a listing that prescribes a period of disability of at least 18 months for people receiving multimodal therapy that includes surgery for low anal cancers and rectal cancers. The commenter noted that neoadjuvant chemotherapy or radiation followed by surgery to eliminate these anal or rectal cancers frequently takes at least 12 months to complete. The treatment may result in prolonged debilitation although the impairment may not meet or medically equal the listings.

Response: We believe the commenter's proposed listing for breast cancer would cover many cases of early cancer. Most people with early breast cancer complete multimodal therapy within 6 months and recover from any adverse effects relatively soon. In these cases, the impairment would not preclude the ability to work for the required 12 months.

However, we agree with the commenter that in some cases multimodal therapy may take substantially longer than 6 months to complete. For example, very serious adverse effects may interrupt and prolong therapy, resulting in an active impairment lasting almost 12 months. It is a long-standing principle that we may make a finding of disability at the listing step if there is the expectation that an impairment that has been active for almost 12 months will preclude a person from engaging in any gainful activity for the required 12 months. We base this finding on the nature of the impairment; prescribed treatment; therapeutic history, including adverse effects of treatment; and other relevant considerations. Therefore, we partially adopted the comment by providing language in final section 13.00G3 to clarify that we can apply this principle to multimodal anticancer therapy for breast cancer and other cancers. We also added the clarifying language in final section 113.00G3 for children.

We did not make changes to listing 13.18 for evaluating anal and rectal cancers. This listing and the commenter's recommendation for a new listing covering multimodal therapy with surgery for anal and rectal cancers

are outside the scope of this rulemaking. However, we believe the changes made in final section 13.00G3 partially address this commenter's concerns.

Listing 13.13—Nervous System

Comment: One commenter recommended that we clarify in the introductory text whether adjudicators should use listing 13.13 to evaluate pituitary gland cancer in adults.

Response: We adopted the commenter's recommendation by providing language in final section 13.00K6a and final section 113.00K4a in the introductory text clarifying that we evaluate cancerous pituitary gland tumors, for example, pituitary carcinoma,¹⁰ under final listing 13.13A1 and final listing 113.13A, respectively.

Comment: The same commenter expressed concern about the statement, in proposed sections 13.00K6b and 113.00K4b, that we consider brain tumors malignant only if they are classified as grade II or higher under the World Health Organization (WHO), "Classification of Tumours of the Central Nervous System, 2007." The commenter asked how an adjudicator should evaluate central nervous system tumors graded under different classification systems.

Response: We believe we have addressed the commenter's concerns in existing operating instructions that help adjudicators determine the WHO grade of specific brain cancers if a different grading system is used or if the medical evidence does not identify a particular grading system.¹¹ These instructions also help adjudicators determine which grade to use when there are inconsistencies in the medical record, such as some medical evidence describing the tumor as grade II while other medical evidence describes it as grade III or grade IV.

Listing 13.23—Cancers of the Female Genital Tract—Carcinoma or Sarcoma

Comment: A commenter recommended that we add criteria in final listing 13.23B3 to take into account a cancer's histologic diagnosis and the age of the claimant at onset.

Response: We did not adopt this comment. We do not believe it is necessary to include such considerations in the listing because the prognosis is already poor for cervical cancer that meets the specific criteria of the listing. Considering the histological

diagnosis would only confirm this prognosis, and the prognosis would remain poor regardless of a person's age.

Comment: A national advocacy group for women with ovarian cancer recommended that we reinstate a listing we deleted in 2009. The listing covered ovarian cancer with ruptured ovarian capsule, tumor on the serosal surface of the ovary, ascites with malignant cells, or positive peritoneal washings. The commenter believed we find most women with this extent of disease disabled at later steps of the sequential evaluation process after the listing step or on appeal. The commenter also believed the adverse effects of cancer treatment might be disabling in themselves, especially for women whose jobs require significant exertion or do not allow time off for recovery from treatment.

Response: We agree we could find a woman with the findings in the prior listing disabled after the listing step of the sequential evaluation process. We realize that adverse effects of ovarian cancer treatment may preclude a woman from working. However, we did not adopt the commenter's recommendation because many women with ovarian cancer that meets the specific criteria in the deleted listing would not have an impairment that precludes *any* gainful activity, which is the standard of severity in the listings.¹²

Other Changes

We made a number of editorial changes and technical corrections in the final rule to increase the clarity and consistency of the listings. For example, we redesignated proposed listing 13.05A3 for evaluating mantle cell lymphoma in adults as final listing 13.05D to make it a stand-alone listing consistent with stand-alone final listing 113.05D for evaluating mantle cell lymphoma in children. We also changed the parenthetical examples in prior sections 13.00H1 and 113.00H1 from "at least 18 months from the date of diagnosis" and "at least 12 months from the date of diagnosis," respectively, to "until at least 12 months from the date of transplantation" to make these adult and child sections consistent.

Additionally, we redesignated proposed listings 13.29A3 and 113.29A3 for evaluating mucosal melanoma as stand-alone listings 13.29C and 113.29C. We made this change because we determined, through our ongoing review of the scientific and medical literature, that mucosal melanoma carries a very poor prognosis and is of listing-level severity regardless of whether it is an

initial disease or a recurrent disease. We also added examples of distant sites frequently affected by metastases from cutaneous and ocular melanomas in 13.29B3 and 113.29B3.

What is our authority to make regulations and set procedures for determining whether a person is disabled under the statutory definition?

Under the Act, we have full power and authority to make rules and regulations and to establish necessary and appropriate procedures to carry out such provisions.¹³

Regulatory Procedures

Executive Order 12866, as Supplemented by Executive Order 13563

We have consulted with the Office of Management and Budget (OMB) and determined that this final rule meets the criteria for a significant regulatory action under Executive Order 12866, as supplemented by Executive Order 13563, and was reviewed by OMB.

Regulatory Flexibility Act

We certify that this final rule has no significant economic impact on a substantial number of small entities because it affects only individuals. Therefore, a regulatory flexibility analysis was not required under the Regulatory Flexibility Act, as amended.

Paperwork Reduction Act

This final rule does not create any new or affect any existing collections and, therefore, does not require OMB approval under the Paperwork Reduction Act.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security—Disability Insurance; 96.002, Social Security—Retirement Insurance; 96.004, Social Security—Survivors Insurance; and 96.006, Supplemental Security Income).

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-age, Survivors, and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

Dated: May 11, 2015.

Carolyn W. Colvin,

Acting Commissioner of Social Security.

For the reasons set out in the preamble, we are amending 20 CFR part 404 subpart P as set forth below:

¹⁰ Pituitary gland carcinoma is highly malignant. Treatment is mainly palliative. People who have pituitary gland carcinoma have a mean survival time of only about 2 years.

¹¹ Program Operations Manual System, available at: <http://policy.ssa.gov/poms.nsf/lnx/0424585001>.

¹² See sections 404.1525 and 416.925.

¹³ Sections 205(a), 702(a)(5), and 1631(d)(1).

**PART 404—FEDERAL OLD-AGE,
SURVIVORS AND DISABILITY
INSURANCE (1950—)**

**Subpart P—Determining Disability and
Blindness**

■ 1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a)–(b) and (d)–(h), 216(i), 221(a), (i), and (j), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a)–(b), and (d)–(h), 416(i), 421(a), (i), and (j), 422(c), 423, 425, and 902(a)(5)); sec. 211(b), Pub. L. 104–193, 110 Stat. 2105, 2189; sec. 202, Pub. L. 108–203, 118 Stat. 509 (42 U.S.C. 902 note).

■ 2. Amend appendix 1 to subpart P of part 404 as follows:

■ a. Revise item 14 of the introductory text before part A.

■ b. Amend part A by revising the body system name for section 13.00 in the table of contents.

■ c. Revise section 13.00 of part A.

■ d. Amend listing 13.02 of part A by revising the heading, revising listing 13.02B, removing listing 13.02C, redesignating listing 13.02D as new 13.02C, adding new listing 13.02D and revising listing 13.02E.

■ e. Amend listing 13.03 of part A by revising listing 13.03B.

■ f. Amend listing 13.04 of part A by revising listing 13.04B.

■ g. Amend listing 13.05 of part A by revising listings 13.05A1, 13.05A2 and 13.05B, and adding listing 13.05D.

■ h. Amend listing 13.06 of part A by revising the first sentence of listing 13.06B1 and revising listing 13.06B2b.

■ i. Amend listing 13.07 of part A by revising listing 13.07A.

■ j. Amend listing 13.10 of part A by revising listings 13.10A and 13.10C, adding the word “OR” after listing 13.10C, adding listing 13.10D, adding the word “OR” after listing 13.10D, and adding listing 13.10E.

■ k. Amend listing 13.11 of part A by revising listings 13.11B and 13.11D.

■ l. Amend listing 13.12 of part A by revising listing 13.12C.

■ m. Revise listing 13.13 of part A.

■ n. Amend listing 13.14C of part A by revising the first sentence.

■ o. Amend listing 13.15 of part A by revising listing 13.15B2 and adding the word “OR” after listing 13.15B2, and adding listing 13.15C.

■ p. Amend listing 13.16 of part A by adding the word “OR” after listing 13.16B, and adding listing 13.16C.

■ q. Amend listing 13.17 of part A by adding the word “OR” after listing 13.17B, and adding listing 13.17C.

■ r. Amend listing 13.18 of part A by adding the word “OR” after listing 13.18C, and adding listing 13.18D.

■ s. Revise listing 13.19 of part A.

■ t. Amend listing 13.20 of part A by revising listing 13.20B.

■ u. Amend listing 13.22 of part A by adding the word “OR” after listing 13.22D, and adding listing 13.22E.

■ v. Amend listing 13.23 of part A by revising the heading, revising listings 13.23A3, 13.23B, 13.23C3, 13.23D2 and 13.23E, adding the word “OR” after listing 13.23E, and adding listing 13.23F.

■ w. Amend listing 13.24 of part A by revising listing 13.24A, adding the word “OR” after listing 13.24B, and adding listing 13.24C.

■ x. Revise listing 13.25 of part A.

■ y. Amend listing 13.28 of part A by revising the heading.

■ z. Add listing 13.29 after listing 13.28 of part A.

■ aa. Amend part B by revising the body system name for section 113.00 in the table of contents.

■ bb. Revise section 113.00 of part B.

■ cc. Revise listing 113.03 of part B.

■ dd. Amend listing 113.05 of part B by revising the heading and listings 113.05A and 113.05B, adding the word “OR” after listing 113.05C, and adding listing 113.05D.

■ ee. Amend listing 113.06 of part B by revising listings 113.06A and 113.06B1.

■ ff. Amend listing 113.12 of part B by revising listing 113.12B.

■ gg. Revise listing 113.13 of part B.

■ hh. Add listing 113.29 after listing 113.21 of part B.

The revised and added text is set forth as follows:

**APPENDIX 1 TO SUBPART P OF PART
404—LISTING OF IMPAIRMENTS**

* * * * *

14. Cancer (Malignant Neoplastic Diseases)
(13.00 and 113.00): July 20, 2020.

* * * * *

Part A

* * * * *

*13.00 Cancer (Malignant Neoplastic
Diseases)*

* * * * *

**13.00 CANCER (MALIGNANT
NEOPLASTIC DISEASES)**

A. *What impairments do these listings cover?* We use these listings to evaluate all cancers (malignant neoplastic diseases), except certain cancers associated with human immunodeficiency virus (HIV) infection. If you have HIV infection, we use the criteria in 14.08E to evaluate carcinoma of the cervix, Kaposi sarcoma, lymphoma, and squamous cell carcinoma of the anal canal and anal margin.

B. *What do we consider when we evaluate cancer under these listings?* We will consider factors including:

1. Origin of the cancer.
2. Extent of involvement.

3. Duration, frequency, and response to anticancer therapy.

4. Effects of any post-therapeutic residuals.

C. *How do we apply these listings?* We apply the criteria in a specific listing to a cancer originating from that specific site.

D. *What evidence do we need?*

1. We need medical evidence that specifies the type, extent, and site of the primary, recurrent, or metastatic lesion. When the primary site cannot be identified, we will use evidence documenting the site(s) of metastasis to evaluate the impairment under 13.27.

2. For operative procedures, including a biopsy or a needle aspiration, we generally need a copy of both the:

- a. Operative note, and
- b. Pathology report.

3. When we cannot get these documents, we will accept the summary of hospitalization(s) or other medical reports. This evidence should include details of the findings at surgery and, whenever appropriate, the pathological findings.

4. In some situations, we may also need evidence about recurrence, persistence, or progression of the cancer, the response to therapy, and any significant residuals. (See 13.00G.)

E. *When do we need longitudinal evidence?*

1. *Cancer with distant metastases.* We generally do not need longitudinal evidence for cancer that has metastasized beyond the regional lymph nodes because this cancer usually meets the requirements of a listing. Exceptions are for cancer with distant metastases that we expect to respond to anticancer therapy. For these exceptions, we usually need a longitudinal record of 3 months after therapy starts to determine whether the therapy achieved its intended effect, and whether this effect is likely to persist.

2. *Other cancers.* When there are no distant metastases, many of the listings require that we consider your response to initial anticancer therapy; that is, the initial planned treatment regimen. This therapy may consist of a single modality or a combination of modalities; that is, multimodal therapy. (See 13.00I4.)

3. *Types of treatment.*

a. Whenever the initial planned therapy is a single modality, enough time must pass to allow a determination about whether the therapy will achieve its intended effect. If the treatment fails, the failure often happens within 6 months after treatment starts, and there will often be a change in the treatment regimen.

b. Whenever the initial planned therapy is multimodal, we usually cannot make a determination about the effectiveness of the therapy until we can determine the effects of all the planned modalities. In some cases, we may need to defer adjudication until we can assess the effectiveness of therapy. However, we do not need to defer adjudication to determine whether the therapy will achieve its intended effect if we can make a fully favorable determination or decision based on the length and effects of therapy, or the residuals of the cancer or therapy (see 13.00G).

c. We need evidence under 13.02E, 13.11D, and 13.14C to establish that your treating

source initiated multimodal anticancer therapy. We do not need to make a determination about the length or effectiveness of your therapy. Multimodal therapy has been initiated, and satisfies the requirements in 13.02E, 13.11D, and 13.14C, when your treating source starts the first modality. We may defer adjudication if your treating source plans multimodal therapy and has not yet initiated it.

F. *How do we evaluate impairments that do not meet one of the cancer listings?*

1. These listings are only examples of cancer that we consider severe enough to prevent you from doing any gainful activity. If your severe impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that meets the criteria of a listing in another body system.

2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. (See §§ 404.1526 and 416.926 of this chapter.) If your impairment(s) does not meet or medically equal a listing, you may or may not have the residual functional capacity to engage in substantial gainful activity. In that situation, we proceed to the fourth, and, if necessary, the fifth steps of the sequential evaluation process in §§ 404.1520 and 416.920 of this chapter. We use the rules in §§ 404.1594 and 416.994 of this chapter, as appropriate, when we decide whether you continue to be disabled.

G. *How do we consider the effects of anticancer therapy?*

1. *How we consider the effects of anticancer therapy under the listings.* In many cases, cancers meet listing criteria only if the therapy is not effective and the cancer persists, progresses, or recurs. However, as explained in the following paragraphs, we will not delay adjudication if we can make a fully favorable determination or decision based on the evidence in the case record.

2. *Effects can vary widely.*

a. We consider each case on an individual basis because the therapy and its toxicity may vary widely. We will request a specific description of the therapy, including these items:

- i. Drugs given.
- ii. Dosage.
- iii. Frequency of drug administration.
- iv. Plans for continued drug administration.
- v. Extent of surgery.
- vi. Schedule and fields of radiation therapy.

b. We will also request a description of the complications or adverse effects of therapy, such as the following:

- i. Continuing gastrointestinal symptoms.
- ii. Persistent weakness.
- iii. Neurological complications.
- iv. Cardiovascular complications.
- v. Reactive mental disorders.

3. *Effects of therapy may change.* The severity of the adverse effects of anticancer therapy may change during treatment; therefore, enough time must pass to allow us to evaluate the therapy's effect. The residual effects of treatment are temporary in most instances; however, on occasion, the effects

may be disabling for a consecutive period of at least 12 months. In some situations, very serious adverse effects may interrupt and prolong multimodal anticancer therapy for a continuous period of almost 12 months. In these situations, we may determine there is an expectation that your impairment will preclude you from engaging in any gainful activity for at least 12 months.

4. *When the initial anticancer therapy is effective.* We evaluate any post-therapeutic residual impairment(s) not included in these listings under the criteria for the affected body system. We must consider any complications of therapy. When the residual impairment(s) does not meet or medically equal a listing, we must consider its effect on your ability to do substantial gainful activity.

H. *How long do we consider your impairment to be disabling?*

1. In some listings, we specify that we will consider your impairment to be disabling until a particular point in time (for example, until at least 12 months from the date of transplantation). We may consider your impairment to be disabling beyond this point when the medical and other evidence justifies it.

2. When a listing does not contain such a specification, we will consider an impairment(s) that meets or medically equals a listing in this body system to be disabling until at least 3 years after onset of complete remission. When the impairment(s) has been in complete remission for at least 3 years, that is, the original tumor or a recurrence (or relapse) and any metastases have not been evident for at least 3 years, the impairment(s) will no longer meet or medically equal the criteria of a listing in this body system.

3. Following the appropriate period, we will consider any residuals, including residuals of the cancer or therapy (see 13.00G), in determining whether you are disabled. If you have a recurrence or relapse of your cancer, your impairment may meet or medically equal one of the listings in this body system again.

I. *What do we mean by the following terms?*

1. *Anticancer therapy* means surgery, radiation, chemotherapy, hormones, immunotherapy, or bone marrow or stem cell transplantation. When we refer to surgery as an anticancer treatment, we mean surgical excision for treatment, not for diagnostic purposes.

2. *Inoperable* means surgery is thought to be of no therapeutic value or the surgery cannot be performed; for example, when you cannot tolerate anesthesia or surgery because of another impairment(s), or you have a cancer that is too large or that has invaded crucial structures. This term does not include situations in which your cancer could have been surgically removed but another method of treatment was chosen; for example, an attempt at organ preservation. Your physician may determine whether the cancer is inoperable before or after you receive neoadjuvant therapy. *Neoadjuvant therapy* is anticancer therapy, such as chemotherapy or radiation, given before surgery in order to reduce the size of the cancer.

3. *Metastases* means the spread of cancer cells by blood, lymph, or other body fluid.

This term does not include the spread of cancer cells by direct extension of the cancer to other tissues or organs.

4. *Multimodal therapy* means anticancer therapy that is a combination of at least two types of treatment given in close proximity as a unified whole and usually planned before any treatment has begun. There are three types of treatment modalities: surgery, radiation, and systemic drug therapy (chemotherapy, hormone therapy, and immunotherapy or biological modifier therapy). Examples of multimodal therapy include:

- a. Surgery followed by chemotherapy or radiation.
- b. Chemotherapy followed by surgery.
- c. Chemotherapy and concurrent radiation.

5. *Persistent* means the planned initial anticancer therapy failed to achieve a complete remission of your cancer; that is, your cancer is evident, even if smaller, after the therapy has ended.

6. *Progressive* means the cancer becomes more extensive after treatment; that is, there is evidence that your cancer is growing after you have completed at least half of your planned initial anticancer therapy.

7. *Recurrent or relapse* means the cancer that was in complete remission or entirely removed by surgery has returned.

8. *Unresectable* means surgery or surgeries did not completely remove the cancer. This term includes situations in which your cancer is incompletely resected or the surgical margins are positive. It does not include situations in which there is a finding of a positive margin(s) if additional surgery obtains a margin(s) that is clear. It also does not include situations in which the cancer is completely resected but you are receiving adjuvant therapy. *Adjuvant therapy* is anticancer therapy, such as chemotherapy or radiation, given after surgery in order to eliminate any remaining cancer cells or lessen the chance of recurrence.

J. *Can we establish the existence of a disabling impairment prior to the date of the evidence that shows the cancer satisfies the criteria of a listing?* Yes. We will consider factors such as:

1. The type of cancer and its location.
2. The extent of involvement when the cancer was first demonstrated.
3. Your symptoms.

K. *How do we evaluate specific cancers?*

1. *Lymphoma.*

a. Many indolent (non-aggressive) lymphomas are controlled by well-tolerated treatment modalities, although the lymphomas may produce intermittent symptoms and signs. We may defer adjudicating these cases for an appropriate period after therapy is initiated to determine whether the therapy will achieve its intended effect, which is usually to stabilize the disease process. (See 13.00E3.) Once your disease stabilizes, we will assess severity based on the extent of involvement of other organ systems and residuals from therapy.

b. A change in therapy for indolent lymphomas is usually an indicator that the therapy is not achieving its intended effect. However, your impairment will not meet the requirements of 13.05A2 if your therapy is changed solely because you or your

physician chooses to change it and not because of a failure to achieve stability.

c. We consider Hodgkin lymphoma that recurs more than 12 months after completing initial anticancer therapy to be a new disease rather than a recurrence.

2. Leukemia.

a. *Acute leukemia.* The initial diagnosis of acute leukemia, including the accelerated or blast phase of chronic myelogenous (granulocytic) leukemia, is based on definitive bone marrow examination. Additional diagnostic information is based on chromosomal analysis, cytochemical and surface marker studies on the abnormal cells, or other methods consistent with the prevailing state of medical knowledge and clinical practice. Recurrent disease must be documented by peripheral blood, bone marrow, or cerebrospinal fluid examination, or by testicular biopsy. The initial and follow-up pathology reports should be included.

b. *Chronic myelogenous leukemia (CML).* We need a diagnosis of CML based on documented granulocytosis, including immature forms such as differentiated or undifferentiated myelocytes and myeloblasts, and a chromosomal analysis that demonstrates the Philadelphia chromosome. In the absence of a chromosomal analysis, or if the Philadelphia chromosome is not present, the diagnosis may be made by other methods consistent with the prevailing state of medical knowledge and clinical practice. The requirement for CML in the accelerated or blast phase is met in 13.06B if laboratory findings show the proportion of blast (immature) cells in the peripheral blood or bone marrow is 10 percent or greater.

c. *Chronic lymphocytic leukemia.*

i. We require the diagnosis of chronic lymphocytic leukemia (CLL) to be documented by evidence of a chronic lymphocytosis of at least 10,000 cells/mm³ for 3 months or longer, or other acceptable diagnostic techniques consistent with the prevailing state of medical knowledge and clinical practice.

ii. We evaluate the complications and residual impairment(s) from CLL under the appropriate listings, such as 13.05A2 or the hematological listings (7.00).

d. *Elevated white cell count.* In cases of chronic leukemia (either myelogenous or lymphocytic), an elevated white cell count, in itself, is not a factor in determining the severity of the impairment.

3. *Macroglobulinemia or heavy chain disease.* We require the diagnosis of these diseases to be confirmed by protein electrophoresis or immunoelectrophoresis. We evaluate the resulting impairment(s) under the appropriate listings, such as 13.05A2 or the hematological listings (7.00).

4. *Primary breast cancer.*

a. We evaluate bilateral primary breast cancer (synchronous or metachronous) under 13.10A, which covers local primary disease, and not as a primary disease that has metastasized.

b. We evaluate secondary lymphedema that results from anticancer therapy for breast cancer under 13.10E if the lymphedema is treated by surgery to salvage or restore the functioning of an upper extremity. Secondary

lymphedema is edema that results from obstruction or destruction of normal lymphatic channels. We may not restrict our determination of the onset of disability to the date of the surgery; we may establish an earlier onset date of disability if the evidence in your case record supports such a finding.

5. *Carcinoma-in-situ.* Carcinoma-in-situ, or preinvasive carcinoma, usually responds to treatment. When we use the term "carcinoma" in these listings, it does not include carcinoma-in-situ.

6. *Primary central nervous system (CNS) cancers.* We use the criteria in 13.13 to evaluate cancers that originate within the CNS (that is, brain and spinal cord cancers).

a. The CNS cancers listed in 13.13A1 are highly malignant and respond poorly to treatment, and therefore we do not require additional criteria to evaluate them. We do not list pituitary gland cancer (for example, pituitary gland carcinoma) in 13.13A1, although this CNS cancer is highly malignant and responds poorly to treatment. We evaluate pituitary gland cancer under 13.13A1 and do not require additional criteria to evaluate it.

b. We consider a CNS tumor to be malignant if it is classified as Grade II, Grade III, or Grade IV under the World Health Organization (WHO) classification of tumors of the CNS (*WHO Classification of Tumours of the Central Nervous System*, 2007).

c. We evaluate benign (for example, WHO Grade I) CNS tumors under 11.05. We evaluate metastasized CNS cancers from non-CNS sites under the primary cancers (see 13.00C). We evaluate any complications of CNS cancers, such as resultant neurological or psychological impairments, under the criteria for the affected body system.

7. *Primary peritoneal carcinoma.* We use the criteria in 13.23E to evaluate primary peritoneal carcinoma in women because this cancer is often indistinguishable from ovarian cancer and is generally treated the same way as ovarian cancer. We use the criteria in 13.15A to evaluate primary peritoneal carcinoma in men because many of these cases are similar to malignant mesothelioma.

8. *Prostate cancer.* We exclude "biochemical recurrence" in 13.24A, which is defined as an increase in the serum prostate-specific antigen (PSA) level following the completion of the hormonal intervention therapy. We need corroborating evidence to document recurrence, such as radiological studies or findings on physical examination.

9. *Melanoma.* We evaluate malignant melanoma that affects the skin (cutaneous melanoma), eye (ocular melanoma), or mucosal membranes (mucosal melanoma) under 13.29. We evaluate melanoma that is not malignant that affects the skin (benign melanocytic tumor) under the listings in 8.00 or other affected body systems.

L. *How do we evaluate cancer treated by bone marrow or stem cell transplantation, including transplantation using stem cells from umbilical cord blood?* Bone marrow or stem cell transplantation is performed for a variety of cancers. We require the transplantation to occur before we evaluate it under these listings. We do not need to

restrict our determination of the onset of disability to the date of the transplantation (13.05, 13.06, or 13.07) or the date of first treatment under the treatment plan that includes transplantation (13.28). We may be able to establish an earlier onset date of disability due to your transplantation if the evidence in your case record supports such a finding.

1. *Acute leukemia (including T-cell lymphoblastic lymphoma) or accelerated or blast phase of CML.* If you undergo bone marrow or stem cell transplantation for any of these disorders, we will consider you to be disabled until at least 24 months from the date of diagnosis or relapse, or at least 12 months from the date of transplantation, whichever is later.

2. *Lymphoma, multiple myeloma, or chronic phase of CML.* If you undergo bone marrow or stem cell transplantation for any of these disorders, we will consider you to be disabled until at least 12 months from the date of transplantation.

3. *Other cancers.* We will evaluate any other cancer treated with bone marrow or stem cell transplantation under 13.28, regardless of whether there is another listing that addresses that impairment. The length of time we will consider you to be disabled depends on whether you undergo allogeneic or autologous transplantation.

a. *Allogeneic bone marrow or stem cell transplantation.* If you undergo allogeneic transplantation (transplantation from an unrelated donor or a related donor other than an identical twin), we will consider you to be disabled until at least 12 months from the date of transplantation.

b. *Autologous bone marrow or stem cell transplantation.* If you undergo autologous transplantation (transplantation of your own cells or cells from your identical twin (syngeneic transplantation)), we will consider you to be disabled until at least 12 months from the date of the first treatment under the treatment plan that includes transplantation. The first treatment usually refers to the initial therapy given to prepare you for transplantation.

4. *Evaluating disability after the appropriate time period has elapsed.* We consider any residual impairment(s), such as complications arising from:

a. Graft-versus-host (GVH) disease.

b. Immunosuppressant therapy, such as frequent infections.

c. Significant deterioration of other organ systems.

* * * * *

13.02 *Soft tissue cancers of the head and neck (except salivary glands—13.08—and thyroid gland—13.09).*

* * * * *

B. Persistent or recurrent disease following initial anticancer therapy, except persistence or recurrence in the true vocal cord.

* * * * *

D. Small-cell (oat cell) carcinoma.
OR

E. Soft tissue cancers originating in the head and neck treated with multimodal anticancer therapy (see 13.00E3c). Consider under a disability until at least 18 months from the date of diagnosis. Thereafter,

evaluate any residual impairment(s) under the criteria for the affected body system.

13.03 *Skin (except malignant melanoma—13.29).*

* * * * *

B. Carcinoma invading deep extradermal structures (for example, skeletal muscle, cartilage, or bone).

13.04 *Soft tissue sarcoma.*

* * * * *

B. Persistent or recurrent following initial anticancer therapy.

13.05 *Lymphoma (including mycosis fungoides, but excluding T-cell lymphoblastic lymphoma—13.06).* (See 13.00K1 and 13.00K2c.)

A. Non-Hodgkin lymphoma, as described in 1 or 2:

1. Aggressive lymphoma (including diffuse large B-cell lymphoma) persistent or recurrent following initial anticancer therapy.

2. Indolent lymphoma (including mycosis fungoides and follicular small cleaved cell) requiring initiation of more than one (single mode or multimodal) anticancer treatment regimen within a period of 12 consecutive months. Consider under a disability from at least the date of initiation of the treatment regimen that failed within 12 months.

OR

B. Hodgkin lymphoma with failure to achieve clinically complete remission, or recurrent lymphoma within 12 months of completing initial anticancer therapy.

* * * * *

OR

D. Mantle cell lymphoma.

13.06 *Leukemia.* (See 13.00K2.)

* * * * *

B. * * *

1. Accelerated or blast phase (see 13.00K2b). * * *

* * * * *

2. Chronic phase, as described in a or b:

* * * * *

b. Progressive disease following initial anticancer therapy.

13.07 *Multiple myeloma (confirmed by appropriate serum or urine protein electrophoresis and bone marrow findings).*

A. Failure to respond or progressive disease following initial anticancer therapy.

* * * * *

13.10 *Breast (except sarcoma—13.04).* (See 13.00K4.)

A. Locally advanced cancer (inflammatory carcinoma, cancer of any size with direct extension to the chest wall or skin, or cancer of any size with metastases to the ipsilateral internal mammary nodes).

* * * * *

C. Recurrent carcinoma, except local recurrence that remits with anticancer therapy.

OR

D. Small-cell (oat cell) carcinoma.

OR

E. With secondary lymphedema that is caused by anticancer therapy and treated by surgery to salvage or restore the functioning of an upper extremity. (See 13.00K4b.) Consider under a disability until at least 12 months from the date of the surgery that

treated the secondary lymphedema.

Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

13.11 *Skeletal system—sarcoma.*

* * * * *

B. Recurrent cancer (except local recurrence) after initial anticancer therapy.

* * * * *

D. All other cancers originating in bone with multimodal anticancer therapy (see 13.00E3c). Consider under a disability for 12 months from the date of diagnosis. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

13.12 *Maxilla, orbit, or temporal fossa.*

* * * * *

C. Cancer with extension to the orbit, meninges, sinuses, or base of the skull.

13.13 *Nervous system.* (See 13.00K6.)

A. Primary central nervous system (CNS; that is, brain and spinal cord) cancers, as described in 1, 2, or 3:

1. Glioblastoma multiforme, ependymoblastoma, and diffuse intrinsic brain stem gliomas (see 13.00K6a).

2. Any Grade III or Grade IV CNS cancer (see 13.00K6b), including astrocytomas, sarcomas, and medulloblastoma and other primitive neuroectodermal tumors (PNETs).

3. Any primary CNS cancer, as described in a or b:

a. Metastatic.

b. Progressive or recurrent following initial anticancer therapy.

OR

B. Primary peripheral nerve or spinal root cancers, as described in 1 or 2:

1. Metastatic.

2. Progressive or recurrent following initial anticancer therapy.

13.14 *Lungs.*

* * * * *

C. Carcinoma of the superior sulcus (including Pancoast tumors) with multimodal anticancer therapy (see 13.00E3c). * * *

* * * * *

13.15 *Pleura or mediastinum.*

* * * * *

B. * * *

2. Persistent or recurrent following initial anticancer therapy.

OR

C. Small-cell (oat cell) carcinoma.

13.16 *Esophagus or stomach.*

* * * * *

B. * * *

OR

C. Small-cell (oat cell) carcinoma.

13.17 *Small intestine—carcinoma, sarcoma, or carcinoid.*

* * * * *

B. * * *

OR

C. Small-cell (oat cell) carcinoma.

13.18 *Large intestine (from ileocecal valve to and including anal canal).*

* * * * *

C. * * *

OR

D. Small-cell (oat cell) carcinoma.

13.19 *Liver or gallbladder—cancer of the liver, gallbladder, or bile ducts.*

13.20 *Pancreas.*

* * * * *

B. Islet cell carcinoma that is physiologically active and is either inoperable or unresectable.

* * * * *

13.22 *Urinary bladder—carcinoma.*

* * * * *

D. * * *

OR

E. Small-cell (oat cell) carcinoma.

13.23 *Cancers of the female genital tract—carcinoma or sarcoma (including primary peritoneal carcinoma).*

A. * * *

3. Persistent or recurrent following initial anticancer therapy.

B. Uterine cervix, as described in 1, 2, or 3:

1. Extending to the pelvic wall, lower portion of the vagina, or adjacent or distant organs.

2. Persistent or recurrent following initial anticancer therapy.

3. With metastases to distant (for example, para-aortic or supraclavicular) lymph nodes.

C. * * *

3. Persistent or recurrent following initial anticancer therapy.

D. * * *

2. Persistent or recurrent following initial anticancer therapy.

E. Ovaries, as described in 1 or 2:

1. All cancers except germ-cell cancers, with at least one of the following:

a. Extension beyond the pelvis; for example, implants on, or direct extension to, peritoneal, omental, or bowel surfaces.

b. Metastases to or beyond the regional lymph nodes.

c. Recurrent following initial anticancer therapy.

2. Germ-cell cancers—progressive or recurrent following initial anticancer therapy.

OR

F. Small-cell (oat cell) carcinoma.

13.24 *Prostate gland—carcinoma.*

A. Progressive or recurrent (not including biochemical recurrence) despite initial hormonal intervention. (See 13.00K8.)

OR

B. * * *

OR

C. Small-cell (oat cell) carcinoma.

13.25 *Testicles—cancer with metastatic disease progressive or recurrent following initial chemotherapy.*

* * * * *

13.28 *Cancer treated by bone marrow or stem cell transplantation.* (See 13.00L.)

* * * * *

13.29 *Malignant melanoma (including skin, ocular, or mucosal melanomas), as described in either A, B, or C:*

A. Recurrent (except an additional primary melanoma at a different site, which is not considered to be recurrent disease) following either 1 or 2:

1. Wide excision (skin melanoma).

2. Enucleation of the eye (ocular melanoma).

OR

B. With metastases as described in 1, 2, or 3:

1. Metastases to one or more clinically apparent nodes; that is, nodes that are detected by imaging studies (excluding lymphoscintigraphy) or by clinical evaluation (palpable).

2. If the nodes are not clinically apparent, with metastases to four or more nodes.

3. Metastases to adjacent skin (satellite lesions) or distant sites (for example, liver, lung, or brain).

OR

C. Mucosal melanoma.

* * * * *

Part B

* * * * *

113.00 Cancer (Malignant Neoplastic Diseases)

* * * * *

113.00 CANCER (MALIGNANT NEOPLASTIC DISEASES)

A. *What impairments do these listings cover?* We use these listings to evaluate all cancers (malignant neoplastic diseases), except certain cancers associated with human immunodeficiency virus (HIV) infection. If you have HIV infection, we use the criteria in 114.08E to evaluate carcinoma of the cervix, Kaposi sarcoma, lymphoma, and squamous cell carcinoma of the anal canal and anal margin.

B. *What do we consider when we evaluate cancer under these listings?* We will consider factors including:

1. Origin of the cancer.
2. Extent of involvement.
3. Duration, frequency, and response to anticancer therapy.

C. *How do we apply these listings?* We apply the criteria in a specific listing to a cancer originating from that specific site.

D. *What evidence do we need?*

1. We need medical evidence that specifies the type, extent, and site of the primary, recurrent, or metastatic lesion. When the primary site cannot be identified, we will use evidence documenting the site(s) of metastasis to evaluate the impairment under 13.27 in part A.

2. For operative procedures, including a biopsy or a needle aspiration, we generally need a copy of both the:

- a. Operative note, and
- b. Pathology report.

3. When we cannot get these documents, we will accept the summary of hospitalization(s) or other medical reports. This evidence should include details of the findings at surgery and, whenever appropriate, the pathological findings.

4. In some situations, we may also need evidence about recurrence, persistence, or progression of the cancer, the response to therapy, and any significant residuals. (See 113.00G.)

E. *When do we need longitudinal evidence?*

1. *Cancer with distant metastases.* Most cancer of childhood consists of a local lesion with metastases to regional lymph nodes and, less often, distant metastases. We generally do not need longitudinal evidence for cancer that has metastasized beyond the regional lymph nodes because this cancer usually

meets the requirements of a listing. Exceptions are for cancer with distant metastases that we expect to respond to anticancer therapy. For these exceptions, we usually need a longitudinal record of 3 months after therapy starts to determine whether the therapy achieved its intended effect, and whether this effect is likely to persist.

2. *Other cancers.* When there are no distant metastases, many of the listings require that we consider your response to initial anticancer therapy; that is, the initial planned treatment regimen. This therapy may consist of a single modality or a combination of modalities; that is, multimodal therapy (see 113.00I3).

3. *Types of treatment.*

a. Whenever the initial planned therapy is a single modality, enough time must pass to allow a determination about whether the therapy will achieve its intended effect. If the treatment fails, the failure often happens within 6 months after treatment starts, and there will often be a change in the treatment regimen.

b. Whenever the initial planned therapy is multimodal, we usually cannot make a determination about the effectiveness of the therapy until we can determine the effects of all the planned modalities. In some cases, we may need to defer adjudication until we can assess the effectiveness of therapy. However, we do not need to defer adjudication to determine whether the therapy will achieve its intended effect if we can make a fully favorable determination or decision based on the length and effects of therapy, or the residuals of the cancer or therapy (see 113.00G).

F. *How do we evaluate impairments that do not meet one of the cancer listings?*

1. These listings are only examples of cancers that we consider severe enough to result in marked and severe functional limitations. If your severe impairment(s) does not meet the criteria of any of these listings, we must also consider whether you have an impairment(s) that meets the criteria of a listing in another body system.

2. If you have a severe medically determinable impairment(s) that does not meet a listing, we will determine whether your impairment(s) medically equals a listing. (See §§ 404.1526 and 416.926 of this chapter.) If your impairment(s) does not meet or medically equal a listing, we will also consider whether you have an impairment(s) that functionally equals the listings. (See § 416.926a of this chapter.) We use the rules in § 416.994a of this chapter when we decide whether you continue to be disabled.

G. *How do we consider the effects of anticancer therapy?*

1. *How we consider the effects of anticancer therapy under the listings.* In many cases, cancers meet listing criteria only if the therapy is not effective and the cancer persists, progresses, or recurs. However, as explained in the following paragraphs, we will not delay adjudication if we can make a fully favorable determination or decision based on the evidence in the case record.

2. *Effects can vary widely.*

a. We consider each case on an individual basis because the therapy and its toxicity

may vary widely. We will request a specific description of the therapy, including these items:

- i. Drugs given.
- ii. Dosage.
- iii. Frequency of drug administration.
- iv. Plans for continued drug administration.
- v. Extent of surgery.
- vi. Schedule and fields of radiation therapy.

b. We will also request a description of the complications or adverse effects of therapy, such as the following:

- i. Continuing gastrointestinal symptoms.
- ii. Persistent weakness.
- iii. Neurological complications.
- iv. Cardiovascular complications.
- v. Reactive mental disorders.

3. *Effects of therapy may change.* The severity of the adverse effects of anticancer therapy may change during treatment; therefore, enough time must pass to allow us to evaluate the therapy's effect. The residual effects of treatment are temporary in most instances; however, on occasion, the effects may be disabling for a consecutive period of at least 12 months. In some situations, very serious adverse effects may interrupt and prolong multimodal anticancer therapy for a continuous period of almost 12 months. In these situations, we may determine there is an expectation that your impairment will preclude you from engaging in any age-appropriate activities for at least 12 months.

4. *When the initial anticancer therapy is effective.* We evaluate any post-therapeutic residual impairment(s) not included in these listings under the criteria for the affected body system. We must consider any complications of the therapy. When the residual impairment(s) does not meet a listing, we must consider whether it medically equals a listing, or, as appropriate, functionally equals the listings.

H. *How long do we consider your impairment to be disabling?*

1. In some listings, we specify that we will consider your impairment to be disabling until a particular point in time (for example, until at least 12 months from the date of transplantation). We may consider your impairment to be disabling beyond this point when the medical and other evidence justifies it.

2. When a listing does not contain such a specification, we will consider an impairment(s) that meets or medically equals a listing in this body system to be disabling until at least 3 years after onset of complete remission. When the impairment(s) has been in complete remission for at least 3 years, that is, the original tumor or a recurrence (or relapse) and any metastases have not been evident for at least 3 years, the impairment(s) will no longer meet or medically equal the criteria of a listing in this body system.

3. Following the appropriate period, we will consider any residuals, including residuals of the cancer or therapy (see 113.00G), in determining whether you are disabled. If you have a recurrence or relapse of your cancer, your impairment may meet or medically equal one of the listings in this body system again.

I. *What do we mean by the following terms?*

1. *Anticancer therapy* means surgery, radiation, chemotherapy, hormones, immunotherapy, or bone marrow or stem cell transplantation. When we refer to surgery as an anticancer treatment, we mean surgical excision for treatment, not for diagnostic purposes.

2. *Metastases* means the spread of cancer cells by blood, lymph, or other body fluid. This term does not include the spread of cancer cells by direct extension of the cancer to other tissues or organs.

3. *Multimodal therapy* means anticancer therapy that is a combination of at least two types of treatment given in close proximity as a unified whole and usually planned before any treatment has begun. There are three types of treatment modalities: Surgery, radiation, and systemic drug therapy (chemotherapy, hormone therapy, and immunotherapy or biological modifier therapy). Examples of multimodal therapy include:

- a. Surgery followed by chemotherapy or radiation.
- b. Chemotherapy followed by surgery.
- c. Chemotherapy and concurrent radiation.

4. *Persistent* means the planned initial anticancer therapy failed to achieve a complete remission of your cancer; that is, your cancer is evident, even if smaller, after the therapy has ended.

5. *Progressive* means the cancer becomes more extensive after treatment; that is, there is evidence that your cancer is growing after you have completed at least half of your planned initial anticancer therapy.

6. *Recurrent or relapse* means the cancer that was in complete remission or entirely removed by surgery has returned.

J. *Can we establish the existence of a disabling impairment prior to the date of the evidence that shows the cancer satisfies the criteria of a listing?* Yes. We will consider factors such as:

1. The type of cancer and its location.
2. The extent of involvement when the cancer was first demonstrated.
3. Your symptoms.

K. *How do we evaluate specific cancers?*

1. *Lymphoma.*

a. We provide criteria for evaluating lymphomas that are disseminated or have not responded to anticancer therapy in 113.05.

b. Lymphoblastic lymphoma is treated with leukemia-based protocols, so we evaluate this type of cancer under 113.06.

2. *Leukemia.*

a. *Acute leukemia.* The initial diagnosis of acute leukemia, including the accelerated or blast phase of chronic myelogenous (granulocytic) leukemia, is based on definitive bone marrow examination. Additional diagnostic information is based on chromosomal analysis, cytochemical and surface marker studies on the abnormal cells, or other methods consistent with the prevailing state of medical knowledge and clinical practice. Recurrent disease must be documented by peripheral blood, bone marrow, or cerebrospinal fluid examination, or by testicular biopsy. The initial and follow-up pathology reports should be included.

b. *Chronic myelogenous leukemia (CML).* We need a diagnosis of CML based on

documented granulocytosis, including immature forms such as differentiated or undifferentiated myelocytes and myeloblasts, and a chromosomal analysis that demonstrates the Philadelphia chromosome. In the absence of a chromosomal analysis, or if the Philadelphia chromosome is not present, the diagnosis may be made by other methods consistent with the prevailing state of medical knowledge and clinical practice. The requirement for CML in the accelerated or blast phase is met in 113.06B if laboratory findings show the proportion of blast (immature) cells in the peripheral blood or bone marrow is 10 percent or greater.

c. *Juvenile chronic myelogenous leukemia (JCML).* JCML is a rare, Philadelphia-chromosome-negative childhood leukemia that is aggressive and clinically similar to acute myelogenous leukemia. We evaluate JCML under 113.06A.

d. *Elevated white cell count.* In cases of chronic leukemia (either myelogenous or lymphocytic), an elevated white cell count, in itself, is not a factor in determining the severity of the impairment.

3. *Malignant solid tumors.* The tumors we consider under 113.03 include the histiocytosis syndromes except for solitary eosinophilic granuloma. We do not evaluate thyroid cancer (see 113.09), retinoblastomas (see 113.12), primary central nervous system (CNS) cancers (see 113.13), neuroblastomas (see 113.21), or malignant melanoma (see 113.29) under this listing.

4. *Primary central nervous system (CNS) cancers.* We use the criteria in 113.13 to evaluate cancers that originate within the CNS (that is, brain and spinal cord cancers).

a. The CNS cancers listed in 113.13A are highly malignant and respond poorly to treatment, and therefore we do not require additional criteria to evaluate them. We do not list pituitary gland cancer (for example, pituitary gland carcinoma) in 113.13A, although this CNS cancer is highly malignant and responds poorly to treatment. We evaluate pituitary gland cancer under 113.13A and do not require additional criteria to evaluate it.

b. We consider a CNS tumor to be malignant if it is classified as Grade II, Grade III, or Grade IV under the World Health Organization (WHO) classification of tumors of the CNS (*WHO Classification of Tumours of the Central Nervous System*, 2007).

c. We evaluate benign (for example, WHO Grade I) CNS tumors under 111.05. We evaluate metastasized CNS cancers from non-CNS sites under the primary cancers (see 113.00C). We evaluate any complications of CNS cancers, such as resultant neurological or psychological impairments, under the criteria for the affected body system.

5. *Retinoblastoma.* The treatment for bilateral retinoblastoma usually results in a visual impairment. We will evaluate any resulting visual impairment under 102.02.

6. *Melanoma.* We evaluate malignant melanoma that affects the skin (cutaneous melanoma), eye (ocular melanoma), or mucosal membranes (mucosal melanoma) under 113.29. We evaluate melanoma that is not malignant that affects the skin (benign melanocytic tumor) under the listings in 108.00 or other affected body systems.

L. *How do we evaluate cancer treated by bone marrow or stem cell transplantation, including transplantation using stem cells from umbilical cord blood?* Bone marrow or stem cell transplantation is performed for a variety of cancers. We require the transplantation to occur before we evaluate it under these listings. We do not need to restrict our determination of the onset of disability to the date of transplantation (113.05 or 113.06). We may be able to establish an earlier onset date of disability due to your transplantation if the evidence in your case record supports such a finding.

1. *Acute leukemia (including all types of lymphoblastic lymphomas and JCML) or accelerated or blast phase of CML.* If you undergo bone marrow or stem cell transplantation for any of these disorders, we will consider you to be disabled until at least 24 months from the date of diagnosis or relapse, or at least 12 months from the date of transplantation, whichever is later.

2. *Lymphoma or chronic phase of CML.* If you undergo bone marrow or stem cell transplantation for any of these disorders, we will consider you to be disabled until at least 12 months from the date of transplantation.

3. *Evaluating disability after the appropriate time period has elapsed.* We consider any residual impairment(s), such as complications arising from:

- a. Graft-versus-host (GVH) disease.
- b. Immunosuppressant therapy, such as frequent infections.
- c. Significant deterioration of other organ systems.

113.01 Category of Impairments, Cancer (Malignant Neoplastic Diseases)

113.03 *Malignant solid tumors.* Consider under a disability:

A. For 24 months from the date of initial diagnosis. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

OR

B. For 24 months from the date of recurrence of active disease. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

113.05 *Lymphoma (excluding all types of lymphoblastic lymphomas—113.06).* (See 113.00K1.)

A. Non-Hodgkin lymphoma (including Burkitt's and anaplastic large cell), with either 1 or 2:

1. Bone marrow, brain, spinal cord, liver, or lung involvement at initial diagnosis. Consider under a disability for 24 months from the date of diagnosis. Thereafter, evaluate under 113.05A2, or any residual impairment(s) under the criteria for the affected body system.

2. Persistent or recurrent following initial anticancer therapy.

OR

B. Hodgkin lymphoma, with either 1 or 2:

1. Bone marrow, brain, spinal cord, liver, or lung involvement at initial diagnosis. Consider under a disability for 24 months from the date of diagnosis. Thereafter, evaluate under 113.05B2, or any residual impairment(s) under the criteria for the affected body system.

2. Persistent or recurrent following initial anticancer therapy.

OR
* * * * *

OR
D. Mantle cell lymphoma.
113.06 Leukemia. (See 113.00K2.)
A. Acute leukemia (including all types of lymphoblastic lymphomas and juvenile chronic myelogenous leukemia (JCML)). Consider under a disability until at least 24 months from the date of diagnosis or relapse, or at least 12 months from the date of bone marrow or stem cell transplantation, whichever is later. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

OR
B. * * *
1. Accelerated or blast phase (see 113.00K2b). Consider under a disability until at least 24 months from the date of diagnosis or relapse, or at least 12 months from the date of bone marrow or stem cell transplantation, whichever is later. Thereafter, evaluate any residual impairment(s) under the criteria for the affected body system.

* * * * *
113.12 Retinoblastoma.
* * * * *

B. Persistent or recurrent following initial anticancer therapy.
* * * * *

113.13 Nervous system. (See 113.00K4.) Primary central nervous system (CNS; that is, brain and spinal cord) cancers, as described in A, B, or C:

A. Glioblastoma multiforme, ependymoblastoma, and diffuse intrinsic brain stem gliomas (see 113.00K4a).

B. Any Grade III or Grade IV CNS cancer (see 113.00K4b), including astrocytomas, sarcomas, and medulloblastoma and other primitive neuroectodermal tumors (PNETs).

C. Any primary CNS cancer, as described in 1 or 2:

- 1. Metastatic.
2. Progressive or recurrent following initial anticancer therapy.

* * * * *

113.29 Malignant melanoma (including skin, ocular, or mucosal melanomas), as described in either A, B, or C:

A. Recurrent (except an additional primary melanoma at a different site, which is not considered to be recurrent disease) following either 1 or 2:

- 1. Wide excision (skin melanoma).
2. Enucleation of the eye (ocular melanoma).

OR
B. With metastases as described in 1, 2, or 3:

- 1. Metastases to one or more clinically apparent nodes; that is, nodes that are

detected by imaging studies (excluding lymphoscintigraphy) or by clinical evaluation (palpable).

2. If the nodes are not clinically apparent, with metastases to four or more nodes.

3. Metastases to adjacent skin (satellite lesions) or distant sites (for example, liver, lung, or brain).

OR
C. Mucosal melanoma.
* * * * *

[FR Doc. 2015-11923 Filed 5-19-15; 8:45 am]

BILLING CODE 4191-02-P

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972

AGENCY: Department of the Navy, DoD.

ACTION: Final rule.

SUMMARY: The Department of the Navy (DoN) is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972, as amended (72 COLREGS), to reflect that the Deputy Assistant Judge Advocate General (DAJAG) (Admiralty and Maritime Law) has determined that USS PRINCETON (CG 59) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with certain provisions of the 72 COLREGS without interfering with its special function as a naval ship. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

DATES: This rule is effective May 20, 2015 and is applicable beginning May 11, 2015.

FOR FURTHER INFORMATION CONTACT: Commander Theron R. Korsak, (Admiralty and Maritime Law), Office of the Judge Advocate General, Department of the Navy, 1322 Patterson Ave. SE., Suite 3000, Washington Navy Yard, DC 20374-5066, telephone 202-685-5040.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the DoN amends 32 CFR part 706.

This amendment provides notice that the DAJAG (Admiralty and Maritime Law), under authority delegated by the Secretary of the Navy, has certified that USS PRINCETON (CG 59) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with the following specific provisions of 72 COLREGS without interfering with its special function as a naval ship: Annex I, paragraph 3(a), pertaining to the horizontal distance between the forward and after masthead lights. The DAJAG (Admiralty and Maritime Law) has also certified that the lights involved are located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

List of Subjects in 32 CFR Part 706

Marine safety, Navigation (water), Vessels.

For the reasons set forth in the preamble, the DoN amends part 706 of title 32 of the Code of Federal Regulations as follows:

PART 706—CERTIFICATIONS AND EXEMPTIONS UNDER THE INTERNATIONAL REGULATIONS FOR PREVENTING COLLISIONS AT SEA, 1972

■ 1. The authority citation for part 706 continues to read as follows:

Authority: 33 U.S.C. 1605.

■ 2. Section 706.2 is amended in Table Five by revising the entry for USS PRINCETON (CG 59) to read as follows:

§ 706.2 Certifications of the Secretary of the Navy under Executive Order 11964 and 33 U.S.C. 1605.

* * * * *

TABLE FIVE

Vessel	Number	Masthead lights not over all other lights and obstruction. annex I, sec.2(f)	Forward masthead light not in forward quarter of ship. annex I, sec.3(a)	After masthead light less than 1/2 ship's length aft of forward masthead light. annex I, sec.3(a)	Percentage horizontal separation attained
USS PRINCETON	CG 59				36.9

Approved: May 11, 2015.
A.B. Fischer,
Captain, JAGC, U.S. Navy, Deputy Assistant Judge Advocate, General (Admiralty and Maritime Law).
 Dated: May 13, 2015.
N.A. Hagerty-Ford,
Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.
 [FR Doc. 2015-12189 Filed 5-19-15; 8:45 am]
BILLING CODE 3810-FF-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket Number USCG-2015-0304]

RIN 1625-AA00

Safety Zones; Apra Outer Harbor and Adjacent Waters, Guam

AGENCY: Coast Guard, DHS.
ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a safety zone for underwater detonation operations in the waters of Apra Outer Harbor, Guam. This rule is effective from 10 a.m. until 4 p.m. on May 15, 2015 and May 21, 2015 (kilo, Local Time). The enforcement period for this rule is from 10 a.m. to 4 p.m. on May 15, 2015 and May 21, 2015. The Coast Guard believes this safety zone regulation is necessary to protect all persons and vessels that would otherwise transit or be within the affected area from possible safety hazards associated with underwater detonation operations.

DATES: This rule is effective without actual notice from May 20, 2015 through 4 p.m. May 21, 2015 (kilo, Local Time). For the purposes of enforcement, actual notice will be used from 10 a.m. on May 15, 2015 until May 20, 2015.

ADDRESSES: Documents indicated in this preamble are part of docket USCG-2015-0304. To view documents

mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov>, type the docket number USCG-2015-03XX in the "SEARCH" box and click "SEARCH". Click on Open Docket Folder on the line associated with this rulemaking. 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. (EST), Monday through Friday, except Federal holidays. You may also visit the Coast Guard Sector Guam, Naval Base Guam, between 7:30 a.m. and 3:30 p.m. (Kilo, Local Time), Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Chief, Kristina Gauthier, Sector Guam, U.S. Coast Guard; (671) 355-4866, Kristina.m.gauthier@uscg.mil. If you have questions on viewing or submitting material to the docket, call Cheryl Collins, Program Manager, Docket Operations, telephone (202) 366-9826.

SUPPLEMENTARY INFORMATION:

Table of Acronyms

DHS Department of Homeland Security
 FR Federal Register
 NPRM Notice of Proposed Rulemaking
 COTP Captain of the Port

A. Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing

so would be impracticable. The Coast Guard received notice of this operation on March 31, 2015, only 46 days before the operation is scheduled. Due to this late notice, the Coast Guard did not have time to issue a notice of proposed rulemaking.

Under 5 U.S.C. 553(d)(3), for the same reason mentioned above, the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Due to the late notice and inherent danger in underwater detonation exercises, delaying the effective period of this safety zone would be contrary to the public interest.

B. Basis and Purpose

The legal basis for this rule is the Coast Guard's authority to establish regulated navigation areas and other limited access areas: 33 U.S.C 1231; 33 CFR 1.05-1, 6.04-6, 160.5; and Department of Homeland Security Delegation No. 0170.1. A safety zone is a water area, shore area, or water and shore area, for which access is limited to authorized person, vehicles, or vessels for safety purposes.

The purpose of this rulemaking is to protect mariners from the potential hazards associated with a U.S. Navy training exercise which include detonation of underwater explosives. Approaching too close to such exercises could potentially expose the mariner to flying debris or other hazardous conditions.

C. Discussion of Rule

In order to protect the public from the hazards of the U.S. Navy training exercise, the Coast Guard is establishing a temporary safety zone, effective from 10 a.m. May 15, 2015 through 4 p.m. May 21, 2015 (Kilo, Local Time). The enforcement periods for this rule will be from 10 a.m. to 4 p.m. on May 15, 2015 and May 21, 2015.

The safety zone is located within the Guam COTP Zone (See 33 CFR 3.70-15), and will cover all waters bounded by a circle with a 700-yard radius for vessels

persons in the water, centered at: 13°27.700' N. and 144°38.500' E., from the surface of the water to the ocean floor.

The general regulations governing safety zones contained in 33 CFR 165.23 apply. Entry into, transit through or anchoring within safety zones is prohibited unless authorized by the COTP or a designated representative thereof. Any Coast Guard commissioned, warrant, or petty officer, and any other COTP representative permitted by law, may enforce the zone. The COTP may waive any of the requirements of this rule for any person, vessel, or class of vessel upon finding that application of the safety zone regulation is unnecessary or impractical for the purpose of maritime safety. Vessels or persons violating this rule may be subject to the penalties set forth in 33 U.S.C. 1232 and/or 50 U.S.C. 192.

D. Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on a number of these statutes or executive orders.

1. Regulatory Planning and Review

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, Improving Regulation and Regulatory Review, and does not require an assessment of potential costs and benefits under section 6(a)(3) of Executive Order 12866 or under section 1 of Executive Order 13563. The Office of Management and Budget has not reviewed it under those Orders. The Coast Guard expects the economic impact of this rule to be extremely minimal based on the short duration of the safety zone regulation and the limited geographic area affected by it.

2. Impact on Small Entities

The Regulatory Flexibility Act of 1980 (RFA), 5 U.S.C. 601–612, as amended, requires federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

This safety zone regulation will not have a significant economic impact on a substantial number of small entities for the following reasons. This rule would affect the following entities, some of which might be small entities: the owners or operators of vessels intending to transit through a portion of the zones from 10 a.m. through 4 p.m. on May 15, 2015 and May 21, 2015. This rule will be enforced for only 6 hours each day and vessel traffic can pass safely around the safety zone. The safety zone does not encompass the entire harbor and safe transit is still allowed to pass through, in and out of Apra Harbor. Further, traffic will be allowed to pass through the zones with the permission of the Coast Guard Patrol Commander 671–487–4817. Before the effective period, we will issue maritime advisories widely available to users of outer Apra Harbor.

If you think that your business, organization, or governmental jurisdiction qualifies as a small entity and that this rule would have a significant economic impact on it, please submit a comment (see **ADDRESSES**) explaining why you think it qualifies and how and to what degree this rule would economically affect it.

3. Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT**, above.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

4. Collection of Information

This rule will not call for a new collection of information under the

Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520.).

5. Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and determined that this rule does not have implications for federalism.

6. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

7. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

8. Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

9. Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

10. Protection of Children From Environmental Health Risks

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and would not create an environmental risk to health or risk to safety that might disproportionately affect children.

11. Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it would not have a substantial direct effect 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.

12. Energy Effects

This rule is not a “significant energy action” under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use.

13. Technical Standards

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

14. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023-01 and Commandant Instruction M16475.1D, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4370f), and have made a preliminary determination that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves a closed area of Apra Outer Harbor, to vessel traffic, for 6 hours on both May 15, 2015 and May 21, 2015. This rule is categorically excluded from further review under paragraph 34(g) of Figure 2-1 of the Commandant Instruction. A preliminary environmental analysis checklist supporting this determination and a Categorical Exclusion Determination are available in the docket where indicated under **ADDRESSES**. This rule is categorically excluded, under figure 2-1, paragraph (34)(g), of the Instruction.

List of Subjects in 33 CFR Part 165

Harbors, Marine safety, Navigation (water), Reporting and record-keeping requirements, Security measures, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

■ 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05-1, 6.04-1, 6.04-6, and 160.5; Pub. L. 107-295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

■ 2. Add § 165.T14-0304 to read as follows:

§ 165. T14-0304 Safety Zones; Apra Outer Harbor and adjacent waters, Guam.

(a) *Location.* The following area, within the Guam Captain of the Port (COTP) Zone (See 33 CFR 3.70-15), from the surface of the water to the ocean floor, is a safety zone: Seven-hundred-yard-radius zone—All waters bounded by a circle with a 700-yard radius centered at 13°27.700' N. and 144°38.500' E., (NAD 1983).

(b) *Effective period.* This section is effective from 10 a.m. on May 15, 2015 to 4 p.m. on May 21, 2015 (Kilo, Local Time).

(c) *Enforcement periods.* The safety zones described in paragraph (a) of this section will be enforced during the U.S. Navy underwater detonation operation, from 10 a.m. until 4 p.m. on May 15, 2015 and May 21, 2015 (Kilo, Local Time).

(d) *Regulations.* The general regulations governing safety zones contained in 33 CFR 165.23 apply. No vessels may enter or transit the safety zone unless authorized by the COTP or a designated representative thereof.

(e) *Enforcement.* Any Coast Guard commissioned, warrant, or petty officer, and any other COTP representative permitted by law, may enforce these temporary safety zones.

(f) *Waiver.* The COTP may waive any of the requirements of this section for any person, vessel, or class of vessel upon finding that application of the safety zone is unnecessary or impractical for the purpose of maritime security.

(g) *Penalties.* Vessels or persons violating this rule are subject to the penalties set forth in 33 U.S.C. 1232 and 50 U.S.C. 192.

Dated: April 30, 2015.

James B. Pruett,

Captain, U.S. Coast Guard, Captain of the Port Guam.

[FR Doc. 2015-12109 Filed 5-19-15; 8:45 am]

BILLING CODE 9110-04-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R05-OAR-2013-0819; FRL-9927-48-Region 5]

Approval and Promulgation of Air Quality Implementation Plans; Illinois; NAAQS Update

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: The Environmental Protection Agency (EPA) is taking direct final action to approve a State Implementation Plan (SIP) revision submitted by the Illinois Environmental Protection Agency (IEPA) on December 2, 2013. The state rule revisions update Illinois' ambient air quality standards for sulfur dioxide (SO₂), ozone, nitrogen dioxide (NO₂), lead, fine particulate matter (PM_{2.5}), particulate matter (PM₁₀), and carbon monoxide (CO) and bring them up to date (through 2012) with EPA-promulgated National Ambient Air Quality Standards (NAAQS). The SIP revision also adopts EPA-promulgated monitoring methods and test procedures for the revised state air quality standards.

DATES: This direct final rule will be effective July 20, 2015, unless EPA receives adverse comments by June 19, 2015. If adverse comments are received by EPA, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** informing the public that the rule will not take effect.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA-R05-OAR-2013-0819, by one of the following methods:

1. *www.regulations.gov:* Follow the on-line instructions for submitting comments.

2. *Email:* Aburano.Douglas@epa.gov.

3. *Fax:* (312) 692-2450.

4. *Mail:* Douglas Aburano, Chief, Air Planning and Maintenance Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.

5. *Hand Delivery:* Douglas Aburano, Chief, Air Planning and Maintenance Section, Air Programs Branch (AR-18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of

business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays?

Instructions: Direct your comments to Docket ID No. EPA-R05-OAR-2013-0819. EPA's policy is that all comments received will be included in the public docket without change and may be made available online at 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 www.regulations.gov or email. The 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 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 disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may 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.

Docket: All documents in the docket are listed in the 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 www.regulations.gov or in hard copy at the Environmental Protection Agency, Region 5, Air and Radiation Division, 77 West Jackson Boulevard, Chicago, Illinois 60604. This facility is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding Federal holidays. We recommend that you telephone Edward Doty, Environmental Scientist, at (312) 886-6057 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Edward Doty, Attainment Planning and Maintenance Section, Air Programs

Branch (AR-18)), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886-6057, Doty.Edward@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document whenever "we," "us," or "our" is used, we mean EPA. This **SUPPLEMENTARY INFORMATION** section is arranged as follows:

- I. Background
 - A. When and why did the state make this submittal?
 - B. Did the state hold public hearings for this submittal?
- II. What is EPA's analysis of IEPA's submittal?
- III. What action is EPA taking?
- IV. Incorporation by Reference
- V. Statutory and Executive Order Reviews

I. Background

A. When and why did the state make this submittal?

Section 109 of the Clean Air Act (CAA) requires the EPA to establish national primary (protective of human health) and secondary (protective of human welfare) air quality standards. Individually or collectively these standards are referred to as NAAQS. Section 109(d)(1) of the CAA requires EPA to review, and if necessary, based on accumulated health or welfare data, to revise each NAAQS every five years. States that maintain state air quality standard definitions in their state rules and SIPs must periodically revise their rules and SIPs to reflect the latest NAAQS.

On December 2, 2013, IEPA submitted a SIP revision containing rule revisions to address the NAAQS for SO₂, ozone, NO₂, lead, PM_{2.5}, PM₁₀, and CO. In this submittal, the state requests EPA to approve into the SIP rule revisions to establish Illinois air quality standards "identical-in-substance"¹ to all NAAQS promulgated by EPA for these pollutants and published in the Code of Federal Regulations (CFR) through the end of 2012. The rule revisions also incorporate by reference all EPA-promulgated Federal Reference Methods (FRMs) and Federal Equivalent Methods (FEMs) for monitoring the subject air pollutants, also specified in the CFR through 2012. The rule revisions remove state air quality standards no longer supported by current NAAQS. The rule revisions remove several existing

¹ "Identical-in-substance" means that all air quality standards adopted by the state and included in the requested SIP revision have the same magnitude, averaging time, and form as the NAAQS they represent. However, the specific language of the state's air quality standard rules may differ from that of EPA's promulgated NAAQS.

Illinois rule elements deemed to be no longer appropriate for the adopted air quality standards and monitoring methods. Finally, the rule revisions add a number of acronym and term definitions needed to fully implement the adopted air quality standards and monitoring methods.

Illinois' rule revisions ensure consistency between the state and Federal definitions of the air quality standards and associated monitoring methods, and support consistency between the state and the EPA in the determination of attainment or nonattainment of the air quality standards.

The state rule revisions were adopted by the Illinois Pollution Control Board (IPCB) on July 25, 2013, and became effective on July 29, 2013.

B. Did the state hold public hearings for this submittal?

A public hearing on the rule revisions was held on June 26, 2013, and the state addressed several comments made during this hearing or received through written comments submitted by the public.

II. What is EPA's analysis of IEPA's submittal?

Illinois' submittal covers revisions to state rules contained in 35 Illinois Administrative Code (IAC) Part 243 (35 IAC 243). Significant additions, modifications, and deletions to Part 243 are discussed and evaluated below.

35 IAC Section 243.101, Definitions, contains term and concentration unit definitions critical to the implementation of the state's air quality standards. This section has been modified to change or add definitions of, terms including, but not limited to, "Exceedance of a NAAQS;" "Exceptional event;" "Federal reference method;" "Federal equivalent method;" "Micrograms per cubic meter;" "Milligrams per cubic meter;" "Parts per million;" "Parts per billion;" "PM₁₀;" and "PM_{2.5}." Definitions for these terms and concentration units were generally derived from their definitions and usage in 40 CFR parts 50 and 53. We find these definitions to be acceptable and in agreement with definitions for these terms and concentration units used by the EPA.

The heading of 35 IAC Section 243.102, Scope, has been revised from "Preamble" to "Scope" to correspond with the Federal regulations. The former preamble statement in 35 IAC Section 243.102(a) has been replaced with the statement of scope from 40 CFR 50.2. This section also adds in parentheses "primary NAAQS" after "National

primary air quality standards” and adds in parentheses “secondary NAAQS” after “National secondary air quality standards.” All older subsections of this section have been deleted to remove provisions no longer needed to implement the state’s air quality standards. This revised section is acceptable.

Section 243.103, Applicability, has been revised to improve its readability and notes that the adopted air quality standards are applicable throughout the entire state of Illinois.

The IPCB has chosen to repeal Section 243.104 (the Non-degradation Rule) from 35 IAC 243 and from the Illinois SIP. The Non-degradation Rule predates the Illinois Environmental Protection Act and adoption of the state’s air quality standard rules. When adopting the air quality standard rules, the IPCB chose to adopt the Non-degradation Rule from earlier rules of the Air Pollution Control Board (a predecessor of the IPCB). This rule section was intended to protect areas in Illinois currently attaining the air quality standards. The IPCB chose to remove this rule section from 35 IAC 243 because: (1) it might conflict with Federal non-degradation rules; (2) it is not necessary in the context of the NAAQS; and, (3) it was not possible to correct its flaws in the context of the state’s air quality standard rules contained in 35 IAC 243. This rule removal is acceptable.

Section 243.105, Air Quality Monitoring Data Influenced by Exceptional Events, has been added to correspond with 40 CFR 50.14 (2012). This section provides for a state request to the EPA for a determination that certain monitored air quality concentrations that are the result of exceptional events may be excluded from the consideration of air quality for purposes of determining exceedances of the air quality standards. This section describes the nature of the state’s exceptional event demonstration to the EPA and specifies the criteria that the exceptional event demonstration must meet for approval by the EPA. Of particular note, this section describes exclusion of air quality data resulting from fireworks and prescribed fires. Finally, this section describes the schedules and procedures to be followed when the state petitions the EPA for a determination of an exceptional event. This section was derived from 40 CFR part 50, and is acceptable.

Section 243.106, Monitoring, which described the general approach to the monitoring of air quality levels, has been repealed. This section provided no

specific criteria for the monitoring of air levels, and its removal is acceptable.

Section 243.107, Reference Conditions, has been revised to improve its readability and specifies the reference temperature and reference air pressure to which monitored air quality concentrations must be adjusted to assure acceptable comparability of the monitored air quality concentrations. The rule revision is acceptable and reflects ambient condition adjustments required by the EPA in 40 CFR part 50.

Section 243.108, Incorporation by Reference, includes Federal rules and documents incorporated by reference into Illinois’ air quality rules. More specifically, this section includes the required reference methods applicable to the monitoring of specific pollutants as specified in the appendices to 40 CFR part 50 and documents published by the National Exposure Research Laboratory, Human Exposure and Atmospheric Sciences Division of EPA. In addition, this section incorporates by reference all appendices in 40 CFR part 50 needed to interpret the adopted air quality standards or to define the FRMs and FEMs for each pollutant. These incorporations by reference are needed to implement the state’s air quality standards in a manner equivalent to the NAAQS.

The air quality standards themselves are contained in sections 243.120 through 243.126, with each of these sections being applicable to a specific pollutant (each section covers all standards applicable to the given pollutant). Illinois has rewritten these sections to eliminate ambient air quality standards that have been revoked or eliminated by EPA and to add or update standards for each pollutant as currently adopted/promulgated by the EPA through 2012. Each section also defines the Federal reference and equivalent monitoring methods applicable to each pollutant. The state has rewritten the air quality standards to be “identical-in-substance” with EPA’s promulgated NAAQS. The state’s adopted air quality standards contain the same air quality levels, averaging times, and forms as the NAAQS, but have been rewritten for consistency in Illinois’ rule system. All NAAQS contained in 40 CFR part 50 (2012) are reflected by the Illinois air quality standards now specified in sections 243.120 through 243.126. EPA has compared the adopted air quality standards to the NAAQS specified in 40 CFR part 50, and has found them to be acceptable.

III. What action is EPA taking?

EPA is approving the requested SIP revision submission pertaining to the

amendments to Illinois’ ambient air quality standards since these revised air quality standards are consistent with the NAAQS promulgated by EPA and in existence during 2012. The state will adopt new air quality standards as new NAAQS are adopted by EPA and will subsequently remove/repeal certain air quality standards as EPA revokes the standards as NAAQS. Specifically, we are approving 35 IAC sections 243.101, 243.102, 243.103, 243.105, 243.107, 243.108, 243.120, 243.122, 243.123, 243.124, 243.125, 243.126, and 243.TableA, and we are incorporating by reference these rules into the Illinois SIP. We are also approving the repeal from the SIP of 35 IAC sections 243.104, 243.106, 243.Appendix A, 243.Appendix B, and 243.Appendix C.

We are publishing this action without prior proposal because we view this as a noncontroversial amendment and anticipate no adverse comments. However, in the proposed rules section of this **Federal Register** publication, we are publishing a separate document that will serve as the proposal to approve the state plan if relevant adverse written comments are filed. This rule will be effective July 20, 2015 without further notice unless we receive relevant adverse written comments by June 19, 2015. If we receive such comments, we will withdraw this action before the effective date by publishing a subsequent document that will withdraw the final action. All public comments received will then be addressed in a subsequent final rule based on the proposed action. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. If we do not receive any comments, this action will be effective July 20, 2015.

IV. Incorporation by Reference

In this rule, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of the Illinois Regulations described in the amendments to 40 CFR part 52 set forth below. EPA has made, and will continue to make, these documents generally available electronically through www.regulations.gov and/or in hard copy at the appropriate EPA office (see

the **ADDRESSES** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);

- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);

- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);

- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);

- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);

- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);

- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

- Is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and

- Does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have

tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by July 20, 2015. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. Parties with objections to this direct final rule are encouraged to file a comment in response to the parallel notice of proposed rulemaking for this action published in the proposed rules section of this **Federal Register**, rather than file an immediate petition for judicial review of this direct final rule, so that EPA can withdraw this direct final rule and address the comment in the proposed rulemaking. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur dioxide.

Dated: May 4, 2015.

Susan Hedman,

Regional Administrator, Region 5.

40 CFR part 52 is amended as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

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

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

■ 2. Section 52.720 is amended by adding paragraph (c)(204) to read as follows:

§ 52.720 Identification of plan.

* * * * *

(c) * * *

(204) On December 2, 2013, Illinois submitted an amendment to its State Implementation Plan at 35 Illinois Administrative Code part 243, which updates Illinois air quality standards to reflect National Ambient Air Quality Standards for sulfur dioxide, ozone, nitrogen dioxide, lead, fine particulate matter, particulate matter, and carbon monoxide and incorporates Federal test procedures for these pollutants.

(i) *Incorporation by reference.* Illinois Administrative Code Title 35: Environmental Protection; Subtitle B: Air Pollution; Chapter I: Pollution Control Board; Subchapter I: Air Quality Standards And Episodes; Part 243: Air Quality Standards; Sections 243.101 Definitions, 243.102 Scope, 243.103 Applicability, 243.105 Air Quality Monitoring Data Influenced by Exceptional Events, 243.107 Reference Conditions, 243.108 Incorporations by Reference, 243.120 PM₁₀ and PM_{2.5}, 243.122 Sulfur Oxides (Sulfur Dioxide), 243.123 Carbon Monoxide, 243.124 Nitrogen Oxides (Nitrogen Dioxide as Indicator), 243.125 Ozone, 243.126 Lead, and 243.TABLE A Schedule of Exceptional Event Flagging and Documentation Submission for New or Revised NAAQS, effective July 29, 2013.

[FR Doc. 2015-12255 Filed 5-19-15; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 170

[EPA-HQ-OPP-2011-0184; FRL-9926-64]

RIN 2070-AJ22

Notification of Submission to the Secretary of Agriculture; Pesticides; Agricultural Worker Protection Standard Revisions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notification of submission to the Secretary of Agriculture.

SUMMARY: This document notifies the public as required by the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) that the EPA Administrator has forwarded to the Secretary of the United States Department of Agriculture (USDA) a draft regulatory document concerning Pesticides; Agricultural Worker Protection Standard Revisions. The draft regulatory document is not available to the public until after it has been signed and made available by EPA.

DATES: See Unit I. under **SUPPLEMENTARY INFORMATION**.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2011-0184, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room 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, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Kathy Davis, Field and External Affairs Division (7506P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington DC 20460-0001; telephone number: (703) 308-7002; email address: davis.kathy@epa.gov.

SUPPLEMENTARY INFORMATION:

I. What action is EPA taking?

Section 25(a)(2)(B) of FIFRA requires the EPA Administrator to provide the Secretary of USDA with a copy of any draft final rule at least 30 days before signing it in final form for publication in the **Federal Register**. The draft final rule is not available to the public until after it has been signed by EPA. If the Secretary of USDA comments in writing regarding the draft final rule within 15 days after receiving it, the EPA Administrator shall include the comments of the Secretary of USDA, if requested by the Secretary of USDA, and the EPA Administrator's response to those comments with the final rule that publishes in the **Federal Register**. If the Secretary of USDA does not comment in writing within 15 days after receiving the draft final rule, the EPA Administrator may sign the final rule for publication in the **Federal Register** any time after the 15-day period.

II. Do any statutory and Executive Order reviews apply to this notification?

No. This document is merely a notification of submission to the Secretary of USDA. As such, none of the regulatory assessment requirements apply to this document.

List of Subjects in 40 CFR Part 170

Agricultural worker safety, Environmental protection, Farmworker, Handler, Pesticide handler, Pesticide safety training, Pesticide worker safety, Worker, Worker Protection Standard regulations, WPS.

Dated: May 12, 2015.

Jack Housenger,

Director, Office of Pesticide Programs.

[FR Doc. 2015-11962 Filed 5-19-15; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2013-0821; FRL-9927-38]

Fragrance Components; Exemption From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of various fragrance component substances when used as inert ingredients in antimicrobial pesticide formulations for use on food contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils. This regulation eliminates the need to establish a maximum permissible level for residues of these various fragrance component substances

DATES: This regulation is effective May 20, 2015. Objections and requests for hearings must be received on or before July 20, 2015, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2013-0821, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301

Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room 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, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. 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:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Publishing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How can I file an objection or hearing request?

Under the Federal Food, Drug, and Cosmetic Act (FFDCA) section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2013-0821 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be

received by the Hearing Clerk on or before July 20, 2015. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2013-0821, 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 CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 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>.

II. Today's Action

A. What is the authority for this action?

EPA is taking this action under section 408(e) the FFDCA, 21 U.S.C. 346a(e), which allows EPA to establish a tolerance exemption under FFDCA section 408, 21 U.S.C. 346a *et se*. Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a

tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue. . . ."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. For further discussion of the regulatory requirements of FFDCA section 408 and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/regulating/tolerances.htm>.

B. What action is the Agency taking?

EPA, on its own initiative under FFDCA section 408(e), is establishing exemptions from the requirement of a tolerance for residues of various fragrance component substances identified at the end of this document.

III. EPA's Proposal

In the **Federal Register** of July 25, 2014 (79 FR 43350) (FRL-9910-53), EPA proposed, on its own initiative under FFDCA section 408(e), 21 U.S.C. 346a(e), to establish exemptions from the requirement of a tolerance for residues of acetaldehyde (CAS Reg. No. 75-07-0), acetic acid (CAS Reg. No. 64-19-7), allyl cyclohexyl propionate (CAS Reg. No. 2705-87-5), butyric acid (CAS Reg. No. 107-92-6), butyl alcohol (CAS Reg. No. 71-36-3), citral (CAS Reg. No. 5392-40-5), citronellol (CAS Reg. No. 106-22-9), citronellyl acetate (CAS Reg. No. 150-84-5), β -damascone, (Z)-(CAS Reg. No. 23726-92-3), decanal (CAS Reg. No. 112-31-2), (E)-4-decenal (CAS Reg. No. 65405-70-1), decanoic acid (CAS Reg. No. 334-48-5), 1-decanol (CAS Reg. No. 112-30-1), 2,6-dimethyl-5-heptanal (CAS Reg. No. 106-72-9), 2-dodecanol, (2E)- (CAS Reg. No. 20407-84-5), d-limonene (CAS Reg. No. 5989-27-5), ethyl 2-methylbutyrate (CAS Reg. No. 452-79-1), (E)-geraniol (CAS Reg. No. 106-24-1), (E)-geraniol acetate (CAS Reg. No. 105-87-3), heptanal (CAS Reg. No. 111-71-7), heptanoic acid (CAS Reg. No. 111-14-8), heptyl alcohol (CAS Reg. No. 111-70-6), hexanal (CAS Reg. No. 66-25-1), hexanoic acid (CAS Reg. No. 142-62-1), (Z)-3-hexenol (CAS Reg. No. 928-96-1), (Z)-3-hexenol acetate (CAS Reg. No. 3681-71-8), hexyl acetate (CAS Reg. No. 142-92-7), hexyl alcohol (CAS Reg. No. 111-27-3), lauric acid (CAS Reg. No. 143-07-7), lauric aldehyde (CAS Reg. No. 112-54-9), lauryl alcohol (CAS Reg. No. 112-53-8),

methyl- α -ionone (CAS Reg. No. 127-42-4), 3-methyl-2-butenyl acetate (CAS Reg. No. 1191-16-8), 2-methylundecanal (CAS Reg. No. 110-41-8), myristaldehyde (CAS Reg. No. 124-25-4), myristic acid (CAS Reg. No. 544-63-8), neryl acetate (CAS Reg. No. 141-12-8), n-hexanol (CAS Reg. No. 111-27-3), nonanal (CAS Reg. No. 124-19-6), nonanoic acid (CAS Reg. No. 112-05-0), nonyl alcohol (CAS Reg. No. 143-08-8), octanal (CAS Reg. No. 124-13-0), octanoic acid (CAS Reg. No. 124-07-2), 1-octanol (CAS Reg. No. 111-87-5), palmitic acid (CAS Reg. No. 57-10-3), propionic acid (CAS Reg. No. 79-09-4), stearic acid (CAS Reg. No. 57-11-4), 2-tridecanal (CAS Reg. No. 7774-82-5), 3,5,5-trimethylhexanal (CAS Reg. No. 5435-64-3), undecanal (CAS Reg. No. 112-44-7), undecyl alcohol (CAS Reg. No. 112-42-5), valeraldehyde (CAS Reg. No. 110-62-3), and valeric acid (CAS Reg. No. 109-52-4) when used as fragrance components (*i.e.*, inert ingredients) in antimicrobial pesticide formulations for use on food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils at end-use concentrations not to exceed 100 parts per million (ppm).

As discussed in that document, EPA has reviewed the available scientific data and other relevant information in support of this action, consistent with FFDCA section 408(c)(2), and the factors specified in FFDCA section 408(b)(2)(C and D). EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for these various fragrance components including exposure resulting from the exemptions from the requirement of a tolerance established by this action. For a detailed discussion of the aggregate risk assessments and determination of safety that support the establishment of these exemptions from the requirement of a tolerance, please refer to the July 25, 2014 **Federal Register** final rule and its supporting documents, available at <http://regulations.gov>.

IV. Public Comments

EPA received nine comments to the proposed rule. Six of the comments were fully supportive of the proposed rule. One comment made specific reference to the fragrance component acetaldehyde and stated that the risk assessment of acetaldehyde should reconsider the compound's cancer risk. The comment noted that part of the safety finding for the fragrance components was based on no structural alerts for genotoxicity or carcinogenicity but in the case of acetaldehyde EPA had previously considered acetaldehyde to

be a probable human carcinogen based on inadequate human cancer studies and animal studies that have shown increased incidence of nasal tumors in rats and laryngeal tumors in hamsters after inhalation exposure. The Agency agrees with the commenter that the safety analysis provided in the proposed rule, which relies on human exposure threshold values for non-cancer risks, is not applicable to acetaldehyde and therefore, cannot be used to support an exemption for acetaldehyde. As such, EPA is not establishing in this final rule an exemption from the requirement of a tolerance for acetaldehyde as a fragrance component for use in antimicrobial pesticide formulations for use on food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils at end-use concentrations not to exceed 100 ppm.

Two comments made reference to fragrance sensitivity among certain individuals. The Agency understands the commenter's concerns, however the legal framework provided by FFDCA section 408 states that tolerances may be set when the pesticide chemical meets the safety standard imposed by that statute. The Agency is required by FFDCA section 408 to estimate the risk of the potential exposure to these residues. Neither the supporting information cited by the commenters or other reliable data demonstrate the occurrence of specific adverse effects directly attributable to exposures to the substances listed in Unit III and EPA has concluded that there is a reasonable certainty that no harm will result to the general population and to infants and children from aggregate exposure to the fragrance components listed in Unit III when used as inert ingredients in antimicrobial formulations for use on food contact surfaces in public eating places, dairy processing equipment, and food processing equipment and utensils at end-use concentrations not to exceed 100 ppm.

V. Final Rule and Determination of Safety

Except for the exclusion of acetaldehyde, EPA is not making any changes to the risk assessment or final rule text that was proposed in July 25, 2014 **Federal Register**. Therefore, EPA concludes that there is a reasonable certainty that no harm will result to the general population and to infants and children from aggregate exposure to acetic acid; allyl cyclohexylpropionate; butyric acid; butyl alcohol; citral; citronellol; citronellyl acetate; β -damascone, (Z)-; decanal; (E)-4-decenal; decanoic acid; 1-decanol; 2,6-dimethyl-

5-heptanal; 2-dodecanol, (2E)-; d-limonene; ethyl 2-methylbutyrate; (E)-geraniol; (E)-geraniol acetate; heptanal; heptanoic acid; heptyl alcohol; hexanal; hexanoic acid; (Z)-3-hexenol; (Z)-3-hexenol acetate; hexyl acetate; hexyl alcohol; lauric acid; lauric aldehyde; lauryl alcohol; methyl- α -ionone; 3-methyl-2-butenyl acetate; 2-methylundecanal; myristaldehyde; myristic acid; neryl acetate; n-hexanol; nonanal; nonanoic acid; nonyl alcohol; octanal; octanoic acid; 1-octanol; palmitic acid; propionic acid; stearic acid; 2-tridecanal; 3,5,5-trimethylhexanal; undecanal; undecyl alcohol; valeraldehyde; and valeric acid residues when used as when used as fragrance components (*i.e.*, inert ingredients) in antimicrobial pesticide formulations for use on food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils at end-use concentrations not to exceed 100 ppm.

VI. Other Considerations

A. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for the fragrance components listed in Unit II above.

VII. Conclusion

Therefore, exemptions from the requirement of a tolerance are established for residues of acetic acid (CAS Reg. No. 64-19-7), allyl

cyclohexyl propionate (CAS Reg. No. 2705-87-5), butyric acid (CAS Reg. No. 107-92-6), butyl alcohol (CAS Reg. No. 71-36-3), citral (CAS Reg. No. 5392-40-5), citronellol (CAS Reg. No. 106-22-9), citronellyl acetate (CAS Reg. No. 150-84-5), β -damascone, (Z)- (CAS Reg. No. 23726-92-3), decanal (CAS Reg. No. 112-31-2), (E)-4-decenal (CAS Reg. No. 65405-70-1), decanoic acid (CAS Reg. No. 334-48-5), 1-decanol (CAS Reg. No. 112-30-1), 2,6-dimethyl-5-heptanal (CAS Reg. No. 106-72-9), 2-dodecanol, (2E)- (CAS Reg. No. 20407-84-5), d-limonene (CAS Reg. No. 5989-27-5), ethyl 2-methylbutyrate (CAS Reg. No. 452-79-1), (E)-geraniol (CAS Reg. No. 106-24-1), (E)-geraniol acetate (CAS Reg. No. 105-87-3), heptanal (CAS Reg. No. 111-71-7), heptanoic acid (CAS Reg. No. 111-14-8), heptyl alcohol (CAS Reg. No. 111-70-6), hexanal (CAS Reg. No. 66-25-1), hexanoic acid (CAS Reg. No. 142-62-1), (Z)-3-hexenol (CAS Reg. No. 928-96-1), (Z)-3-hexenol acetate (CAS Reg. No. 3681-71-8), hexyl acetate (CAS Reg. No. 142-92-7), hexyl alcohol (CAS Reg. No. 111-27-3), lauric acid (CAS Reg. No. 143-07-7), lauric aldehyde (CAS Reg. No. 112-54-9), lauryl alcohol (CAS Reg. No. 112-53-8), methyl- α -ionone (CAS Reg. No. 127-42-4), 3-methyl-2-butenyl acetate (CAS Reg. No. 1191-16-8), 2-methylundecanal (CAS Reg. No. 110-41-8), myristaldehyde (CAS Reg. No. 124-25-4), myristic acid (CAS Reg. No. 544-63-8), neryl acetate (CAS Reg. No. 141-12-8), n-hexanol (CAS Reg. No. 111-27-3), nonanal (CAS Reg. No. 124-19-6), nonanoic acid (CAS Reg. No. 112-05-0), nonyl alcohol (CAS Reg. No. 143-08-8), octanal (CAS Reg. No. 124-13-0), octanoic acid (CAS Reg. No. 124-07-2), 1-octanol (CAS Reg. No. 111-87-5), palmitic acid (CAS Reg. No. 57-10-3), propionic acid (CAS Reg. No. 79-09-4), stearic acid (CAS Reg. No. 57-11-4), 2-tridecanal (CAS Reg. No. 7774-82-5), 3,5,5-trimethylhexanal (CAS Reg. No. 5435-64-3), undecanal (CAS Reg. No. 112-44-7), undecyl alcohol (CAS Reg. No. 112-42-5), valeraldehyde (CAS Reg. No. 110-62-3), and valeric acid (CAS Reg. No. 109-52-4) when used as fragrance components (*i.e.*, inert ingredients) in antimicrobial pesticide formulations for use on food-contact surfaces in public eating places, dairy-processing equipment, and food-processing equipment and utensils at end-use concentrations not to exceed 100 ppm.

VIII. Statutory and Executive Order Reviews

This action establishes exemptions from the requirement of a tolerance under FFDCA section 408(e). The Office

of Management and Budget (OMB) has exempted tolerance actions from review under Executive Orders 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993) and 13563, entitled *Improving Regulation and Regulatory Review* (76 FR 3821, January 21, 2011). As a result, this action is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001). Nor does it require OMB review or any Agency action under Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997).

This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*); does not require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994); and does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

This action directly regulates growers, food processors, food handlers, and food

retailers, but it does not regulate State or tribal governments. Nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). Therefore, the Agency has determined that Executive Orders 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty, contain any unfunded mandate, or otherwise significantly or uniquely affect small governments as described in the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

Under the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that this action will not have significant negative economic impact on a substantial number of small entities. Establishing an exemption from the requirement of a pesticide tolerance is, in effect, the removal of a regulatory restriction on pesticide residues in food and thus such an action will not have any negative economic impact on any entities, including small entities.

X. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S.

Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: May 8, 2015.

G. Jeffrey Herndon,
Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. In § 180.940, revise the entry for “Acetic acid” and alphabetically add the following inert ingredients to the table in paragraph (a) to read as follows:

§ 180.940 Tolerance exemptions for active and inert ingredients for use in antimicrobial formulations (Food-contact surface sanitizing solutions).

* * * * *
(a) * * *

Pesticide chemical	CAS Reg. No.	Limits
Acetic acid	64–19–7	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
Allyl cyclohexylpropionate	2705–87–5	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
Butyric acid	107–92–6	When ready for use, the end-use concentration is not to exceed 100 ppm.
Butyl alcohol	71–36–3	When ready for use, the end-use concentration is not to exceed 100 ppm.
Citral	5392–40–5	When ready for use, the end-use concentration is not to exceed 100 ppm.
Citronellol	106–22–9	When ready for use, the end-use concentration is not to exceed 100 ppm.
Citronellyl acetate	150–84–5	When ready for use, the end-use concentration is not to exceed 100 ppm.
β-Damascone, (Z)-	23726–92–3	When ready for use, the end-use concentration is not to exceed 100 ppm.
Decanal	112–31–2	When ready for use, the end-use concentration is not to exceed 100 ppm.
(E)-4-Decenal	65405–70–1	When ready for use, the end-use concentration is not to exceed 100 ppm.
Decanoic acid	334–48–5	When ready for use, the end-use concentration is not to exceed 100 ppm.
1-Decanol	112–30–1	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
2,6-Dimethyl-5-heptanal	106–72–9	When ready for use, the end-use concentration is not to exceed 100 ppm.
2-Dodecanol, (2E)-	20407–84–5	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
Ethyl 2-methylbutyrate	452–79–1	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
(E)-Geraniol	106–24–1	When ready for use, the end-use concentration is not to exceed 100 ppm.
(E)-Geraniol acetate	105–87–3	When ready for use, the end-use concentration is not to exceed 100 ppm.
Heptanal	111–71–7	When ready for use, the end-use concentration is not to exceed 100 ppm.
Heptanoic acid	111–14–8	When ready for use, the end-use concentration is not to exceed 100 ppm.

Pesticide chemical	CAS Reg. No.	Limits
Heptyl alcohol	111-70-6	When ready for use, the end-use concentration is not to exceed 100 ppm.
Hexanal	66-25-1	When ready for use, the end-use concentration is not to exceed 100 ppm.
Hexanoic acid	142-62-1	When ready for use, the end-use concentration is not to exceed 100 ppm.
n-Hexanol	111-27-3	When ready for use, the end-use concentration is not to exceed 100 ppm.
(Z)-3-Hexenol	928-96-1	When ready for use, the end-use concentration is not to exceed 100 ppm.
(Z)-3-Hexenol acetate	3681-71-8	When ready for use, the end-use concentration is not to exceed 100 ppm.
Hexyl acetate	142-92-7	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
Lauric acid	143-07-7	When ready for use, the end-use concentration is not to exceed 100 ppm.
Lauric aldehyde	112-54-9	When ready for use, the end-use concentration is not to exceed 100 ppm.
Lauryl alcohol	112-53-8	When ready for use, the end-use concentration is not to exceed 100 ppm.
d-Limonene	5989-27-5	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
Methyl- α -ionone	127-42-4	When ready for use, the end-use concentration is not to exceed 100 ppm.
3-Methyl-2-butenyl acetate	1191-16-8	When ready for use, the end-use concentration is not to exceed 100 ppm.
2-Methylundecanal	110-41-8	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
Myristaldehyde	124-25-4	When ready for use, the end-use concentration is not to exceed 100 ppm.
Myristic acid	544-63-8	When ready for use, the end-use concentration is not to exceed 100 ppm.
Neryl acetate	141-12-8	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
Nonanal	124-19-6	When ready for use, the end-use concentration is not to exceed 100 ppm.
Nonanoic acid	112-05-0	When ready for use, the end-use concentration is not to exceed 100 ppm.
Nonyl alcohol	143-08-8	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
Octanal	124-13-0	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
Octanoic acid	124-07-2	When ready for use, the end-use concentration is not to exceed 100 ppm.
1-Octanol	111-87-5	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
Palmitic acid	57-10-3	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
Propionic acid	79-09-4	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
Stearic acid.	57-11-4	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *
2-Tridecanal	7774-82-5	When ready for use, the end-use concentration is not to exceed 100 ppm.
3,5,5-Trimethylhexanal	5435-64-3	When ready for use, the end-use concentration is not to exceed 100 ppm.
Undecanal	112-44-7	When ready for use, the end-use concentration is not to exceed 100 ppm.
Undecyl alcohol	112-42-5	When ready for use, the end-use concentration is not to exceed 100 ppm.
Valeraldehyde	110-62-3	When ready for use, the end-use concentration is not to exceed 100 ppm.
Valeric acid	109-52-4	When ready for use, the end-use concentration is not to exceed 100 ppm.
* * *	* * *	* * *

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 [FR Doc. 2015-11959 Filed 5-19-15; 8:45 am]
 BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2014-0340; FRL-9926-62]

Trinexapac-ethyl; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of trinexapac-

ethyl in or on multiple commodities which are identified and discussed later in this document. Syngenta Crop protection LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective May 20, 2015. Objections and requests for hearings must be received on or before July 20, 2015, and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also

Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2014-0340, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room 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, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Susan Lewis, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: RDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. 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:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How can I get electronic access to other related information?

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Publishing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How can I file an objection or hearing request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation

and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2014-0340 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before July 20, 2015. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2014-0340, 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 CBI or other information whose disclosure is restricted by statute.

- *Mail:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 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>.

II. Summary of Petitioned-For Tolerance

In the **Federal Register** of August 1, 2014 (79 FR 44731) (FRL-9911-67), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 4F8254) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419. The petition requested that 40 CFR 180.662 be amended by establishing tolerances for residues of the plant growth regulator trinexapac-ethyl, (4-(cyclopropyl-a-hydroxy-methylene)-3,5-dioxo-cyclohexanecarboxylic acid ethyl ester), and its primary metabolite CGA-

179500 in or on rice, bran at 1.5 parts per million (ppm); rice, grain at 0.4 ppm; rice, straw at 0.07 ppm; rice, wild, grain at 0.4 ppm; rye, bran at 2.5 ppm; rye, grain at 2.0 ppm; rye, hay at 0.8 ppm; and rye, straw at 0.4 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection LLC, the registrant, which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based upon review of the data supporting the petition, EPA has modified the proposed tolerances on rye commodities to rye, bran at 6.0 ppm; rye, grain at 4.0 ppm; rye, hay at 1.5 ppm; and rye, straw at 0.9 ppm. The reason for these changes are explained in Unit IV.C.

III. Aggregate Risk Assessment and Determination of Safety

Section 408(b)(2)(A)(i) of FFDCA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the tolerance is "safe." Section 408(b)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue"

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for trinexapac-ethyl including exposure resulting from the tolerances established by this action. EPA's assessment of exposures and risks associated with trinexapac-ethyl follows.

A. Toxicological Profile

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the

studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Trinexapac-ethyl exhibits low acute toxicity as shown in the standard acute toxicity battery as well as in the acute neurotoxicity study in rats with no systemic or neurotoxic effects up to the limit dose. The dog appears to be the most sensitive species while no systemic adverse effects were seen in rats, rabbits, or mice up to the limit dose (1,000 milligram/kilogram/day (mg/kg/day)) following subchronic or chronic oral exposure. In the dogs; however, decreased body weight gain and food consumption, diffuse thymic atrophy, and changes in the epithelial cells of the renal tubules were seen in the 90-day dog study at 516/582 mg/kg/day (males/females). Following chronic exposure, dose-related neuropathology of the brain characterized as focal bilateral vacuolation of the dorsal medial hippocampus and/or lateral midbrain was seen at $\geq 365/357$ mg/kg/day in male and female dogs, respectively. The lesions remained confined to the supporting cells in the central nervous system and did not progress to more advanced or more extensive damage of the nervous tissue. These lesions were not associated with other neuropathological findings or overt neurological signs, so their biological significance is unknown. Similar lesions were not observed in the rat or mouse following subchronic or chronic dietary exposure, and there was no other evidence in any other species tested to indicate a neurotoxicity potential. Furthermore, the brain lesions observed in the chronic dog study are not likely to develop from a short-term exposure and were not observed in either the rat or mouse short-term studies. In support of these findings, no evidence of neurotoxicity in the acute or subchronic rat neurotoxicity studies was found.

In the rat and rabbit developmental toxicity studies, there is evidence of increased qualitative and quantitative susceptibility in the rat (increased incidence of asymmetrical sternalbrae at the limit dose) and rabbit (decreased number of live fetuses/litter and increased post-implantation loss and early resorption at 360 mg/kg/day) in the absence of maternal toxicity. Qualitative sensitivity was observed in the 2-generation reproduction study but only in excess of the limit dose (1,212 mg/kg/day). The decreased pup survival when analyzed with sexes combined, resulted in statistical significance (5–7%); this finding was not significant

when the data were analyzed separately. Further evaluation of the individual litters suggested that one or two litters were the cause of the reduced pup survival at the highest dose tested. Reproductive toxicity was not observed up to the limit dose. There was also no indication of immunotoxicity in mice up to the limit dose.

Data from the combined chronic toxicity/carcinogenicity study in the rat did not demonstrate an increase in any tumor type that would be relevant to humans. The observation of squamous cell carcinomas in the non-glandular portion of the stomach of two males at 806 mg/kg/day does not provide reasonable evidence of a possible deleterious effect of trinexapac-ethyl on the pharynx and/or esophagus (non-glandular areas) of the human. This is because trinexapac-ethyl would not be in contact with human tissues for a significant period of time compared to the length of time it was in contact with the non-glandular portion of the rat stomach. Follicular adenocarcinomas of the thyroid were significantly increased in males (5%) at 806 mg/kg/day but this value was within the historical control range. In the mouse, there was no evidence of carcinogenicity. The mutagenicity database is complete, with no evidence of mutagenicity. The cancer classification for trinexapac-ethyl is “Not Likely to be Carcinogenic to Humans.”

Specific information on the studies received and the nature of the adverse effects caused by trinexapac-ethyl as well as the no-observed-adverse-effect-level (NOAEL) and the lowest-observed-adverse-effect-level (LOAEL) from the toxicity studies can be found at <http://www.regulations.gov> in document “Trinexapac-ethyl: Human Health Risk Assessment to Support New Uses on Rice and Rye” on page 34 in docket ID number EPA–HQ–OPP–2014–0340.

B. Toxicological Points of Departure/Levels of Concern

Once a pesticide's toxicological profile is determined, EPA identifies toxicological points of departure (POD) and levels of concern to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/

safety factors are used in conjunction with the POD to calculate a safe exposure level—generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD)—and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <http://www.epa.gov/pesticides/factsheets/riskassess.htm>.

A summary of the toxicological endpoints for trinexapac-ethyl used for human risk assessment is discussed in Unit III B. of the final rule published in the **Federal Register** of March 2, 2012 (77 FR 12742) (FRL–9337–9).

C. Exposure Assessment

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to trinexapac-ethyl, EPA considered exposure under the petitioned-for tolerances (as revised in this regulation) as well as all existing trinexapac-ethyl tolerances in 40 CFR 180.662. EPA assessed dietary exposures from trinexapac-ethyl in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for trinexapac-ethyl. In estimating acute dietary exposure, EPA used food consumption information from the United States Department of Agriculture (USDA) 2003–2008 National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). As to residue levels in food, EPA assumed that residues are present in all commodities at the tolerance level and that 100% of all commodities with trinexapac-ethyl tolerances are treated. The acute dietary exposure was only estimated for females 13 to 49 years old based on an *in utero* effect (decrease in mean number of fetuses/litter and an increase in post-implantation loss) identified in the rabbit developmental study. An endpoint of concern was not identified for the general U.S. population; however, the acute dietary assessment will ensure protection of women that may become pregnant.

ii. *Chronic exposure.* In conducting the chronic dietary exposure assessment EPA used the food consumption data

from the USDA 2003–2008 (NHANES/WWEIA). As to residue levels in food, EPA assumed that residues are present in all commodities at the tolerance level and that 100% of all commodities with trinexapac-ethyl tolerances are treated.

iii. *Cancer.* Based on the data summarized in Unit III.A., EPA has concluded that trinexapac-ethyl does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk is unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for trinexapac-ethyl. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* The Agency used screening level water exposure models in the dietary exposure analysis and risk assessment for trinexapac-ethyl in drinking water. These simulation models take into account data on the physical, chemical, and fate/transport characteristics of trinexapac-ethyl. Further information regarding EPA drinking water models used in pesticide exposure assessment can be found at <http://www.epa.gov/oppefed1/models/water/index.htm>.

Based on the Tier 1 Rice Model and Pesticide Root Zone Model Ground Water (PRZM GW), the estimated drinking water concentrations (EDWCs) of trinexapac-ethyl for acute exposures are estimated to be 31.68 parts per billion (ppb) for surface water and 0.116 ppb for ground water. The EDWCs of trinexapac-ethyl for chronic exposures for non-cancer assessments are estimated to be 31.68 ppb for surface water and 0.054 ppb for ground water.

Modeled estimates of drinking water concentrations were directly entered into the dietary exposure model. For acute dietary risk assessment, the water concentration value of 31.68 ppb was used to assess the contribution to drinking water. For chronic dietary risk assessment, the water concentration of value 31.68 ppb was used to assess the contribution to drinking water.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and flea and tick control on pets). Trinexapac-ethyl is currently registered for the following uses that could result in residential exposures: Residential lawns, athletic fields, parks, and golf courses. EPA assessed residential exposure using the following assumptions: That homeowner handlers

wear shorts, short-sleeved shirts, socks, and shoes, and that they complete all tasks associated with the use of a pesticide product including mixing/loading, if needed, as well as the application. Residential handler exposure scenarios for both dermal and inhalation are considered to be short-term only, due to the infrequent use patterns associated with homeowner products.

EPA uses the term “post-application” to describe exposure to individuals that occur as a result of being in an environment that has been previously treated with a pesticide. Trinexapac-ethyl can be used in many areas that can be frequented by the general population including residential areas (e.g., home lawns, recreational turf). As a result, individuals can be exposed by entering these areas if they have been previously treated. Therefore, short- and intermediate-term dermal post-application exposures and risks were also assessed for trinexapac-ethyl. There is the potential for dermal and incidental oral exposure to children; however, since there is no toxicological endpoint of concern for that route, a quantitative assessment was not conducted. Further information regarding EPA standard assumptions and generic inputs for residential exposures may be found at <http://www.epa.gov/pesticides/trac/science/trac6a05.pdf>.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.” EPA has not found trinexapac-ethyl to share a common mechanism of toxicity with any other substances, and trinexapac-ethyl does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that trinexapac-ethyl does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s Web site at <http://www.epa.gov/pesticides/cumulative>.

D. Safety Factor for Infants and Children

1. *In general.* Section 408(b)(2)(C) of FFDCA provides that EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X, or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* Evidence of increased qualitative and/or quantitative susceptibility of the offspring was seen only at high doses in the developmental rat and rabbit studies, and in the rat reproduction study. Developmental toxicity in the rat was only observed at the limit dose (increased incidence of asymmetrical sternebrae at 1,000 mg/kg) in the absence of maternal toxicity. In the rabbit, no maternal toxicity was demonstrated at the highest dose tested (360 mg/kg/day), but there was a decrease in the mean number of fetuses/litter and an increase in post-implantation loss and early resorptions at this dose level.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF were reduced to 1x. That decision is based on the following findings:

i. The toxicity database for trinexapac-ethyl is complete.

ii. There is no indication that trinexapac-ethyl is a neurotoxic chemical and there is no need for a developmental neurotoxicity study or additional Uncertainty Factor’s to account for neurotoxicity.

iii. Although, there is evidence of susceptibility in the rat and rabbit developmental studies and qualitative susceptibility in the 2-generation rat reproduction study, these effects only occurred at the highest doses tested for each study, and there were clearly identified NOAELs/LOAELs for the rabbit developmental study, the rat developmental study and for the reproduction study for each fetal/offspring effect. Therefore, there are no residual concerns with respect to developmental and reproductive effects.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessments were performed based on 100 PCT and tolerance-level residues. EPA made conservative (protective) assumptions in the ground and surface water modeling used to assess exposure to trinexapac-ethyl in drinking water. EPA used similarly conservative assumptions to assess postapplication exposure of children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by trinexapac-ethyl.

E. Aggregate Risks and Determination of Safety

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the acute PAD (aPAD) and chronic PAD (cPAD). For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* An acute aggregate risk assessment takes into account acute exposure estimates from dietary consumption of food and drinking water. Therefore, acute aggregate risk is equivalent to the acute dietary risk as discussed in Unit III.C.1.i. All risk estimates are below EPA's level of concern. The acute dietary exposure estimate for females 13 to 49 years old will only utilize 2% of the aPAD, which is well below the Agency's level of concern (100% of the aPAD).

2. *Chronic risk.* Using the exposure assumptions described in this unit for chronic exposure, EPA has concluded that chronic exposure to trinexapac-ethyl from food and water will utilize 6% of the cPAD for children 1 to 2 years old, the population group receiving the greatest exposure.

3. *Short- and intermediate-term risk:* Short- and immediate-term aggregate exposure take into account short-term and intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Trinexapac-ethyl is currently registered for uses that could result in short- and intermediate-term residential exposure, and the Agency has determined that it is appropriate to aggregate chronic exposure through food and water with short-term and intermediate-term residential exposures to trinexapac-ethyl. The short- and intermediate-term

toxicological endpoints for trinexapac-ethyl are the same for each route of exposure. Therefore, for residential exposure scenarios, only short-term exposures were assessed, and are considered to be protective of intermediate-term exposure and risk.

Using the exposure assumptions described in this unit for short-term exposures, EPA has concluded the combined short-term food, water, and residential exposures result in aggregate MOEs of 4500 for children 11–16 years old and 230 for adult females. Because EPA's level of concern for trinexapac-ethyl is a MOE of 100 or below, these MOEs are not of concern.

4. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, chemical name is not expected to pose a cancer risk to humans.

5. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general population, or to infants and children from aggregate exposure to trinexapac-ethyl residues.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (Method GRM020.01A, which utilizes high performance liquid chromatography with triple-quadrupole mass spectrometry (LC-MS/MS) is available to enforce the tolerance expression.

The method may be requested from: Chief, Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Rd., Ft. Meade, MD 20755–5350; telephone number: (410) 305–2905; email address: residuemethods@epa.gov.

B. International Residue Limits

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is

different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level. The Codex has not established a MRL for trinexapac-ethyl.

C. Revisions to Petitioned-For Tolerances

EPA revised the petitioned-for tolerances on rye which were determined by extrapolating from residue data on barley. EPA concurs with translating from the existing cereal grains, however, from a residue perspective, rye is more similar to wheat than to barley. Since the tolerances for wheat commodities are higher than the tolerances for barley commodities, EPA has revised the tolerances for rye to be consistent with the wheat tolerances. The use of the higher wheat tolerances also represents a more conservative (protective) approach for assessing risk from total residues.

V. Conclusion

Therefore, tolerances are established for residues of trinexapac-ethyl, (4-(cyclopropyl-a-hydroxy-methylene)-3,5-dioxo-cyclohexanecarboxylic acid ethyl ester), and the associated metabolite trinexapac, (4-(cyclopropylhydroxymethylene)-3,5-dioxocyclohexanecarboxylic acid), calculated as the stoichiometric equivalent of trinexapac-ethyl, in or on rice, bran at 1.5 ppm; rice, grain at 0.4 ppm; rice, straw at 0.07 ppm; rice, wild, grain at 0.4 ppm; rye, bran at 6.0 ppm; rye, grain at 4.0 ppm; rye, hay at 1.5 ppm; and rye, straw at 0.9 ppm.

VI. Statutory and Executive Order Reviews

This action establishes tolerances under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under

Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDC section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDC section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

VII. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides

and pests, Reporting and recordkeeping requirements.

Dated: May 8, 2015.

G. Jeffery Herndon,

Acting Director, Registration Division, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180—[AMENDED]

■ 1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

■ 2. Section 180.662, is amended by alphabetically adding the following commodities to the table in paragraph (a) to read as follows:

§ 180.662 Trinexapac-ethyl; tolerances for residues.

(a) * * *

Commodity	Parts per million
* * * * *	
Rice, bran	1.5
Rice, grain	0.4
Rice, straw	0.07
Rice, wild, grain	0.4
Rye, bran	6.0
Rye, grain	4.0
Rye, hay	1.5
Rye, straw	0.9
* * * * *	

[FR Doc. 2015-11972 Filed 5-19-15; 8:45 am]
BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 73

[**MB Docket No. 15-88; RM-11747; DA 15-584**]

Television Broadcasting Services; Bend, Oregon

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Commission has before it a Notice of Proposed Rulemaking issued in response to a petition for rulemaking filed by TDS Broadcasting LLC (“TDS”), the licensee of KOHD, channel 51, Bend, Oregon, requesting the substitution of channel 18 for channel 51 at Bend. TDS filed comments reaffirming its interest in the proposed channel substitution and stated that if the proposal is granted, it will promptly

file an application for the facilities specified in its rulemaking petition and construct the station. TDS also reiterates that the grant of the petition would serve the public interest because its operation on channel 18 would eliminate potential interference to and from wireless operations in the Lower 700 MHz A Block located adjacent to channel 51 in Portland, Oregon market, permitting the wireless licensee to expand service to additional consumers sooner than would otherwise be possible.

DATES: This rule is effective May 20, 2015.

FOR FURTHER INFORMATION CONTACT: Joyce Bernstein, *Joyce.Bernstein@fcc.gov*, Media Bureau, (202) 418-1647.

SUPPLEMENTARY INFORMATION: This is a synopsis of the Commission’s *Report and Order*, MB Docket No. 15-88, adopted May 14, 2015, and released May 14, 2015. The full text of this document is available for public inspection and copying during normal business hours in the FCC’s Reference Information Center at Portals II, CY-A257, 445 12th Street SW., Washington, DC 20554. This document will also be available via ECFS (<http://fjallfoss.fcc.gov/ecfs/>). To request materials in accessible formats for people with disabilities (braille, large print, electronic files, audio format), send an email to *fcc504@fcc.gov* or call the Consumer & Governmental Affairs Bureau at 202-418-0530 (voice), 202-418-0432 (tty).

This document does not contain information collection requirements subject to the Paperwork Reduction Act of 1995, Public Law 104-13. In addition, therefore, it does not contain any information collection burden “for small business concerns with fewer than 25 employees,” pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107-198, *see* 44 U.S.C. 3506(c)(4). Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

The Commission will send a copy of this *Report and Order* in a report to be sent to Congress and the Government Accountability Office pursuant to the Congressional review Act, *see* 5 U.S.C. 801(a)(1)(A).

List of Subjects in 47 CFR Part 73

Television.
 Federal Communications Commission.
Barbara A. Kreisman,
Chief, Video Division, Media Bureau.

Final Rule

For the reasons discussed in the preamble, the Federal Communications

Commission amends 47 CFR part 73 as follows:

PART 73—RADIO BROADCAST SERVICES

■ 1. The authority citation for part 73 continues to read as follows:

Authority: 47 U.S.C. 154, 303, 334, 336, and 339.

§ 73.622 [Amended]

■ 2. Section 73.622(i), the Post-Transition Table of DTV Allotments under Oregon is amended by removing channel 51 and adding channel 18 at Bend.

[FR Doc. 2015-12232 Filed 5-19-15; 8:45 am]

BILLING CODE 6712-01-P

GENERAL SERVICES ADMINISTRATION

48 CFR Parts 511 and 552

[GSAR Change 63; GSAR Case 2014-G504; Docket No. 2015-0003; Sequence No. 1]

RIN 3090-AJ53

General Services Administration Acquisition Regulation (GSAR); Unique Item Identification (UID)

AGENCIES: Office of Acquisition Policy, General Services Administration (GSA).

ACTION: Final rule.

SUMMARY: The General Services Administration (GSA) is issuing a final rule amending the General Services Administration Acquisition Regulation (GSAR) to remove the GSAR clause Unique Item Identification.

DATES: *Effective:* May 20, 2015.

FOR FURTHER INFORMATION CONTACT: Mr. James Tsujimoto, Program Analyst, at 202-208-3585, or via email at james.tsujimoto@gsa.gov for

clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat at 202-501-4755. Please cite GSAR case 2014-G504.

SUPPLEMENTARY INFORMATION:

I. Background

GSA published a proposed rule with a request for public comments in the **Federal Register** at 80 FR 6037 on February 4, 2015, to amend the GSAR to delete GSAR clause 552.211-93, Unique Item Identification (UID), and provide other conforming changes. No public comments were received on the proposed rule.

II. Discussion and Analysis

There were no comments received in response to the proposed rule by its closing date of April 6, 2015. Therefore, there are no changes made in the proposed rule.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under Section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

The General Services Administration certifies that this final rule will not have

a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, because the deletion of the clause will not substantively change the reporting, recordkeeping, or compliance requirements for contractors.

V. Paperwork Reduction Act

The final rule does not contain any information collection requirements that require the approval of the Office of Management and Budget under the Paperwork Reduction Act (44 U.S.C. chapter 35).

List of Subjects in 48 CFR Parts 511 and 552

Government procurement.

Dated: May 13, 2015.

Jeffrey A. Koses,

Senior Procurement Executive, Office of Acquisition Policy, Office of Government-wide Policy.

Therefore, GSA amends 48 CFR parts 511 and 552 as set forth below:

■ 1. The authority citation for 48 CFR parts 511 and 552 continues to read as follows:

Authority: 40 U.S.C. 121(c).

PART 511—DESCRIBING AGENCY NEEDS

511.204 [Amended]

■ 2. Amend section 511.204 by removing paragraph (b)(12).

PART 552—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

552.211-93 [Removed and Reserved]

■ 3. Remove and reserve section 552.211-93.

[FR Doc. 2015-12208 Filed 5-19-15; 8:45 am]

BILLING CODE 6820-61-P

Proposed Rules

Federal Register

Vol. 80, No. 97

Wednesday, May 20, 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.

DEPARTMENT OF ENERGY

10 CFR Parts 429, 430, and 431

[Docket Number EERE-2015-BT-TP-0007]

RIN 1904-AC91

Energy Conservation Program for Consumer Products and Certain Commercial and Industrial Equipment: Test Procedures for Consumer and Commercial Water Heaters

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Reopening of the public comment period and announcement of public meeting.

SUMMARY: On April 14, 2015, the U.S. Department of Energy (DOE) published in the **Federal Register** a notice of proposed rulemaking (NOPR) that proposes mathematical conversion factors for converting from the current efficiency metrics (*i.e.*, energy factor for residential water heaters, and thermal efficiency and standby loss for commercial water heaters) to the uniform efficiency descriptor (*i.e.*, uniform energy factor metric). The comment period for the NOPR pertaining to the test procedures for water heaters was scheduled to end May 14, 2015. After receiving a request for additional time to comment for stakeholders, DOE is reopening the comment period for the NOPR for the Conversion Factor for Test Procedures for Consumer and Certain Commercial Water Heaters to June 15, 2015. Additionally, at the request of stakeholders, DOE is announcing a public meeting to discuss the conversion factors for consumer and commercial water heaters.

DATES: *Comments:* The comment period for the NOPR for the Conversion Factor for Test Procedures for Consumer and Certain Commercial Water Heaters published on April 14, 2015 (80 FR 20116), is reopened. DOE will accept comments, data, and information regarding this NOPR before and after the

public meeting, but no later than June 15, 2015.

Meeting: DOE will hold a public meeting on Thursday, May 28, 2015 from 10:00 a.m. to 4:00 p.m., in Washington, DC. The meeting will also be broadcast as a webinar.

ADDRESSES: *Meeting:* The meeting will be held at the U.S. Department of Energy, 950 L'Enfant Plaza, Room 7140, 950 L'Enfant Plaza, Washington, DC 20585. If you plan to attend the public meeting, please notify Ms. Brenda Edwards at (202) 586-2945 or *Brenda.Edwards@ee.doe.gov*. For further details, see the "Public Participation" section near the end of this document.

Comments: All comments submitted must identify the NOPR for the Conversion Factor for Test Procedures for Consumer and Certain Commercial Water Heaters, and provide docket number EERE-2015-BT-TP-0007 and/or RIN 1904-AC91. Interested persons are encouraged to submit comments using the Federal eRulemaking Portal at *www.regulations.gov*. Follow the instructions for submitting comments. Alternatively, interested persons may submit comments by any of the following methods:

- *Email: ConsumerCommWaterHtrs 2015TP0007@ee.doe.gov.* Include the docket number and/or RIN in the subject line of the message. Submit electronic comments in WordPerfect, Microsoft Word, PDF, or ASCII file format, and avoid the use of special characters or any form of encryption.

- *Postal Mail:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Office, Mailstop EE-5B, 1000 Independence Avenue SW., Washington, DC 20585-0121. If possible, please submit all items on a compact disc (CD), in which case it is not necessary to include printed copies.

- *Hand Delivery/Courier:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza SW., 6th Floor, Washington, DC 20024. Telephone: (202) 586-2945. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimilies (faxes) will be accepted. For detailed instructions on submitting comments and additional information on the rulemaking process, see section V (Public Participation) of the April 14, 2015 NOPR for the

Conversion Factor for Test Procedures for Consumer and Certain Commercial Water Heaters. 80 FR 20116.

Docket: The docket is available for review at *www.regulations.gov*, including **Federal Register** notices, comments, and other supporting documents/materials. All documents in the docket are listed in the *www.regulations.gov* index. However, not all documents listed in the index may be publicly available, such as information that is exempt from public disclosure.

A link to the docket Web page can be found at: *http://www.regulations.gov/#!docketDetail;D=EERE-2015-BT-TP-0007*. This Web page contains a link to the docket for this notice of proposed rulemaking on the *www.regulations.gov* site. The *www.regulations.gov* Web page contains simple instructions on how to access all documents, including public comments, in the docket. See section V, "Public Participation," of the April 14, 2015 NOPR for information on how to submit comments through *www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Ms. Ashley Armstrong, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE-5B, 1000 Independence Avenue SW., Washington, DC 20585-0121. Telephone: (202) 586-6590. Email: *Ashley.Armstrong@ee.doe.gov*.

Mr. Eric Stas, U.S. Department of Energy, Office of the General Counsel, GC-33, 1000 Independence Avenue SW., Washington, DC 20585-0121. Telephone: (202) 586-9507. Email: *Eric.Stas@hq.doe.gov*.

For information on how to submit a comment, to review other public comments and the docket, or to attend the public meeting, contact Ms. Brenda Edwards at (202) 586-2945 or by email: *Brenda.Edwards@ee.doe.gov*.

SUPPLEMENTARY INFORMATION: The Energy Policy and Conservation Act of 1975 (EPCA), as amended by the American Energy Manufacturing Technical Corrections Act (AEMTCA), Public Law 112-210, requires that DOE establish a uniform efficiency descriptor and accompanying test methods for covered residential water heaters and commercial water heating equipment within one year of the enactment of AEMTCA. (42 U.S.C. 6295(e)(5)(B)) Further, beginning one year after the

date of publication of DOE's final rule establishing the uniform descriptor, EPCA requires that the efficiency standards for covered water heaters to be denominated according to the uniform efficiency descriptor established in the final rule (42 U.S.C. 6295(e)(5)(D)) and that DOE develop a mathematical conversion factor for converting the measurement of efficiency for covered water heaters from the test procedures and metrics currently in effect to the new uniform energy descriptor. (42 U.S.C. 6295(e)(5)(E)(i)–(ii)). On July 11, 2014, DOE published a final rule amending the test procedure for residential and certain commercial water heaters that satisfied the AEMTCA requirements to develop a uniform efficiency descriptor to replace the existing energy factor, thermal efficiency, and standby loss metrics. 79 FR 40542. Use of the amended test procedure is required beginning on July 13, 2015, for new testing. All representations must be based on the amended test procedure as of one year after the publication of a final rule that establishes a mathematical conversion factor. On April 14, 2015, DOE published a NOPR proposing mathematical conversion factors for converting from the current efficiency metrics (*i.e.*, energy factor for residential water heaters, and thermal efficiency and standby loss for commercial water heaters) to the uniform efficiency descriptor (*i.e.*, uniform energy factor metric). 80 FR 20116 (April 14, 2015).

In response to the NOPR for the Conversion Factor for Test Procedures for Consumer and Certain Commercial Water Heaters, the Air-Conditioning, Heating, and Refrigeration Institute (AHRI) requested a 60-day extension to the comment period, a public meeting, and a delay in compliance date for the test procedure. AHRI stated in its request that it needed additional time to analyze the specific conversion factors and underlying analysis, review the water heater tests conducted by DOE to assess to what extent those tests reflected the range of models covered by the test procedure, and evaluate the validity of the conclusions derived from the testing conducted by DOE as provided in the conversion factors and translated energy conservation standards. After careful consideration of this request, DOE has determined that extending the public comment period by reopening to allow additional time for interested parties to submit comments and that convening a public meeting are appropriate based on the foregoing reasons. Accordingly, DOE is

granting approximately 30-day comment period extension and announcing a public meeting. In this document, DOE is reopening the comment period for the NOPR for the Conversion Factor for Test Procedures for Consumer and Certain Commercial Water Heaters to midnight of June 15, 2015 and will deem any comments received by that time to be timely submitted. Also, DOE will host a public meeting on Thursday, May 28, 2015. Additional details on the public meeting are provided in the **DATES** and **ADDRESSES** sections of this document.

DOE is not extending the compliance dates, which were set by statute based on the completion of various rulemakings. The test method will have been final for a year, and manufacturers should be able to test any new basic models using that test method. Furthermore, because the energy conservation standards for residential water heaters changed earlier this year, DOE expects that very few, new basic models will be introduced in the interim between July 13, 2015, and when the conversion factor final rule is effective.

Public Participation

All participants will undergo security processing upon building entry. Any participant with a laptop computer or similar device (*e.g.*, tablets), must undergo additional screening. Note that any foreign national who requests to participate in the public meeting is subject to advance security screening prior to the date of the public meeting, and such persons should contact Ms. Brenda Edwards as soon as possible at (202) 586–2945 to commence the necessary procedures.

Due to the REAL ID Act implemented by the Department of Homeland Security (DHS), there have been recent changes regarding identification (ID) requirements for individuals wishing to enter Federal buildings from specific States and U.S. territories. As a result, driver's licenses from the following States or territory will not be accepted for building entry, and instead, one of the alternate forms of ID listed below will be required.

DHS has determined that regular driver's licenses (and ID cards) from the following jurisdictions are not acceptable for entry into DOE facilities: Alaska, American Samoa, Arizona, Louisiana, Maine, Massachusetts, Minnesota, New York, Oklahoma, and Washington.

Acceptable alternate forms of Photo-ID include: U.S. Passport or Passport Card; an Enhanced Driver's License or Enhanced ID-Card issued by the States of Minnesota, New York or Washington

(Enhanced licenses issued by these States are clearly marked Enhanced or Enhanced Driver's License); a military ID or other Federal government-issued Photo-ID card.

In addition, you can attend the public meeting via webinar. Webinar registration information, participant instructions, and information about the capabilities available to webinar participants at: <https://attendee.gotowebinar.com/register/7036563622426238210> Participants are responsible for ensuring their systems are compatible with the webinar software.

Issued in Washington, DC, on May 12, 2015.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

[FR Doc. 2015–12221 Filed 5–19–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

10 CFR Part 430

[Docket Number EERE–2014–BT–STD–0031]

RIN 1904–AD20

Energy Conservation Program for Consumer Products: Energy Conservation Standards for Residential Furnaces

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Extension of public comment period.

SUMMARY: On March 12, 2015, the U.S. Department of Energy (DOE) published in the **Federal Register** a notice of proposed rulemaking (NOPR) and technical support document (TSD) that analyze the potential economic impacts and energy savings that could result from potential energy conservation standards for certain residential furnaces. DOE published this NOPR and analysis so stakeholders can review and provide input on the relevant outputs and the underlying assumptions and calculations. The comment period for the NOPR pertaining to the subject residential furnaces was scheduled to end June 10, 2015. After receiving requests for additional time to comment, DOE has decided to extend the comment period for the NOPR pertaining to the energy conservation standards for residential furnaces until July 10, 2015.

DATES: DOE will accept comments, data, and information regarding the notice of proposed rulemaking no later than July 10, 2015.

ADDRESSES: Instructions: All comments submitted must identify the NOPR for Energy Conservation Standards for Residential Furnaces, and provide docket number EERE-2014-BT-STD-0031 and/or regulatory information number (RIN) number 1904-AD20. Comments may be submitted using any of the following methods:

1. *Federal eRulemaking Portal:* www.regulations.gov. Follow the instructions for submitting comments.
2. *Email:* ResFurnaces2014STD0031@ee.doe.gov. Include the docket number and/or RIN in the subject line of the message. Submit electronic comments in Word Perfect, Microsoft Word, PDF, or ASCII file format, and avoid the use of special characters or any form on encryption.

3. *Postal Mail:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Office, Mailstop EE-5B, 1000 Independence Avenue SW., Washington, DC 20585-0121. If possible, please submit all items on a compact disc (CD), in which case it is not necessary to include printed copies.

4. *Hand Delivery/Courier:* Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza SW., Suite 600, Washington, DC 20024. Telephone: (202) 586-2945. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimilies (faxes) will be accepted. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Public Participation" section of the March 12, 2015 NOPR. 80 FR 13120.

Docket: The docket, which includes **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials, is available for review at www.regulations.gov. All documents in the docket are listed in the www.regulations.gov index. However, not all documents listed in the index may be publically available, such as those containing information that is exempt from public disclosure.

A link to the docket Web page can be found at: <http://www.regulations.gov/#/docketDetail;D=EERE-2014-BT-STD-0031>. This Web page contains a link to the docket for this notice on the www.regulations.gov site. The www.regulations.gov Web page contains simple instructions on how to access all documents, including public comments,

in the docket. See section VII, "Public Participation," of the March 12, 2015 NOPR for further information on how to submit comments through www.regulations.gov.

For further information on how to submit a comment or review other public comments and the docket, contact Ms. Brenda Edwards at (202) 586-2945 or by email: Brenda.Edwards@ee.doe.gov.

FOR FURTHER INFORMATION CONTACT: Mr. John Cymbalsky, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE-5B, 1000 Independence Avenue SW., Washington, DC 20585-0121. Telephone: (202) 287-1692. Email: residential_furnaces_and_boilers@ee.doe.gov.

Mr. Eric Stas, U.S. Department of Energy, Office of the General Counsel, GC-33, 1000 Independence Avenue SW., Washington, DC 20585-0121. Telephone: (202) 5869507. Email: Eric.Stas@hq.doe.gov.

For information on how to submit or review public comments and the docket, contact Ms. Brenda Edwards at (202) 586-2945 or by email: Brenda.Edwards@ee.doe.gov.

SUPPLEMENTARY INFORMATION: DOE published a NOPR in the **Federal Register** to make available and invite public comments on its analysis regarding potential energy conservation standards for certain residential furnaces. 80 FR 13120 (March 12, 2015). The document set a deadline for the submission of written comments by June 10, 2015. The American Gas Association (AGA) and the Southern California Gas Company (SoCalGas) each requested an extension of the public comment period, stating that additional time is necessary to review the published analysis in order to prepare and submit comments. After careful consideration of these requests, DOE has determined that extending the comment period to allow additional time for interested parties to submit comments is appropriate based on the foregoing reason. DOE believes that extending the comment period by 30 days will provide the public with sufficient time to submit comments responding to DOE's analysis. Accordingly, DOE is extending the comment period to midnight of July 10, 2015 and will deem any comments received (or postmarked) by that date to be timely submitted.

Issued in Washington, DC, on May 12, 2015.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency and Renewable Energy.

[FR Doc. 2015-12218 Filed 5-19-15; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

10 CFR Part 430

[Docket Number EERE-2012-BT-STD-0047]

RIN 1904-AC88

Energy Conservation Program for Consumer Products: Energy Conservation Standards for Residential Boilers

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Extension of public comment period.

SUMMARY: On March 31, 2015, the U.S. Department of Energy (DOE) published in the **Federal Register** a notice of proposed rulemaking (NOPR) and technical support document (TSD) that analyze the potential economic impacts and energy savings that could result from potential energy conservation standards for residential boilers. DOE published this NOPR and analysis so stakeholders can review and provide input on the relevant outputs and the underlying assumptions and calculations. The comment period for the NOPR pertaining to residential boilers was scheduled to end June 1, 2015. After receiving requests for additional time to comment, DOE has decided to extend the comment period for the NOPR pertaining to the energy conservation standards for residential boilers until July 1, 2015.

DATES: The comment period for the notice of proposed rulemaking published March 31, 2015, at 80 FR 17222, is extended. DOE will accept comments, data, and information no later than July 1, 2015.

ADDRESSES: Instructions: All comments submitted must identify the NOPR for Energy Conservation Standards for Residential Boilers, and provide docket number EE-2012-BT-STD-0047 and/or regulatory information number (RIN) number 1904-AC88. Comments may be submitted using any of the following methods:

1. *Federal eRulemaking Portal:* www.regulations.gov. Follow the instructions for submitting comments.

2. *Email:* ResBoilers2012STD0047@ee.doe.gov. Include the docket number

and/or RIN in the subject line of the message. Submit electronic comments in Word Perfect, Microsoft Word, PDF, or ASCII file format, and avoid the use of special characters or any form on encryption.

3. *Postal Mail*: Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Office, Mailstop EE-5B, 1000 Independence Avenue SW., Washington, DC 20585-0121. If possible, please submit all items on a compact disc (CD), in which case it is not necessary to include printed copies.

4. *Hand Delivery/Courier*: Ms. Brenda Edwards, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza SW., Suite 600, Washington, DC 20024. Telephone: (202) 586-2945. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

No telefacsimilies (faxes) will be accepted. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Public Participation" section of the March 31, 2015 NÖPR. 80 FR 17222.

Docket: The docket, which includes **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials, is available for review at www.regulations.gov. All documents in the docket are listed in the www.regulations.gov index. However, not all documents listed in the index may be publically available, such as those containing information that is exempt from public disclosure.

A link to the docket Web page can be found at: <http://www.regulations.gov/#!docketDetail;D=EERE-2012-BT-STD-0047>. This Web page contains a link to the docket for this notice on the www.regulations.gov site. The www.regulations.gov Web page contains simple instructions on how to access all documents, including public comments, in the docket. See section VII, "Public Participation," of the March 31, 2015 NÖPR for further information on how to submit comments through www.regulations.gov.

For further information on how to submit a comment or review other public comments and the docket, contact Ms. Brenda Edwards at (202) 586-2945 or by email: Brenda.Edwards@ee.doe.gov.

FOR FURTHER INFORMATION CONTACT: Mr. John Cymbalsky, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE-5B, 1000 Independence Avenue SW., Washington, DC 20585-0121.

Telephone: (202) 287-1692. Email: residential_furnaces_and_boilers@ee.doe.gov.

Mr. Eric Stas, U.S. Department of Energy, Office of the General Counsel, GC-33, 1000 Independence Avenue SW., Washington, DC 20585-0121. Telephone: (202)-5869507. Email: Eric.Stas@hq.doe.gov.

For information on how to submit or review public comments and the docket, contact Ms. Brenda Edwards at (202) 586-2945 or by email: Brenda.Edwards@ee.doe.gov.

SUPPLEMENTARY INFORMATION: DOE published a NÖPR in the **Federal Register** to make available and invite public comments on its analysis regarding potential energy conservation standards for residential boilers. 80 FR 17222 (March 31, 2015). The document set a deadline for the submission of written comments by June 1, 2015. The Air-Conditioning, Heating, and Refrigeration Institute (AHRI) and the Oil Heat Manufacturers Association each requested an extension of the public comment period, stating that additional time is necessary to review the published analysis in order to prepare and submit comments. After careful consideration of these requests, DOE has determined that extending the comment period to allow additional time for interested parties to submit comments is appropriate based on the foregoing reason. DOE believes that extending the comment period by 30 days will provide the public with sufficient time to submit comments responding to DOE's analysis. Accordingly, DOE is extending the comment period to midnight of July 1, 2015, and will deem any comments received (or postmarked) by that date to be timely submitted.

Issued in Washington, DC, on May 12, 2015.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency and Renewable Energy.

[FR Doc. 2015-12219 Filed 5-19-15; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 740, 742, 748, 772, 774

[Docket No. 150304218-5218-01]

RIN 0694-AG49

Wassenaar Arrangement 2013 Plenary Agreements Implementation: Intrusion and Surveillance Items

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Proposed rule, with request for comments.

SUMMARY: The Bureau of Industry and Security (BIS) proposes to implement the agreements by the Wassenaar Arrangement (WA) at the Plenary meeting in December 2013 with regard to systems, equipment or components specially designed for the generation, operation or delivery of, or communication with, intrusion software; software specially designed or modified for the development or production of such systems, equipment or components; software specially designed for the generation, operation or delivery of, or communication with, intrusion software; technology required for the development of intrusion software; Internet Protocol (IP) network communications surveillance systems or equipment and test, inspection, production equipment, specially designed components therefor, and development and production software and technology therefor. BIS proposes a license requirement for the export, reexport, or transfer (in-country) of these cybersecurity items to all destinations, except Canada. Although these cybersecurity capabilities were not previously designated for export control, many of these items have been controlled for their "information security" functionality, including encryption and cryptanalysis. This rule thus continues applicable Encryption Items (EI) registration and review requirements, while setting forth proposed license review policies and special submission requirements to address the new cybersecurity controls, including submission of a letter of explanation with regard to the technical capabilities of the cybersecurity items.

BIS also proposes to add the definition of "intrusion software" to the definition section of the EAR pursuant to the WA 2013 agreements.

DATES: Submit comments on or before July 20, 2015.

ADDRESSES: Comments on this rule may be submitted to the Federal rulemaking

portal (www.regulations.gov). The regulations.gov ID for this rule is: BIS-2015-0011. Comments may also be submitted via email to publiccomments@bis.doc.gov or on paper to Regulatory Policy Division, Bureau of Industry and Security, Room 2099B, U.S. Department of Commerce, 14th St. and Pennsylvania Ave. NW., Washington, DC 20230. Please refer to RIN 0694-AG49 in all comments and in the subject line of email comments.

FOR FURTHER INFORMATION CONTACT: Catherine Wheeler, Director, Information Technology Control Division, Phone: (202) 482-0707 or by email at Catherine.Wheeler@bis.doc.gov.

SUPPLEMENTARY INFORMATION:

Background

The Wassenaar Arrangement (WA) on Export Controls for Conventional Arms and Dual-Use Goods and Technologies is a group of 41 like-minded states committed to promoting responsibility and transparency in the global arms trade, and preventing destabilizing accumulations of arms. As a Participating State, the United States has committed to controlling for export all items on the WA control lists. The lists were first established in 1996 and have been revised annually thereafter. Proposals for changes to the WA control lists that achieve consensus are approved by Participating States at annual December Plenary meetings. Participating States are charged with implementing the agreed list changes as soon as possible after approval. Implementation of WA list changes ensures U.S. companies have a level playing field with their competitors in other WA member states.

In 2013, WA agreed to add the following to their list of dual-use goods: systems, equipment or components specially designed for the generation, operation or delivery of, or communication with, intrusion software; software specially designed or modified for the development or production of such systems, equipment or components; software specially designed for the generation, operation or delivery of, or communication with, intrusion software; technology required for the development of intrusion software; Internet Protocol (IP) network communications surveillance systems or equipment and test, inspection, production equipment, specially designed components therefor, and development and production software and technology therefor. BIS, the Departments of Defense and State, as well as other agencies have been discussing the best way to add these

items, which we have named “cybersecurity items,” to the Commerce Control List (CCL) (Supplement No. 1 to part 774 of the Export Administration Regulations) without reducing encryption controls and while balancing the national security and foreign policy. For resource planning purposes, as well as license requirements, license exceptions, license submission requirements, and internal license reviews and processing planning purposes, this rule is published as a proposed rule.

Scope of the New Entries

Systems, equipment, components and software specially designed for the generation, operation or delivery of, or communication with, intrusion software include network penetration testing products that use intrusion software to identify vulnerabilities of computers and network-capable devices. Certain penetration testing products are currently classified as encryption items due to their cryptographic and/or cryptanalytic functionality. Technology for the development of intrusion software includes proprietary research on the vulnerabilities and exploitation of computers and network-capable devices. The new entry on the CCL that would control Internet Protocol (IP) network communications surveillance systems or equipment is restricted to products that perform all of the functions listed; however, the Export Administration Regulations (EAR) also prohibits the export of equipment if the exporter intends it will be combined with other equipment to comprise a system described in the new entry.

Addition of ECCNs 4A005 and 4D004 to the Commerce Control List

This rule proposes to add Export Control Classification Number (ECCN) 4A005 (“systems,” “equipment,” or “components” therefor, “specially designed” for the generation, operation or delivery of, or communication with, “intrusion software”) and ECCN 4D004 (“software” “specially designed” for the generation, operation or delivery of, or communication with, “intrusion software”) to the CCL. These ECCNs are proposed to be controlled for national security (NS), regional stability (RS), and anti-terrorism (AT) reasons to all destinations, except Canada. No license exceptions would be available for these items, except certain provisions of License Exception GOV, e.g., exports to or on behalf of the United States Government pursuant to § 740.11(b) of the EAR. This rule also proposes adding a License Requirement Note and a Note in the Related Controls paragraph for

these ECCNs, to alert exporters to include all relevant information when submitting classification requests and licensing applications.

ECCN 4D001

This rule also proposes to amend ECCN 4D001 by adding ECCN 4A005 to Items paragraph 4D001.a in order to add control of “software” “specially designed” or modified for the “development” or “production,” of equipment controlled by 4A005; adding an RS:1 license requirement paragraph for 4D001.a (as it applies to 4A005 or 4D004), removing License Exceptions TSR and STA eligibility; and adding the same explanatory License Requirement Note and Related Controls Note that would be added to ECCNs 4A005 and 4D004.

As a technical correction, this rule proposes to remove from the “Reason for control” paragraph “NP,” and from the License Requirement section the two sentences, “NP applies, unless a license exception is available. See § 742.3(b) of the EAR for information on applicable licensing review policies.” That text does not articulate any license requirement, and no nuclear non-proliferation license requirement for software classified as 4D001 is set forth elsewhere in the EAR. BIS’s regular practice is to impose a license requirement for nuclear non-proliferation reasons on items that are specified on the “List of Nuclear-Related Dual-Use Equipment, Materials, Software, and Related Technology” by the Nuclear Suppliers Group. ECCN 4D001 software is not so specified.

ECCN 4E001

This rule also proposes to amend ECCN 4E001 by adding a new Items paragraph 4E001.c to control “technology” “required” for the “development” of “intrusion software.” ECCN 4E001.a controls ““technology” according to the General Technology Note, for the “development,” “production,” or “use” of equipment or “software” controlled by 4A (except 4A980 or 4A994) or 4D (except 4D980, 4D993 or 4D994).” Therefore, ECCN 4E001.a would control “technology” for the newly added 4A005 and 4D004, as well as 4D001.a (for 4A005 and 4D004). This rule also proposes to add an RS:1 license requirement paragraph for 4E001.a “technology” (as it applies to 4A005, 4D001.a (as it applies to 4A005 or 4D004) and 4E001.c, which would require a license to export, reexport, and transfer (in-country) to all destinations, except Canada. BIS also proposes to remove License Exception Technology and Software Under

Restriction (TSR) and Strategic Trade Authorization (STA) eligibility and add the same explanatory License Requirement Note and Related Controls Note added to ECCNs 4A005, 4D001 and 4D004. Also, a reference to § 772.1 is proposed to be added to ECCNs 4A005, 4D001 and 4E001 to point to the location of the “intrusion software” definition, as this rule may be of interest to many new exporters that would not otherwise know that double quoted terms in the EAR are defined in § 772.1.

Lastly, the same technical correction regarding the Nuclear Non-proliferation (NP) control is proposed for 4E001 as is proposed for 4D001, see explanation above.

ECCN 5A001.j: Internet Protocol (IP) Network Communications Surveillance Systems or Equipment and Test, Inspection, Production Equipment, Specially Designed Components Therefor

Network communication traffic analysis systems are becoming an increasingly sensitive issue, which is why WA agreed to add the control of these items to the WA dual-use list. These systems are using the process of intercepting and analyzing messages to produce personal, human and social information from the communications traffic. BIS proposes to add these items in paragraph 5A001.j and group them with cybersecurity items. The license requirements for these items are proposed to under NS Column 1, RS Column 1 and AT Column 1 on the Commerce Country Chart (Supplement No. 1 to part 738 of the EAR) and would require a license for export, reexport, and transfer (in-country) to all destinations, except Canada. Only certain provisions of License Exception GOV, *e.g.*, exports to or on behalf of the United States Government pursuant to § 740.11(b) of the EAR, would be available for these items.

The same addition of a License Requirement Note and Related Control Note is proposed for ECCNs 5A001, 5D001, and 5E001 as is proposed for ECCNs 4A005, 4D001, 4D004 and 4E001 (see explanation under 4A005 and 4D005 above).

§ 740.13—License Exception TSU

BIS proposes to remove cybersecurity software from the mass market provision of License Exception TSU eligibility by adding a new paragraph (d)(2)(ii). This is consistent with the existing encryption exclusion.

Cybersecurity Items That Are Designed or Modified To Use “Cryptography” or Cryptanalysis

As previously introduced and explained in the preamble, this rule proposes to add a Related Control note to ECCNs 4A005, 4D004, 4E001, 5A001, 5A002, 5D002 and 5E002 that states that cybersecurity items are classified in cybersecurity ECCNs, even if the items are designed or modified to use “cryptography” or cryptanalysis; however, all such cybersecurity items using or incorporating encryption or other “information security” functionality classified under ECCNs 5A002, 5D002, 5A992.c, 5D992.c or 5E002, must also satisfy the registration, review and reporting requirements set forth in §§ 740.17, 742.15(b) and 748.3(d) of the EAR, including submissions to the ENC Encryption Request Coordinator, Ft. Meade, MD. This note is added so that people will not be confused under which ECCN to classify their products and when a cybersecurity item is designed or modified to use “cryptography” or cryptanalysis, after the relevant Encryption Items (EI) requirements for registration and review have been separately satisfied. One effect this will have is that these cybersecurity items will not be eligible for License Exception ENC. However, BIS anticipates licensing broad authorizations to certain types of end users and destinations that will counterbalance the loss of the use of License Exception ENC.

Information To Be Submitted With a License Application To Export, Reexport, or Transfer (In-Country) Cybersecurity Items

In addition to the general information required by § 748.3(b) of the EAR and the requirement that all encryption registration and review provisions must be separately satisfied with BIS and the ENC Encryption Request Coordinator, Ft. Meade, MD, this rule proposes to add a requirement to submit specific technical information in support of applications to export, reexport, or transfer (in-country) cybersecurity items. The specified technical information is set forth in newly added paragraph (z) of Supplement No. 2 to part 748 “Unique application and submission requirements.” The Commodity Classification Application Tracking System (CCATS) number(s) or license number(s) for the cyber security item(s) must be included in the license application. If no classification or license application has been done for the cybersecurity item, then the answers

to three (3) questions are to be submitted in a letter of explanation.

Also, this rule proposes that upon request from BIS, the applicant must include a copy of the sections of source code and other software (*e.g.*, libraries and header files) that implement or invoke the controlled cybersecurity functionality.

License Review Policy for Cybersecurity Items

The license review policies for cybersecurity items controlled under NS and AT will not be revised. A new license review policy for cybersecurity items is proposed under § 742.6(b) for regional stability. Cybersecurity items controlled for RS are proposed to be reviewed favorably if destined to a U.S. company or subsidiary not located in Country Group D:1 or E:1, foreign commercial partners located in Country Group A:5, government end users in Australia, Canada, New Zealand or the United Kingdom, and on a case-by-case basis to determine whether the transaction is contrary to the national security or foreign policy interests of the United States, including the foreign policy interest of promoting the observance of human rights throughout the world. Note that there is a policy of presumptive denial for items that have or support rootkit or zero-day exploit capabilities. The governments of Australia, Canada, New Zealand or the United Kingdom have partnered with the United States on cybersecurity policy and issues, which affords these countries with favorable treatment for license applications. A note that describes “foreign commercial partner” is proposed to be added to § 742.6(b). Any “information security” functionality incorporated in the cybersecurity item will also receive a focused case-by-case review for reasons of Encryption Items (EI) control.

§ 772.1 Definitions of Terms as Used in the EAR: Addition of Definition for “Intrusion Software”

The WA-agreed definition for “intrusion software” is proposed to be added to § 772.1 of the EAR. The definition also includes a Note that describes some items not included as “intrusion software,” *e.g.*, hypervisors, debuggers or Software Reverse Engineering (SRE).

Request for Comments

BIS is seeking information about the effect of this rule and would appreciate the submission of comments, and especially answers to the following questions:

1. How many additional license applications would your company be required to submit per year under the requirements of this proposed rule? If any, of those applications:

a. How many additional applications would be for products that are currently eligible for license exceptions?

b. How many additional applications would be for products that currently are classified EAR99?

2. How many deemed export, reexport or transfer (in-country) license applications would your company be required to submit per year under the requirements of this rule?

3. Would the rule have negative effects on your legitimate vulnerability research, audits, testing or screening and your company's ability to protect your own or your client's networks? If so, explain how.

4. How long would it take you to answer the questions in proposed paragraph (z) to Supplement No. 2 to part 748? Is this information you already have for your products?

* The **ADDRESSES** section of this proposed rule includes information about how to submit comments.

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 designated a "significant regulatory action," under Executive Order 12866.

2. Notwithstanding any other provision of 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 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 rule would involve one collection of information subject to the PRA. One of the collections has been approved by OMB under control number 0694-0088, "Multi-Purpose Application," and carries a burden hour estimate of 58 minutes for a manual or electronic submission. The additional information proposed to be required under

Supplement No. 2 to part 748 paragraph (z) falls under the usual technical information that is submitted with applications to describe the abilities of the items on the license application. This information allows the licensing officer to verify the classification of the product and determine the effect it would have on U.S. national security and foreign policy. Send comments regarding these burden estimates or any other aspect of these collections of information, including suggestions for reducing the burden, to OMB Desk Officer, New Executive Office Building, Washington, DC 20503; and to Jasmeet Seehra, OMB Desk Officer, by email at Jasmeet_K_Seehra@omb.eop.gov or by fax to (202) 395-7285; and to the Office of Administration, Bureau of Industry and Security, Department of Commerce, 1401 Constitution Ave. NW., Room 6622, Washington, DC 20230.

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

4. The provisions of the Administrative Procedure Act (APA) (5 U.S.C. 553) requiring notice of proposed rulemaking, the opportunity for public participation, and a 30-day delay in effective date, are inapplicable because this regulation involves a military and foreign affairs function of the United States (5 U.S.C. 553(a)(1)). Nonetheless, BIS is providing the public with an opportunity to review and comment on this rule, despite its being exempted from that requirement of the APA. Because this rule is not required by the APA to undergo a period of notice and comment, the requirements of the Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.*, do not apply. Accordingly, no regulatory flexibility analysis is required, and none has been prepared.

BIS is interested in the potential impacts to businesses of this rule. Because most of the items impacted by this rule have encryption capabilities, BIS believes they are already being controlled under Category 5 part 2 of the EAR. Even though most encryption items are eligible for License Exception ENC and these cybersecurity items will not be eligible for License Exception ENC, BIS anticipates issuing broad licenses for these items. The impact of this rule is unknown to BIS, therefore the implementation of the Wassenaar Arrangement agreement of 2013 with regard to cybersecurity items is issued as a proposed rule with request for comments concerning the impact of the rule. Comments should be submitted to Sharron Cook, Office of Exporter Services, Bureau of Industry and Security, Department of Commerce,

14th and Pennsylvania Ave. NW., Room 2099, Washington, DC 20230 or emailed to publiccomments@bis.doc.gov. Please refer to RIN 0694-AG49 in all comments and in the subject line of email comments.

List of Subjects

15 CFR Part 740

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

15 CFR Part 742

Exports, Terrorism.

15 CFR Part 748

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

15 CFR Part 772

Exports.

15 CFR Part 774

Exports, Reporting and recordkeeping requirements.

Accordingly, parts 740, 742, 748, 772, and 774 of the Export Administration Regulations (15 CFR parts 730 through 774) are proposed to be amended as follows:

PART 740 [AMENDED]

■ 1. The authority citation for part 740 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. 7201 *et seq.*; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 7, 2014, 79 FR 46959 (August 11, 2014).

■ 2. Section 740.2 is amended by adding paragraph (a)(19) to read as follows:

§ 740.2 Restrictions on all License Exceptions.

(a) * * *

(19) The item is a cybersecurity item, *i.e.*, those controlled by ECCNs 4A005, 4D001.a ("specially designed" or modified for 4A005 or 4D004 items), 4D004, 4E001.a ("required" for 4A005, 4D001.a ("specially designed" or modified for 4A005 or 4D004) or 4D004 items), 4E001.c, 5A001.j, 5B001.a ("specially designed" for 5A001.j items), 5D001.a ("specially designed" for 5A001.j items), 5D001.c ("specially designed" for 5A001.j or 5B001.a items) or 5E001.a ("required" for 5A001.j, 5B001.a, 5D001.a (for 5A001.j items) or 5D001.c ("specially designed" for 5A001.j or 5B001.a items) and the export, reexport or transfer (in-country) is not authorized by § 740.11(b)(2)(ii) (made by or consigned to a department or agency of the U.S. government), or

§ 740.11(b)(2)(iii) (made for or on behalf of a department or agency of the U.S. Government).

* * * * *

■ 3. Section 740.11 is amended by:

- a. Adding paragraph (a)(2)(vi);
- b. Removing the “or” from the end of paragraph (c)(3)(vi);
- c. Removing the period from paragraph (c)(3)(vii) and adding a semicolon in its place; and
- d. Adding paragraph (c)(3)(viii).

The revisions and addition read as follows:

§ 740.11 Governments, international organizations, international inspections under the Chemical Weapons Convention, and the International Space Station (GOV).

(a) * * *

(2) * * *

(vi) Cybersecurity items, *i.e.*, those controlled by ECCNs 4A005, 4D001.a (“specially designed” or modified for 4A005 or 4D004 items), 4D004, 4E001.a (“required” for 4A005, 4D001.a (“specially designed” or modified for 4A005 or 4D004) or 4D004 items), 4E001.c, 5A001.j, 5B001.a (“specially designed” for 5A001.j items), 5D001.a (“specially designed” or modified for 5A001.j items), 5D001.c (“specially designed” or modified for 5A001.j or 5B001.a items) or 5E001.a (“required” for 5A001.j, 5B001.a, 5D001.a (“specially designed” or modified for 5A001.j items) or 5D001.c (“specially designed” or modified for 5A001.j or 5B001.a items).

* * * * *

(c) * * *

(3) * * *

(viii) Cybersecurity items, *i.e.*, those controlled by ECCNs 4A005, 4D001.a (“specially designed” or modified for 4A005 or 4D004 items), 4D004, 4E001.a (“required” for 4A005, 4D001.a (“specially designed” or modified for 4A005 or 4D004) or 4D004 items), 4E001.c, 5A001.j, 5B001.a (“specially designed” for 5A001.j items), 5D001.a (“specially designed” or modified for 5A001.j items), 5D001.c (“specially designed” or modified for 5A001.j or 5B001.a items) or 5E001.a (“required” for 5A001.j, 5B001.a, 5D001.a (“specially designed” or modified for 5A001.j items) or 5D001.c (“specially designed” or modified for 5A001.j or 5B001.a items).

* * * * *

■ 4. Section 740.13 is amended by revising the section heading and paragraph (d)(2) to read as follows:

§ 740.13 Technology and Software—Unrestricted (TSU).

* * * * *

(d) * * *

(2) *Exclusions*—(i) *Encryption software*. The provisions of this paragraph (d) are not available for encryption software controlled for “EI” reasons under ECCN 5D002 or for encryption software with symmetric key length exceeding 64-bits that qualifies as mass market encryption software under the criteria in the Cryptography Note (Note 3) of Category 5, Part 2, of the Commerce Control List (Supplement No. 1 to part 774 of the EAR). (Once such mass market encryption software has been reviewed by BIS and released from “EI” and “NS” controls pursuant to § 742.15(b) of the EAR, it is controlled under ECCN 5D992.c and is thus outside the scope of License Exception TSU.) See § 742.15(b) of the EAR for exports and reexports of mass market encryption products controlled under ECCN 5D992.c.

(ii) *Cybersecurity software*. The provisions of this paragraph (d) are not available for cybersecurity “software” that is classified under ECCNs 4D001.a (“specially designed” or modified for 4A005 or 4D004 items), 4D004, or for “software” under ECCN 5D001.a or .c (“specially designed” for “production,” “development” or “use” of 5A001.j equipment or systems, or providing the characteristics, functions or features of 5A001.j or 5B001.a equipment or systems).

* * * * *

■ 5. Section 740.17 is amended by revising paragraph (b)(3)(iii) introductory text to read as follows:

§ 740.17 Encryption commodities, software and technology (ENC).

* * * * *

(b) * * *

(3) * * *

(iii) Encryption commodities and software not described by paragraph (b)(2) of this section, and not further controlled for NS and RS reasons under ECCNs 5A001.j, 5B001.a (“specially designed” for 5A001.j), 5D001.a (“specially designed” or modified for 5A001.j) or 5D001.c (“specially designed” or modified for 5A001.j or 5B001.a), that provide or perform vulnerability analysis, network forensics, or computer forensics functions characterized by any of the following:

* * * * *

■ 6. Section 740.20 is amended by adding paragraph (b)(2)(ix) to read as follows:

§ 740.20 License Exception Strategic Trade Authorization (STA).

* * * * *

(b) * * *

(2) * * *

(ix) License Exception STA may not be used for any cybersecurity items, *i.e.*, those controlled by ECCNs 4A005, 4D001.a (“specially designed” or modified for 4A005 or 4D004 items), 4D004, 4E001.a (“required” for 4A005, 4D001.a (“specially designed” or modified for 4A005 or 4D004 items) or 4D004 items), 4E001.c, 5A001.j, 5B001.a (“specially designed” for 5A001.j items), 5D001.a (“specially designed” or modified for 5A001.j items), 5D001.c (“specially designed” or modified for 5A001.j or 5B001.a items) or 5E001.a (“required” for 5A001.j, 5B001.a, 5D001.a (“specially designed” or modified for 5A001.j items) or 5D001.c (“specially designed” or modified for 5A001.j or 5B001.a items) items).

* * * * *

PART 742 [AMENDED]

■ 7. The authority citation for part 742 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; Sec. 1503, Pub. L. 108–11, 117 Stat. 559; 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. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Presidential Determination 2003–23 of May 7, 2003, 68 FR 26459, May 16, 2003; Notice of August 7, 2014, 79 FR 46959 (August 11, 2014); Notice of November 7, 2014, 79 FR 67035 (November 12, 2014).

■ 8. Section 742.6 is amended by adding paragraph (b)(5) to read as follows:

§ 742.6 Regional stability.

* * * * *

(b) * * *

(5) *Licensing policy for cybersecurity items*. Applications for exports, reexports and transfers of cybersecurity items, *i.e.*, those controlled by ECCNs 4A005, 4D001.a (“specially designed” or modified for 4A005 or 4D004 items), 4D004, 4E001.a (“required” for 4A005, 4D001.a (“specially designed” or modified for 4A005 or 4D004 items) or 4D004 items), 4E001.c, 5A001.j, 5B001.a (“specially designed” for 5A001.j items), 5D001.a (“specially designed” or modified for 5A001.j items), 5D001.c (“specially designed” or modified for 5A001.j or 5B001.a items) or 5E001.a (“required” for 5A001.j, 5B001.a, 5D001.a (“specially designed” or modified for 5A001.j items) or 5D001.c (“specially designed” or modified for 5A001.j or 5B001.a items) items), controlled for RS will be reviewed favorably if destined to a U.S. company or subsidiary not located in Country Group D:1 or E:1, “foreign commercial

partners' located in Country Group A:5, Government end users in Australia, Canada, New Zealand or United Kingdom and on a case-by-case basis to determine whether the transaction is contrary to the national security or foreign policy interests of the United States, including the foreign policy interest of promoting the observance of human rights throughout the world, except that there is a policy of presumptive denial for items that have or support rootkit or zero-day exploit capabilities. Any "information security" functionality incorporated in the cybersecurity item will also receive a focused case-by-case review for reasons of Encryption Items (EI) control.

Note to paragraph (b)(5): A 'foreign commercial partner' means a foreign-based non-governmental end-user that has a business need to share the proprietary information of the U.S. company and is contractually bound to the U.S. company (e.g., has an established pattern of continuing or recurring contractual relations). In addition to the information required in § 748.3(c)(1), (c)(2) and paragraph (z) of Supplement No. 2 to part 748 of the EAR, you must explain in a letter of explanation how the end user meets the criteria of a 'foreign commercial partner' and how the end user will safeguard the items from unauthorized transfers (in-country) and reexports.

* * * * *

PART 748—[AMENDED]

■ 9. The authority citation for part 748 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 7, 2014, 79 FR 46959 (August 11, 2014).

■ 10. Section 748.8 is amended by adding paragraph (z) to read as follows:

§ 748.8 Unique application and submission requirements.

* * * * *

(z) Cybersecurity Items.

■ 11. Supplement No. 2 is amended by adding paragraph (z) to read as follows:

Supplement No. 2 to Part 748—Unique Application and Submission Requirements

* * * * *

(z) *Cybersecurity items.* For license applications to export, reexport, transfer (in-country) cybersecurity items, *i.e.*, ECCNs 4A005, 4D001.a ("specially designed" or modified for 4A005 or 4D004 items), 4D004, 4E001.a ("required" for 4A005, 4D001.a ("specially designed" or modified for 4A005 or 4D004) or 4D004 items), 4E001.c, 5A001.j,

5B001.a ("specially designed" for 5A001.j items), 5D001.a ("specially designed" or modified for 5A001.j items), 5D001.c ("specially designed" or modified for 5A001.j or 5B001.a items) or 5E001.a ("required" for 5A001.j, 5B001.a, 5D001.a ("specially designed" or modified for 5A001.j items) or 5D001.c ("specially designed" or modified for 5A001.j or 5B001.a items) items) you must follow the unique application requirements set forth in this paragraph (z). If the cybersecurity item has encryption or other "information security" functionality classified under ECCNs 5A002, 5D002, 5A992.c, 5D992.c or 5E002, all encryption registration and review requirements must be separately completed with BIS and the ENC Encryption Request Coordinator, Ft. Meade, MD, before license applications for a cybersecurity item will be considered, see §§ 740.17 and 742.15 of the EAR.

(1) In block 9 of the application (Special Purpose) indicate the phrase "Cybersecurity Item." In addition to the information required by § 748.3(b) of the EAR, submit the following information in a letter of explanation:

(i) Whether the cybersecurity item has encryption or other "information security" functionality, Encryption Registration Number (ERN) and encryption Commodity Classification Application Tracking System (CCATS) number(s);

(ii) Whether the cybersecurity item has been previously classified or included in a license application submitted on or after May 20, 2015 for which all requirements of this section (including the questions set forth in paragraph (z)(1)(iii) of this section) have been satisfied. If so, then provide the Commodity Classification Automated Tracking System (CCATS) number(s) or issued license number(s).

(iii) If the cybersecurity item has not been previously classified or included in a license application, then:

(A) Describe the cybersecurity functions and user interfaces (e.g., Application Programming Interfaces (APIs), Command Line Interfaces (CLIs) or Graphical User Interfaces (GUIs) that are implemented and/or supported. Explain which are for internal use private to the developer of the product, and/or which are for use by the customer or other operator.

(B) Describe the cybersecurity functionality (including as related to "intrusion software") that is provided by third-party frameworks, platforms, tools, modules or components (if any). Identify the manufacturers of the cybersecurity items, including specific part numbers and version information as needed to describe the item. As applicable, describe whether the third-party cybersecurity software is statically or dynamically linked.

(C) For items related to "intrusion software," describe how rootkit or zero-day exploit functionality is precluded from the item. Otherwise, for items that incorporate or otherwise support rootkit or zero-day exploit functionality, this must be explicitly stated in the application.

(2) Upon request, include a copy of the sections of source code and other software (e.g., libraries and header files) that implement or invoke the controlled cybersecurity functionality.

PART 772 [AMENDED]

■ 12. The authority citation for part 772 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 7, 2014, 79 FR 46959 (August 11, 2014).

■ 13. Section 772.1 is amended by adding the term "Intrusion software" in alphabetic order to read as follows:

§ 772.1 Definitions of terms as used in the Export Administration Regulations (EAR).

* * * * *

Intrusion software. (Cat 4) "Software" "specially designed" or modified to avoid detection by 'monitoring tools,' or to defeat 'protective countermeasures,' of a computer or network-capable device, and performing any of the following:

- (a) The extraction of data or information, from a computer or network-capable device, or the modification of system or user data; or
- (b) The modification of the standard execution path of a program or process in order to allow the execution of externally provided instructions.

Notes: 1. "Intrusion software" does not include any of the following:

- a. *Hypervisors, debuggers or Software Reverse Engineering (SRE) tools;*
- b. *Digital Rights Management (DRM) "software";* or
- c. *"Software" designed to be installed by manufacturers, administrators or users, for the purposes of asset tracking or recovery.*

2. *Network-capable devices include mobile devices and smart meters.*

Technical Notes: 1. 'Monitoring tools': "software" or hardware devices, that monitor system behaviors or processes running on a device. This includes antivirus (AV) products, end point security products, Personal Security Products (PSP), Intrusion Detection Systems (IDS), Intrusion Prevention Systems (IPS) or firewalls.

2. 'Protective countermeasures': techniques designed to ensure the safe execution of code, such as Data Execution Prevention (DEP), Address Space Layout Randomization (ASLR) or sandboxing.

* * * * *

PART 774 [AMENDED]

■ 14. The authority citation for part 774 continues to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.*; 50 U.S.C. 1701 *et seq.*; 10 U.S.C. 7420; 10 U.S.C. 7430(e); 22 U.S.C. 287c, 22 U.S.C. 3201 *et seq.*; 22 U.S.C. 6004; 30 U.S.C. 185(s), 185(u); 42 U.S.C. 2139a; 42 U.S.C. 6212; 43 U.S.C. 1354; 15 U.S.C. 1824a; 50 U.S.C. app. 5; 22

U.S.C. 7201 *et seq.*; 22 U.S.C. 7210; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 7, 2014, 79 FR 46959 (August 11, 2014).

**Supplement No. 1 to Part 774—
[Amended]**

■ 15. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 4 is amended by adding ECCN 4A005 after ECCN 4A004 to read as follows:

**Supplement No. 1 to Part 774—The
Commerce Control List**

* * * * *

4A005 “Systems,” “equipment,” or “components” therefor, “specially designed” or modified for the generation, operation or delivery of, or communication with, “intrusion software”.

License Requirements

Reason for Control: NS, RS, AT

<i>Control(s)</i>	<i>Country chart (see supp. No. 1 to part 738)</i>
NS applies to entire entry.	NS Column 1
RS applies to the entire entry.	RS Column 1
AT applies to entire entry.	AT Column 1

License Requirement Note: *All license applications for 4A005 must include the information required in Supplement No. 2 to part 748 of the EAR, paragraph (z). Also, all such cybersecurity items using or incorporating encryption or other “information security” functionality classified under ECCNs 5A002, 5D002, 5A992.c, 5D992.c or 5E002, must also satisfy the registration, review and reporting requirements set forth in §§ 740.17, 742.15(b) and 748.3(d) of the EAR, including submissions to the ENC Encryption Request Coordinator, Ft. Meade, MD prior to applying for a license.*

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A
GBS: N/A
CIV: N/A

Special Conditions for STA

STA: License Exception STA may not be used to export, reexport, or transfer (in-country) commodities controlled by ECCN 4A005 to any destination.

List of Items Controlled

Related Controls: (1) “Systems”, “equipment” and “components” described under ECCN 4A005 are classified under this ECCN, even if the “systems”, “equipment” or “components” are designed or modified to use “cryptography” or cryptanalysis. (2) See Categories XI(b) and XIII in the International Traffic in Arms Regulations (ITAR) (22 CFR parts 120 through 130) and

the U.S. Munitions List (22 CFR part 121). (3) See also ECCN 4D001.a (“development” and “production” “software”), 4D004 and 4E001.a and .c.
Related Definitions: See § 772.1 of this EAR for the definition of “intrusion software.”
Items: The list of items controlled is contained in the ECCN heading.

■ 16. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 4, ECCN 4D001 is amended by:

- a. Revising the Reason for Control paragraph in the License Requirements section;
 - b. Adding an entry for “RS” after the entry for “NS” in the table in the License Requirements section;
 - c. Removing the NP note after the table in the License Requirements section and adding in its place a License Requirement Note;
 - d. Revising the TSR paragraph in the List Based License Exceptions section;
 - e. Revising the Special Conditions for STA section;
 - f. Revising the Related Controls paragraph in the List of Items Controlled section;
 - g. Revising Items paragraph a.
- The revisions and addition read as follows:

**4D001 “Software” as follows (see List of
Items Controlled).**

License Requirements

Reason for Control: NS, RS, CC, AT

<i>Control(s)</i>	<i>Country chart (see supp. No. 1 to part 738)</i>
RS applies to 4D001.a (if “specially designed” or modified for 4A005 or 4D004).	RS Column 1

License Requirement Note: *All license applications for 4D001.a (if “specially designed” or modified for 4A005 or 4D004) must include the information required in Supplement No. 2 to part 748 of the EAR, paragraph (z). Also, all such cybersecurity items using or incorporating encryption or other “information security” functionality classified under ECCNs 5A002, 5D002, 5A992.c, 5D992.c or 5E002, must also satisfy the registration, review and reporting requirements set forth in §§ 740.17, 742.15(b) and 748.3(d) of the EAR, including submissions to the ENC Encryption Request Coordinator, Ft. Meade, MD prior to applying for a license.*

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

TSR: Yes, except for: (1) “software” “specially designed” or modified for the

“development” or “production” of commodities with an “Adjusted Peak Performance” (“APP”) exceeding 1.0 WT; or (2) “software” if “specially designed” or modified for the “development” or “production” of commodities or “software” specified by ECCNs 4A005 or 4D004.

* * * * *

Special Conditions for STA

STA: License Exception STA may not be used to: (1) Ship or transmit “software” “specially designed” or modified for the “development” or “production” of equipment specified by ECCN 4A001.a.2 or for the “development” or “production” of “digital computers” having an ‘Adjusted Peak Performance’ (“APP”) exceeding 1.0 Weighted TeraFLOPS (WT) to any of the destinations listed in Country Group A:6 (See Supplement No.1 to part 740 of the EAR); or (2) ship or transmit “software” “specially designed” or modified for the “production” or “development” of commodities or “software” specified by ECCNs 4A005 or 4D004, to any destination.

List of Items Controlled

Related Controls: (1) “Software” described under ECCN 4D001 (if “specially designed” or modified for 4A005 or 4D004) is classified under this ECCN, even if the “software” is designed or modified to use “cryptography” or cryptanalysis. (2) See also the International Traffic in Arms Regulations (ITAR) (22 CFR parts 120 through 130) and the U.S. Munitions List (22 CFR part 121).

* * * * *

Items: a. “Software” “specially designed” or modified for the “development” or “production”, of equipment controlled by 4A001, 4A003, 4A004, 4A005 or “software” controlled by 4D (except 4D980, 4D993 or 4D994).

* * * * *

■ 17. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 4 is amended by adding ECCN 4D004 after ECCN 4D002 to read as follows:

4D004 “Software” “specially designed” or modified for the generation, operation or delivery of, or communication with, “intrusion software”.

License Requirements

Reason for Control: NS, RS, AT

<i>Control(s)</i>	<i>Country chart (see supp. No.1 to part 738)</i>
NS applies to entire entry.	NS Column 1
RS applies to entire entry.	RS Column 1
AT applies to entire entry.	AT Column 1

License Requirement Note: *All license applications for 4D004 must include the information required in Supplement No. 2 to part 748 of this EAR, paragraph (z). Also, all such cybersecurity items using or incorporating encryption or other*

"information security" functionality classified under ECCNs 5A002, 5D002, 5A992.c, 5D992.c or 5E002, must also satisfy the registration, review and reporting requirements set forth in §§ 740.17, 742.15(b) and 748.3(d) of the EAR, including submissions to the ENC Encryption Request Coordinator, Ft. Meade, MD prior to applying for a license.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

CIV: N/A
TSR: N/A

Special Conditions for STA

STA: License Exception STA may not be used to export, reexport, or transfer (in-country) "software" controlled by ECCN 4D004 to any destination.

List of Items Controlled

Related Controls: (1) "Software" described under ECCN 4D004 is classified under this ECCN, even if the "software" is designed or modified to use "cryptography" or cryptanalysis. (2) See also the International Traffic in Arms Regulations (ITAR) (22 CFR parts 120 through 130) and the U.S. Munitions List (22 CFR part 121). (3) See also ECCN 4E001.a.

Related Definitions: See § 772.1 of the EAR for the definition of "intrusion software."

Items: The list of items controlled is contained in the ECCN heading.

18. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 4, ECCN 4E001 is amended by:

- a. Revising the Reasons for Control paragraph in the License Requirements section;
b. Adding an entry for "RS" after the entry for "MT" in the table in the License Requirements section;
c. Removing the NP note after the table in the License Requirements section and adding in its place a License Requirement Note;
d. Revising the TSR paragraph in the List Based License Exceptions section;
e. Revising the Special Conditions for STA section;
f. Revising the Related Controls and Related Definitions paragraphs in the List of Items Controlled section;
g. Adding paragraph c to the Items paragraph of the List of Items Controlled section.

The revisions and additions read as follows:

4E001 "Technology" as follows (see List of Items Controlled).

License Requirements

Reason for Control: NS, MT, RS, CC, AT

Table with 2 columns: Control(s), Country chart (see supp. No. 1 to part 738)

Control(s) Country chart (see supp. No. 1 to part 738)

* * * * *
RS applies to 4E001.a "technology" (if "required" for 4A005, 4D001.a (if "specially designed" or modified for 4A005 or 4D004) or modified for 4A005 or 4D004) and if "required" for 4E001.c.

License Requirement Note: All license applications for 4E001.a "technology" (if "required" for 4A005, 4D001.a (if "specially designed" or modified for 4A005 or 4D004) and if "required" for 4E001.c must include the information required in Supplement No. 2 to part 748 of the EAR, paragraph (z). Also, all such cybersecurity items using or incorporating encryption or other "information security" functionality classified under ECCNs 5A002, 5D002, 5A992.c, 5D992.c or 5E002, must also satisfy the registration, review and reporting requirements set forth in §§ 740.17, 742.15(b) and 748.3(d) of the EAR, including submissions to the ENC Encryption Request Coordinator, Ft. Meade, MD prior to applying for a license.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

* * * * *
TSR: Yes, except for: "technology" for the "development" or "production" of "commodities" with an "Adjusted Peak Performance" ("APP") exceeding 1.0 WT, "commodities" in 4A005 or "software" in 4D001.a (if "specially designed" or modified for 4A005 or 4D004) or "required" for 4D004; or "technology" specified by 4E001.c.

Special Conditions for STA

STA: License Exception STA may not be used to ship or transmit "technology" according to the General Technology Note for the "development" or "production" of any of the following equipment or "software": a. Equipment specified by ECCN 4A001.a.2; b. "Digital computers" having an 'Adjusted Peak Performance' ('APP') exceeding 1.0 Weighted TeraFLOPS (WT); or c. "software" specified in the License Exception STA paragraph found in the License Exception section of ECCN 4D001 to any of the destinations listed in Country Group A:6 (See Supplement No. 1 to part 740 of the EAR); or to ship any "technology" specified by 4E001.a "required" for "commodities" in 4A005 or "software" in 4D001.a (if "specially designed" or modified for 4A005 or 4D004), 4D004, or by 4E001.c, to any destination.

List of Items Controlled

Related Controls: (1) "Technology" described under ECCN 4E001.a ("required" for equipment in 4A005 or "software" in 4D001.a (if "specially designed" or modified for 4A005 or 4D004) or 4E001.c is classified under this ECCN, even if it includes "technology" for the "development" or "production" of cryptographic or cryptanalytic items. (2) See also the International Traffic in Arms Regulations (ITAR) (22 CFR parts 120 through 130) and the U.S. Munitions List (22 CFR part 121).

Related Definitions: See § 772.1 for the definition of "intrusion software."

Items: * * *

c. "Technology" "required" for the "development" of "intrusion software".

- 19. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 5, ECCN 5A001 is amended by:
a. Revising the Reason for Control paragraph in the License Requirements section;
b. Revising the first entry in the table in the License Requirements section;
c. Adding an entry for "RS" after the second entry in the table in the License Requirements section;
d. Adding a License Requirement Note after the table in the License Requirements section;
e. Revising the List Based License Exceptions section;
f. Revising the Special Conditions for STA section;
g. Revising the Related Controls paragraph of the List of Items Controlled section; and
h. Adding paragraph j to the Items paragraph of the List of Items Controlled section.

The revisions and additions read as follows:

5A001 Telecommunications systems, equipment, "components" and "accessories," as follows (see List of Items Controlled).

License Requirements

Reason for Control: NS, RS, SL, AT

Table with 2 columns: Control(s), Country chart (see supp. No. 1 to part 738)

NS applies to 5A001.a, .e, .b.5, f.3, .h and .j.

* * * * *
RS applies to 5A001.j RS Column 1

License Requirement Note: All license applications for cybersecurity items (5A001.j) must include the information required in Supplement No. 2 to part 748 of the EAR, paragraph (z). Also, all such cybersecurity items using or incorporating encryption or other "information security" functionality

classified under ECCNs 5A002, 5D002, 5A992.c, 5D992.c or 5E002, must also satisfy the registration, review and reporting requirements set forth in §§ 740.17, 742.15(b) and 748.3(d) of the EAR, including submissions to the ENC Encryption Request Coordinator, Ft. Meade, MD prior to applying for a license.

* * * * *

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: N/A for 5A001.a, .b.5, .e, .f, .h, and .j; \$5000 for 5A001.b.1, .b.2, .b.3, .b.6, .d, and .g; \$3000 for 5A001.c.
 GBS: Yes, except 5A001.a, .b.5, .e, .f, .h, and .j.
 CIV: Yes, except 5A001.a, .b.3, .b.5, .e, .f, .h, and .j.

Special Conditions for STA

STA: License Exception STA may not be used to ship any commodity in 5A001.b.3, .b.5, or .h to any of the destinations listed in Country Group A:6 (See Supplement No. 1 to part 740 of the EAR), or to ship any commodity in 5A001.j to any destination.

List of Items Controlled

Related Controls: (1) See USML Category XI for controls on direction-finding "equipment" including types of "equipment" in ECCN 5A001.e and any other military or intelligence electronic "equipment" that is "subject to the ITAR." (2) See USML Category XI(a)(4)(iii) for controls on electronic attack and jamming "equipment" defined in 5A001.f and .h that are subject to the ITAR. (3) "Systems," "equipment" and "components" described under ECCN 5A001.j are classified under this ECCN even if the "systems," "equipment" or "components" are designed or modified to use "cryptography" or cryptanalysis. (4) ECCN 5A001.j includes a note that explicitly excludes equipment designed for marketing purposes, quality of service (QoS) or quality of experience (QoE) purposes. The intent of the entry is to capture only products that are not "specially designed" for legitimate network operator functions. The control has very specific parameters and includes only systems or equipment that perform all five of the capabilities listed in 5A001.j below. Equipment that is not described in the new ECCN 5A001.j entry because it does not have all five capabilities required is likely to be described in ECCNs 5A002 or 5A992 if it has encryption functionality, or ECCNs 5A991 or 4A994 if it does not. However, such equipment may not be sold separately with knowledge that it will be combined with other equipment to comprise a system described in new paragraph ECCN 5A001.j. (see § 764.2(h) of the EAR) (5) See also 5A101, 5A980, and 5A991.

* * * * *

Items: * * *

j. IP network communications surveillance "systems" or "equipment", and "specially designed" components therefor, having all of the following:

j.1. Performing all of the following on a carrier class IP network (e.g., national grade IP backbone):

j.1.a. Analysis at the application layer (e.g., Layer 7 of Open Systems Interconnection (OSI) model (ISO/IEC 7498-1));

j.1.b. Extraction of selected metadata and application content (e.g., voice, video, messages, attachments); and

j.1.c. Indexing of extracted data; and
 j.2. Being "specially designed" to carry out all of the following:

j.2.a. Execution of searches on the basis of 'hard selectors'; and

j.2.b. Mapping of the relational network of an individual or of a group of people.

Note: 5A001.j does not apply to "systems" or "equipment", "specially designed" for any of the following:

- a. Marketing purpose;
- b. Network Quality of Service (QoS); or
- c. Quality of Experience (QoE).

Technical Note: 'Hard selectors': data or set of data, related to an individual (e.g., family name, given name, email or street address, phone number or group affiliations).

■ 20. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 5, ECCN 5B001 is amended by:

■ a. Revising the Reasons for Control paragraph of the License Requirements section;

■ b. Revising the table in the License Requirements section;

■ c. Adding a License Requirement Note after the table in the License Requirements section;

■ d. Revising the List Based License Exceptions section; and

■ e. Revising the Special Conditions for STA section.

The revisions and addition to read as follows:

5B001 Telecommunication test, inspection and production equipment, "components" and "accessories," as follows (See List of Items Controlled).

License Requirements

Reason for Control: NS, RS, AT

Control(s)	Country chart (see supp. No. 1 to part 738)
NS applies to 5B001.a equipment, "components" and "accessories" "specially designed" for 5A001.j.	NS Column 1
NS applies to entire entry (except 5B001.a for 5A001.j).	NS Column 2
RS applies to 5B001.a equipment, "components" and "accessories" "specially designed" for 5A001.j.	RS Column 1

Control(s) Country chart
(see supp. No. 1 to part 738)

AT applies to entire entry. AT Column 1

License Requirement Note: All license applications for cybersecurity items (5B001.a equipment, "components" and "accessories" "specially designed" for 5A001.j) must include the information required in Supplement No. 2 to part 748 of the EAR, paragraph (z). Also, all such cybersecurity items using or incorporating encryption or other "information security" functionality classified under ECCNs 5A002, 5D002, 5A992.c, 5D992.c or 5E002, must also satisfy the registration, review and reporting requirements set forth in §§ 740.17, 742.15(b) and 748.3(d) of the EAR, including submissions to the ENC Encryption Request Coordinator, Ft. Meade, MD prior to applying for a license.

* * * * *

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

LVS: \$5000, except N/A for 5B001.a (for 5A001.f.1 or .j)
 GBS: Yes, except for 5B001.a (for 5A001.f.1 or .j)
 CIV: Yes, except for 5B001.a (for 5A001.f.1 or .j)

Special Conditions for STA

STA: License Exception STA may not be used to ship 5B001.a equipment and "specially designed" "components" or "accessories" therefor, "specially designed" for the "development" or "production" of equipment, functions or features specified by ECCN 5A001.b.3, .b.5 or .h to any of the destinations listed in Country Group A:6 (See Supplement No.1 to part 740 of the EAR), or to ship any commodity in 5B001.a for equipment or systems specified by 5A001.f.1, or .j to any destination.

* * * * *

■ 21. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 5, ECCN 5D001 is amended by:

■ a. Revising the Reasons for Control paragraph in the License Requirements section;

■ b. Adding an entry for "RS" after the entry for "NS" in the table in the License Requirements section;

■ c. Adding a License Requirement Note after the table in the License Requirements section;

■ d. Revising the List Based License Exceptions section;

■ e. Revising the Special Conditions for STA section; and

■ f. Revising the Related Controls paragraph in the List of Items Controlled section.

The revisions and additions read as follows:

5D001 "Software" as follows (see List of Items Controlled).

License Requirements

Reason for Control: NS, RS, SL, AT

Control(s)	Country chart (see supp. No. 1 to part 738)
RS applies to 5D001.a "software" "specially de- signed" or modified for 5A001.j, and 5D001.c "software" "specially de- signed" or modified for 5A001.j or 5B001.a.	RS Column 1

License Requirement Note: All license applications for cybersecurity items (5D001.a "software" "specially designed" or modified for 5A001.j, and 5D001.c "software" "specially designed" or modified for 5A001.j or 5B001.a) must include the information required in Supplement No. 2 to part 748 of the EAR, paragraph (z). Also, all such cybersecurity items using or incorporating encryption or other "information security" functionality classified under ECCNs 5A002, 5D002, 5A992.c, 5D992.c or 5E002, must also satisfy the registration, review and reporting requirements set forth in §§ 740.17, 742.15(b) and 748.3(d) of the EAR, including submissions to the ENC Encryption Request Coordinator, Ft. Meade, MD prior to applying for a license.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

CIV: Yes, except for "software" controlled by 5D001.a and "specially designed" or modified for the "development" or "production" of items controlled by 5A001.b.5, 5A001.f.1, 5A001.h and 5A001.j.

TSR: Yes, except for exports and reexports to destinations outside of those countries listed in Country Group A:5 (See Supplement No. 1 to part 740 of the EAR) of "software" controlled by 5D001.a and "specially designed" or modified for items controlled by 5A001.b.5, 5A001.f.1, 5A001.h and 5A001.j.

Special Conditions for STA

STA: License Exception STA may not be used to ship or transmit 5D001.a "software" "specially designed" or modified for the "development" or "production" of equipment, functions or features, specified by ECCN 5A001.b.3, .b.5, .f.1, .h or .j; and for 5D001.b. for "software" "specially designed" or modified to support "technology" specified by the STA paragraph in the License Exception section of ECCN 5E001 to any of the destinations listed in Country Group A:6 (See Supplement No.1 to part 740 of the EAR); and for 5D001.c. for "software" "specially designed" or modified to provide characteristics, functions or features of equipment or

systems classified under ECCNs 5A001.f.1 or .j, or 5B001.a (for 5A001.f.1 or .j)).

List of Items Controlled

Related Controls: (1) "Software" described under ECCN 5D001.a or .c (if "specially designed" or modified for 5A001.j) is classified under this ECCN, even if the "software" is designed or modified to use "cryptography" or cryptanalysis. (2) See also 5D980 and 5D991.

- 22. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 5, Part 1, ECCN 5E001 is amended by:
 - a. Revising the Reasons for Control paragraph in the License Requirements section;
 - b. Adding an entry for "RS" after the entry for "NS" in the table in the License Requirements section;
 - c. Adding a License Requirement Note after the table in the License Requirements section;
 - d. Revising the TSR paragraph in the List Based License Exceptions section;
 - e. Revising the Special Conditions for STA section; and
 - f. Adding paragraph (3) to the Related Control paragraph in the List of Items Controlled section.

The revisions and additions read as follows:

5E001 "Technology" as follows (see List of Items Controlled).

License Requirements

Reason for Control: NS, RS, SL, AT

Control(s)	Country chart (see supp. No. 1 to part 738)
RS applies to 5E001.a for commodities controlled under 5A001.j or "software" controlled under 5D001.a (if "specially designed" or modified for 5A001.j), and 5D001.c (if "specially designed" or modified for 5A001.j or 5B001.a) for RS reasons.	RS Column 1

License Requirement Note: All license applications for cybersecurity items (5A001.j or "software" controlled under 5D001.a (if "specially designed" or modified for 5A001.j), and 5D001.c (if "specially designed" or modified for 5A001.j or 5B001.a)) must include the information required in Supplement No. 2 to part 748 of the EAR, paragraph (z). Also, all such cybersecurity items using or incorporating

encryption or other "information security" functionality classified under ECCNs 5A002, 5D002, 5A992.c, 5D992.c or 5E002, must also satisfy the registration, review and reporting requirements set forth in §§ 740.17, 742.15(b) and 748.3(d) of the EAR, including submissions to the ENC Encryption Request Coordinator, Ft. Meade, MD prior to applying for a license.

List Based License Exceptions (See Part 740 for a Description of All License Exceptions)

TSR: Yes, except: N/A for "technology" controlled by 5E001.a if "required" for the "development" or "production" of items controlled by 5A001.f.1 or .j, 5D001.a (if "specially designed" or modified for 5A001.f.1 or .j) or 5D001.c (if "specially designed" or modified for 5A001.j or 5B001.a) to any destination; or for exports or reexports to destinations outside of those countries listed in Country Group A:5 (See Supplement No. 1 to part 740 of the EAR) of "technology" controlled by 5E001.a for the "development" or "production" of the following: (1) Items controlled by 5A001.b.5 or 5A001.h; or (2) "Software" controlled by 5D001.a that is "specially designed" or modified for the "development" or "production" of equipment, functions or features controlled by 5A001.b.5 or 5A001.h.

Special Conditions for STA

STA: License Exception STA may not be used to ship or transmit "technology" according to the General Technology Note for the "development" or "production" of equipment, functions or features specified by 5A001.b.3, .b.5 or .h; or for "software" in 5D001.a that is specified in the STA paragraph in the License Exception section of ECCN 5D001 to any of the destinations listed in Country Group A:6 (See Supplement No.1 to part 740 of the EAR); or to ship any "technology" in 5E001.a if "required" for any commodity in 5A001.f.1 or .j, or if "required" for any "software" in 5D001.a or .c ("specially" or modified designed for any commodity in 5A001.f.1 or .j or 5B001.a ("specially designed" for 5A001.f.1 or .j)), to any destination.

List of Items Controlled

Related Controls: * * * (3) "Technology" described under ECCN 5E001.a if "required" for "systems," "equipment" or "components" classified under 5A001.j or "software" classified under 5D001.a ("specially designed" or modified for 5A001.j) or 5D001.c ("specially designed" or modified for 5A001.j or 5B001.a) is classified under this ECCN even if it includes "technology" for the "development" or "production" of cryptographic or cryptanalytic items.

- 23. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 5 Part 2, ECCN 5A002 is amended by adding paragraph (4) to the Related Controls paragraph in the List of Items Controlled section to read as follows:

5A002 “Information security” systems, equipment “components” therefor, as follows (see List of Items Controlled).

* * * * *

List of Items Controlled

Related Controls: * * * (4) “Systems,” “equipment” and “components” described under ECCNs 4A005 or 5A001.j are classified under ECCNs 4A005 or 5A001.j, even if the “systems,” “equipment” or “components” are designed or modified to use “cryptography” or cryptanalysis.

* * * * *

■ 24. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 5 Part 2, ECCN 5D002 is amended by adding paragraph (3) to the Related Controls paragraph in the List of Items Controlled section to read as follows:

5D002 “Software” as follows (see List of Items Controlled).

* * * * *

List of Items Controlled

Related Controls: * * * (3) “Software” described under ECCN 4D001.a (“specially designed” or modified for 4A005 or 4D004), 4D004, 5D001.a (“specially designed” or modified for 5A001.j) or 5D001.c (“specially designed” or modified for 5A001.j or 5B001.a) is classified under those ECCNs, even if the “software” is designed or modified to use “cryptography” or cryptanalysis.

* * * * *

■ 25. In Supplement No. 1 to Part 774 (the Commerce Control List), Category 5 Part 2, ECCN 5E002 is amended by revising the Related Controls paragraph in the List of Items Controlled section to read as follows:

5E002 “Technology” as follows (see List of Items Controlled).

* * * * *

List of Items Controlled

Related Controls: (1) See also 5E992. This entry does not control “technology” “required” for the “use” of equipment excluded from control under the Related Controls paragraph or the Technical Notes in ECCN 5A002 or “technology” related to equipment excluded from control under ECCN 5A002. This “technology” is classified as ECCN 5E992. (2) “Technology” described under ECCN 4E001.a (“required” for equipment in 4A005 or “software” in 4D004), 4E001.c, or 5E001.a (“required” for 5A001.j or 5D001.a) that is designed or modified to use “cryptography” or cryptanalysis is classified under ECCNs 4E001.a or .c, or ECCN 5E001.a, respectively.

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Dated: May 11, 2015.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2015–11642 Filed 5–19–15; 8:45 am]

BILLING CODE 3351–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 514

[Docket No. FDA–2012–N–0447; 0910–AG45]

Antimicrobial Animal Drug Sales and Distribution Reporting

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Animal Drug User Fee Amendments of 2008 (ADUFA) amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) to require that sponsors of approved or conditionally approved applications for new animal drugs containing an antimicrobial active ingredient submit an annual report to the Food and Drug Administration (FDA or Agency) on the amount of each such ingredient in the drug that is sold or distributed for use in food-producing animals, and further requires FDA to publish annual summary reports of the data it receives from sponsors. At this time, FDA is issuing proposed regulations for the administrative practices and procedures for animal drug sponsors who must report under this law. This proposal also includes an additional reporting provision intended to enhance FDA’s understanding of antimicrobial animal drug sales intended for use in specific food-producing animal species.

DATES: Submit either electronic or written comments on the proposed rule by August 18, 2015. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 (the PRA) by June 19, 2015 (see the “Paperwork Reduction Act of 1995” section of this document).

ADDRESSES: You may submit comments by any of the following methods, except that comments on information collection issues under the PRA must be submitted to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB) (see the “Paperwork Reduction Act of 1995” section).

Electronic Submissions

Submit electronic comments in the following way:

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

Written Submissions

Submit written submissions in the following way:

- Mail/Hand delivery/Courier (for paper submissions): Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the Docket No. FDA–2012–N–0447 for this rulemaking. All comments received may be posted without change to <http://www.regulations.gov>, including any personal information provided. For additional information on submitting comments, see the “Comments” heading of the **SUPPLEMENTARY INFORMATION** section.

Docket: For access to the docket to read background documents or comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Neal Bataller, Center for Veterinary Medicine (HFV–210), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–276–9062, Neal.Bataller@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

Executive Summary

Purpose of Proposed Rule

Section 105 of ADUFA (ADUFA 105) amended section 512 of the FD&C Act (21 U.S.C. 360b) to require that sponsors of approved or conditionally approved applications for new animal drugs containing an antimicrobial active ingredient submit an annual report to FDA on the amount of each such ingredient in the drug that is sold or distributed for use in food-producing animals. ADUFA 105 also requires FDA to publish annual summary reports of the data it receives. In accordance with the new law, sponsors of the affected antimicrobial new animal drug products began submitting their sales and distribution data to FDA on an annual basis, and FDA published summaries of such data for each calendar year beginning with 2009. The purpose of this rulemaking is to amend the Agency’s existing records and reports regulation in part 514 (21 CFR part 514) to incorporate the sales and distribution data reporting requirements specific to antimicrobial new animal drugs that were added to the FD&C Act by ADUFA 105. This proposal also includes an additional reporting provision intended to further enhance FDA’s understanding of antimicrobial animal drug sales

intended for use in specific food-producing animal species.

Summary of Major Provisions

The proposed rule, if finalized, will amend the records and reports regulation in part 514 to include the following:

- Procedures relating to the submission to FDA of annual sales and distribution data reports by sponsors of approved new animal drug products sold or distributed for use in food-producing animals. The proposal includes specific reporting criteria, including the requirement that sponsors submit species-specific estimates of product sales as a percentage of total sales.
- Procedures applicable to FDA's preparation and publication of summary reports on an annual basis based on the sales and distribution data it receives from sponsors of approved antimicrobial new animal drug products. The proposal includes specific parameters for the content of the annual summary reports as well as provisions intended to protect confidential business information and national security, consistent with ADUFA 105.
- Provisions that will give sponsors of approved new animal drug products containing antimicrobial active ingredients that are sold or distributed for use in food-producing animals the opportunity to avoid duplicative reporting of product sales and distribution data to FDA under part 514.

Costs and Benefits

FDA estimates one-time costs to industry from this proposed rule, if finalized, at about \$138,800. FDA estimates annual costs at about \$55,700. These costs equate to an estimated total annualized cost of about \$75,400 at a 7 percent discount rate over 10 years and about \$71,900 at a 3 percent discount rate over 10 years. The total annualized costs include the administrative cost to review the rule (\$9,700), plus the cost to those sponsors who wish to avoid duplicative reporting requirements under part 514 (\$4,800), plus the cost of providing the species-specific estimate of the percent of the drug product distributed domestically (\$61,000).

The proposed rule would provide some flexibility for the manner in which new animal drug sponsors report the sales and distribution data under both § 514.80 and proposed § 514.87, by allowing for only one set of report submissions under certain circumstances. FDA estimates that this will reduce labor costs for new animal drug sponsors by \$100,200 annually.

Another benefit of this proposed rule would be the cost savings associated with reporting monthly sales and distribution data to FDA in terms of product units rather than calculating the amount of antimicrobial active ingredients associated with these monthly product sales and distribution data. FDA estimates the calculation reductions would amount to an annual benefit of about \$18,600. FDA estimates total annual benefits at about \$118,800.

I. Background

Section 105 of ADUFA (Pub. L. 110–316) amends section 512(I) of the FD&C Act by adding new section 512(I)(3). Section 512(I) of the FD&C Act requires sponsors of approved or conditionally approved new animal drug applications to establish and maintain records and make such reports to FDA of data and other information relating to experience with their new animal drugs as required by regulation or order. Under new section 512(I)(3) of the FD&C Act, sponsors of antimicrobial new animal drugs approved for use in food-producing animals must submit to FDA on an annual basis a report specifying the amount of each antimicrobial active ingredient in the drug that is sold or distributed for use in food-producing animals. Specifically, sponsors are required to report the amount of each antimicrobial active ingredient as follows: (1) By container size, strength, and dosage form; (2) by quantities distributed domestically and quantities exported; and (3) for each dosage form, a listing of the target animals, indications, and production classes that are specified on the approved label of the product. The information must be reported for the preceding calendar year, include separate information for each month of the calendar year, and be submitted to FDA each year no later than March 31. Section 512(I)(3) of the FD&C Act also requires FDA to publish an annual summary report of the antimicrobial drug sales and distribution data collected from the drug sponsors, and further provides that such data must be reported by antimicrobial class.

The first reporting year under new section 512(I)(3) of the FD&C Act was calendar year 2009. In accordance with the new law, sponsors of affected new animal drug products submitted their 2009 sales and distribution data to FDA by March 31, 2010, and FDA published a summary report of these data later that same year. To date, FDA has collected sales and distribution data, and published summary reports of such data, for each calendar year from 2009 through and including 2012. As noted

earlier, the purpose of this rulemaking is to amend FDA's animal drug records and reports regulation at part 514 to include administrative practices and procedures for sponsors of antimicrobial new animal drugs sold or distributed for use in food-producing animals who must report annually under section 512(I)(3) of the FD&C Act, including a proposed provision intended to enhance understanding of antimicrobial new animal drug sales intended for use in specific food-producing animal species. Collecting species-specific data is expected to assist FDA in assessing antimicrobial sales trends in the major food-producing animal species and examining how such trends may relate to antimicrobial resistance. Having improved data would also support this Agency's ongoing efforts to encourage the judicious use of antimicrobials in food-producing animals to help ensure the continued availability of safe and effective antimicrobials for animals and humans.

FDA previously issued an advance notice of proposed rulemaking (ANPRM) to obtain public input on potential amendments to its animal drug records and reports regulation at part 514, including the proposed provision to require data about specific food-producing animal species discussed in this document. The comments FDA received in response to the ANPRM were considered in preparing this proposed rule.

II. Proposed Regulations

A. Records and Reports—Conforming Changes (Proposed § 514.80(b)(4)(i))

Under current § 514.80(b)(4) of the Agency's regulations, sponsors of approved new animal drugs are required to submit a periodic drug experience report to FDA. Such reports include information regarding known adverse drug experiences, study reports from any recently conducted laboratory or clinical studies, current product labeling, and, under paragraph (b)(4)(i), product distribution data. In order to avoid duplicative reporting, FDA proposes that applicants submitting annual sales and distribution reports for antimicrobial new animal drug products under proposed § 514.87 would have the option to choose not to report distribution data under current § 514.80(b)(4)(i) for their approved applications that include these same products. However, this exemption from reporting under § 514.80(b)(4)(i) would only apply provided the following proposed conditions are met:

- Applicants would have to submit complete periodic drug experience

reports under § 514.80(b)(4), including paragraph (b)(4)(i), for such applications for at least 2 full years after the date of the initial approval of their drug product application, in addition to the reporting that would be required under proposed § 514.87. Under current § 514.80(b)(4), applicants of newly approved applications must submit periodic drug experience reports every 6 months for the first 2 years and such reporting is only required annually after that. This requirement provides FDA with enhanced drug experience feedback on newly approved animal drug products for which the Agency and animal drug industry have less practical experience compared to mature animal drug products that have been marketed for 2 or more years. In contrast, proposed § 514.87, which implements recently added section 512(J)(3) of the FD&C Act, would only require sales and distribution reports for antimicrobial new animal drug products once per year. By retaining the requirement that applicants of such drug products submit complete periodic drug experience reports at 6-month intervals under § 514.80(b)(4) for 2 full years after the date of the initial approval of their drug product application, this proposal would assure that enhanced drug experience surveillance for newly approved products is maintained.

- Applicants who wish to have the option of not providing distribution data as part of the periodic drug experience reports they submit under current § 514.80(b)(4)(i) for those approved applications that include the same antimicrobial new animal drug products that are covered by the reporting requirements under proposed § 514.87 would have to assure that the beginning of the reporting period for the annual periodic drug experience reports for such applications is January 1. Under § 514.80(b)(4), the reporting period and submission deadline of yearly periodic drug experience reports is tied to the anniversary date of the drug's approval unless the applicant petitions for, and is granted, approval to change the reporting timeframes. For approved applications that have a reporting period that begins on a date other than January 1, applicants would submit a one-time request to change the submission date for their yearly (annual) periodic drug experience report such that the reporting period begins on January 1 and ends on December 31, as currently provided for in § 514.80(b)(4). Such requests may be made at any time, but, consistent with the timeframe discussed in the previous paragraph, FDA will only grant such requests after

at least 2 full years have elapsed since the date of the initial approval of the subject application. In accordance with section 512(J)(3) of the FD&C Act, reporting of antimicrobial drug sales and distribution data under proposed § 514.87 would be by calendar year. The purpose of having affected applicants assure that the reporting period for their annual periodic drug experience reports begins on January 1 is so that the reporting periods for all annual reports submitted under part 514 for a particular application will be consistent and cover the same time period beginning January 1 of each year, regardless of whether submitted under § 514.80(b)(4) or proposed § 514.87.

- Once an applicant has changed the submission date to align with the reporting period for proposed § 514.87 (beginning January 1 of each year), the Agency would also expect the applicant to submit, on a one-time basis, a special drug experience report as described in current § 514.80(b)(5)(i), that would address any gaps in distribution data caused by the change in reporting periods.

- Sponsors who hold approved applications for antimicrobial new animal drugs intended for use in food-producing animals who choose not to separately report distribution data for their products under § 514.80(b)(4)(i) would have to assure that full sales and distribution data for each product approved under such applications are alternatively reported under proposed § 514.87, including products approved under such applications that are labeled only for use in nonfood-producing animals. This would assure that all distribution data for every drug product under approved applications for antimicrobial new animal drugs intended for use in food-producing animals are reported to FDA and that all such data are reported under one regulation, proposed § 514.87.

FDA also proposes to revise § 514.80(b)(4) by extending the deadline for submission of annual periodic drug experience reports from within 60 days to within 90 days of the anniversary date of the approval. For those applicants whose reporting period under § 514.80(b)(4) begins on January 1—either because the anniversary of the drug application's approval falls on that date or because the applicant petitions for, and is granted, a new submission date that aligns the reporting period under § 514.80(b)(4) with the reporting period under proposed § 514.87 (*i.e.*, beginning January 1 of each year)—this revision would harmonize the timeframe for submitting annual periodic drug experience reports

following the close of the reporting period with the 90-day timeframe sponsors have to submit annual antimicrobial animal drug sales and distribution reports for the preceding calendar year (by no later than March 31) as required by section 512(J)(3) of the FD&C Act.

B. Annual Sponsor Reports of Antimicrobial Animal Drug Sales and Distribution Information (Proposed § 514.87(a) Through (e))

Proposed paragraph (a) would reflect the requirement, under section 512(J)(3) of the FD&C Act, for each sponsor of a new animal drug product that is approved or conditionally approved and contains an antimicrobial active ingredient, to report to FDA on an annual basis the amount of each antimicrobial active ingredient in the drug product that is sold or distributed for use in food-producing animals. This includes products that are the subject of an approved new animal drug application or abbreviated new animal drug application, as well as products that are conditionally approved under section 571 of the FD&C Act (21 U.S.C. 360ccc). Proposed paragraph (a) would also incorporate the requirement from section 512(J)(3) of the FD&C Act for animal drug sponsors to capture in their sales and distribution data reports information regarding any distributor-labeled products (see section 512(J)(3)(A) of the FD&C Act).

Proposed paragraph (b) sets out what information would need to be included in the drug sponsor's annual report in order to satisfy paragraph (a). Specifically, proposed paragraph (b) would require each annual report to identify the approved or conditionally approved application for the subject antimicrobial new animal drug product and include the following product-specific information (see section 512(J)(3)(B) and (C)(iii) of the FD&C Act):

- A listing of each antimicrobial active ingredient contained in the product;
- a description of each unique marketed product by unit (*i.e.*, container size, strength, and dosage form);
- for each such product, a listing of the target animal species, indications, and production classes that are specified on the approved label;
- for each such product, the number of units sold or distributed in the United States (*i.e.*, domestic sales) for each month of the reporting year; and
- for each such product, the number of units sold or distributed outside the United States (*i.e.*, quantities exported) for each month of the reporting year.

Currently, animal drug sponsors are complying with the requirements of section 512(I)(3) of the FD&C Act through a two-step process. First, they collect monthly sales and distribution data for their affected new animal drug products in terms of unit sales. Then they calculate the amount of antimicrobial active ingredients associated with those product sales and report those figures to FDA. After several years of collecting and collating sales and distribution data under section 512(I)(3) of the FD&C Act, FDA believes the most effective and efficient method for achieving the goals of this statutory provision is for animal drug sponsors to limit their annual reporting to product sales and distribution data in terms of unit sales, and then FDA can use that information to calculate the exact amounts of antimicrobial active ingredients associated with those product sales. Animal drug sponsors are very experienced at collecting and reporting accurate sales and distribution data in terms of units of product sold or distributed because of their current obligation to annually report such information to FDA in their periodic drug experience reports under § 514.80(b)(4). However, our experience has shown great variability in reporting accuracy when sponsors are asked to convert product sales data into active ingredient sales data. Such variability causes confusion for the Agency and requires more time to verify submitted data with sponsors. Therefore, FDA believes this approach will not only reduce the burden on both the sponsors and the Agency, but will greatly increase the accuracy of the final results.

The Agency also believes a “reporting by product” approach is consistent with the requirements of ADUFA 105. Section 512(I)(3)(B) of the FD&C Act acknowledges that antimicrobial active ingredients are sold and distributed as products through its requirement that sponsors report their antimicrobial data by, among other things, “container size, strength, and dosage form,” and, “for each such dosage form, a listing of the target animals, indications, and production classes that are specified on the approved label of the product.” The container size, strength, and dosage form define a unique marketed product within an approved or conditionally approved application; therefore, under this proposal, if finalized, drug sponsors subject to the ADUFA 105 reporting requirements would need to continue to provide separate antimicrobial sales and distribution data for each of these unique marketed products in their

reports. With knowledge of all the unique marketed products within an approved or conditionally approved application, along with the unit sales and distribution data for each of these products, the amount of antimicrobial active ingredient associated with those sales can then be calculated. The only question is who will perform the calculations and, as noted earlier, FDA believes that the Agency is best suited to perform this function in order to maximize accuracy and efficiency.

Further, proposed paragraph (b) would require the sponsor of an approved or conditionally approved antimicrobial new animal drug product to list in its annual report the target animals, indications, and production classes that are specified on the approved label of each unique product. FDA believes this requirement is consistent with the reporting requirements added to the FD&C Act by ADUFA 105. Section 512(I)(3)(B) of the FD&C Act provides for sponsors to report their antimicrobial data by, among other things, container size, strength, and dosage form and, “for each such dosage form, a listing of the target animals, indications, and production classes that are specified on the approved label of the product.” As previously stated, the container size, strength, and dosage form define a unique marketed product within an approved or conditionally approved application. The dosage form is part of what defines a unique marketed product; thus, listing the target animals, indications, and production classes that are specified on the approved label of each unique product provides the information required by ADUFA 105.

Proposed paragraph (c) would require that each annual report to FDA provide a species-specific estimate of the percentage of each new animal drug product containing an antimicrobial active ingredient that was sold or distributed domestically for use in cattle, swine, chickens, or turkeys, but only if such animal species appears on the approved label. This provision is not intended to require animal drug sponsors to conduct studies of on-farm drug use practices. FDA believes that animal drug sponsors have access to information obtained in the ordinary course of their business (for example, through marketing activities) to estimate the percentage of annual product sales that are sold or distributed domestically for use in any of these four major food-producing species that appear on the approved product label. While certain products may be legally used in an extralabel manner, promotion of such extralabel use is prohibited, and FDA

believes that drug sponsors are unlikely to possess meaningful data on the percentage of their products that may be sold for extralabel use, especially for species not on the product label. If, however, a sponsor *is* aware of extralabel product sales for use in any of the four major food-producing species listed on the product’s label, these sales would be included in deriving the estimate reported under proposed paragraph (c) for that species.

The Agency believes having species-specific estimates of product sales and distribution for use in the four major food-producing categories of animal species (cattle, swine, chickens, turkeys) would be important in supporting efforts such as the National Antimicrobial Resistance Monitoring System (NARMS), a surveillance program that monitors trends in antimicrobial resistance among foodborne bacteria from humans, retail meats, and animals. NARMS retail meat and animal sampling focus on the same four major food-producing species proposed here. Since there is currently limited resistance data related to minor food-producing animals and companion animals, requiring estimates of these additional species would cause additional burden without clear benefit.

In order to assure that the total of the species-specific percentages reported for each product adds up to 100 percent of its sales and distribution, a fifth category for “other species/unknown” would also be included in this provision. This category would be used to capture the percentage of each new animal drug product that was sold or distributed for use in animal species other than the four major food-producing species or otherwise unknown to the reporting drug sponsor.

The following hypothetical scenarios are presented here as illustration:

- An antimicrobial product is approved for use only in cattle and swine, and the sponsor estimates that 100 percent of the annual sales were for use in cattle. In this situation, the sponsor would report: Cattle 100 percent, swine 0 percent, chickens 0 percent, turkeys 0 percent, other species/unknown 0 percent.
- An antimicrobial product is approved for use only in cattle and swine, and the sponsor estimates that 50 percent of the annual sales were for use in cattle, 30 percent were for use in swine, and 20 percent were unknown to the sponsor. In this situation, the sponsor would report: Cattle 50 percent, swine 30 percent, chickens 0 percent, turkeys 0 percent, other species/unknown 20 percent.

• An antimicrobial product is approved for use only in cattle, sheep, and dogs, and the sponsor estimates that 50 percent of the annual sales were for use in cattle, 10 percent were for use in sheep, and 40 percent were for use in dogs. Since dogs are companion animals and sheep are a minor species, sales estimates for these would be reported together in the “other species/unknown” category. Thus, in this situation, the sponsor would report: Cattle 50 percent, swine 0 percent, chickens 0 percent, turkeys 0 percent, other species/unknown 50 percent.

As noted earlier, under this proposal, sponsors who hold approved applications for antimicrobial new animal drugs intended for use in food-producing animals who choose not to separately report distribution data for their products under § 514.80(b)(4)(i) would have to assure that full sales and distribution data for each product approved under such applications are alternatively reported under proposed § 514.87, including products approved under such applications that are labeled only for use in nonfood-producing animals. In this situation, sponsors would report the species-specific estimate of sales for the products labeled only for use in nonfood-producing animals as 100 percent “other species/unknown.”

All species-specific estimates would reflect domestic sales for the entire reporting year and would not include separate information for each month of the reporting year. ADUFA 105 requires drug sponsors to report sales and distribution data to FDA broken out by month; however, antimicrobial drug products may be used at any time up to several years after distribution. The Agency considers monthly fluctuations in drug product sales to be of limited value in reflecting when products may actually be administered to animals and interpreting antimicrobial resistance trends; therefore, FDA reports yearly sales and distribution information in its annual summary reports instead of monthly amounts. The Agency believes that requiring sponsors to report monthly species-specific estimates would entail a greater burden to drug sponsors without providing meaningful information.

Most antimicrobial new animal drug products that are approved for use in food-producing animals are labeled for use in more than one animal species, in some cases five or more species. Therefore, since the antimicrobial sales and distribution data reported to FDA by drug sponsors under section 512(l)(3) of the FD& Act are derived from drug product sales, very little can be

concluded about antimicrobial sales intended for use in any one particular species for products that are approved for use in more than one species. The Agency believes having species-specific estimates of product sales and distribution for use in the four major food-producing categories of animal species (cattle, swine, chickens, turkeys) would be important in supporting efforts such as NARMS, a surveillance program that tracks trends related to antimicrobial resistance in food-producing animals and humans. FDA believes that this additional sales and distribution information would be useful to better understand how the use of medically important antimicrobial drugs in food-producing animals may contribute to the emergence or selection of antimicrobial resistant bacteria. Specifically, this information could inform microbial food safety risk assessments by providing a better indication of the extent to which a drug or drug class is used in a specific food animal species by a specific route of administration. From this, it may be possible to draw conclusions about how antimicrobial sales and distribution data compare with data from NARMS. In addition, such information could further enhance FDA’s ongoing activities related to slowing the development of antimicrobial resistance and is consistent with the recommendations in guidance recently issued by this Agency addressing the judicious use of medically important antimicrobial drugs in food-producing animals (Guidance for Industry #209, entitled “The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals”).

Since it is likely that many sponsors would consider their species-specific sales and distribution estimates as proprietary information, and that such estimates may often be derived from proprietary marketing analyses, FDA would, as described in proposed paragraph (e), consider the species-specific information reported by individual sponsors under paragraph (c) to be confidential business information consistent with section 512(l)(3) of the FD&C Act and this Agency’s regulations at 21 CFR 20.61.

Proposed paragraph (d) would incorporate the requirement specified in section 512(l)(3)(C) of the FD&C Act that each annual antimicrobial drug sales and distribution data report be submitted to FDA not later than March 31 of each year and cover the period of the preceding calendar year (see section 512(l)(3)(C)(i) and (ii) of the FD&C Act). Proposed paragraph (d) would also require that each such report be

submitted to FDA using Form FDA 3744, “Antimicrobial Animal Drug Distribution Report.”

C. Annual Summary Reports Published by FDA (Proposed § 514.87(f))

Proposed paragraph (f) would incorporate the requirement established by ADUFA 105 for FDA to publish an annual summary report of the antimicrobial drug sales and distribution data collected from drug sponsors by antimicrobial class (see section 512(l)(3)(E) of the FD&C Act). Consistent with the statute, this proposed paragraph would also require that FDA not independently report those antimicrobial classes with fewer than three distinct sponsors, and would further require that, in reporting the antimicrobial drug sales and distribution data it receives from drug sponsors, FDA must do so in a manner consistent with protecting both national security and confidential business information (see section 512(l)(3)(E)(i) and (ii) of the FD&C Act).

Proposed paragraph (f) would also require FDA to publish its annual summary report of the information it receives under this section for each calendar year by December 31 of the following year. Proposed paragraph (f) also provides that, in addition to summarizing sales and distribution data by antimicrobial drug class, the annual summary report may also include additional summaries of the data received under this section, as determined by FDA. For example, on October 2, 2014, FDA published annual summary reports that include additional data tables on the importance of each drug class in human medicine, the approved routes of administration for these antimicrobials, whether these antimicrobials are available over-the-counter or require veterinary oversight, and whether the antimicrobial drug products are approved for therapeutic purposes or for production purposes, or both therapeutic and production purposes.

Paragraph (f) also proposes that the publication of any summary data in addition to drug class would be limited by the same confidentiality and national security protections as is required by the statute, as noted previously, for the publication of summary data by drug class. Specifically, each individual datum appearing in the summary report, regardless of its classification or source, would be required to: (1) Reflect cumulative product sales and distribution data from three or more distinct sponsors of approved products that were actively sold or distributed that reporting year and (2) be reported

in a manner consistent with protecting both national security and confidential business information. This approach would make it possible to present sales and distribution data in a manner consistent with the confidentiality provisions of section 512(I) of the FD&C Act.¹

III. Legal Authority

FDA's authority for issuing this proposed rule is provided by section 512(I) of the FD&C Act. In addition, section 701(a) of the FD&C Act (21 U.S.C. 371(a)) gives FDA general rulemaking authority to issue regulations for the efficient enforcement of the FD&C Act.

IV. Preliminary Regulatory Impact Analysis

FDA has examined the impacts of the proposed rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct Agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The Agency believes that this proposed rule is not an economically significant regulatory action as defined by Executive Order 12866.

FDA has developed a preliminary regulatory impact analysis (PRIA) that presents the benefits and costs of this proposed rule to stakeholders and the government. The summary analysis of benefits and costs included in the Executive Summary of this document is drawn from the detailed PRIA, which is available at <http://www.regulations.gov> (Docket No. FDA–2012–N–0447), and is also available on FDA's Web site at <http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/Default.htm>.

V. Paperwork Reduction Act of 1995

This proposed rule contains information collection provisions that are subject to review by OMB under the PRA of 1995 (44 U.S.C. 3501–3520). A description of these provisions is given

in the *Description* section that follows with an estimate of the annual reporting and recordkeeping burden. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Section 105 of the Animal Drug User Fee Amendments of 2008 (ADUFA 105) Regulation Information Collection.

Description: The ADUFA 105 legislation was enacted to address the problem of antimicrobial resistance and to help ensure safety related to the use of antibiotics in food-producing animals.

With these concerns in mind, Congress passed and the President signed ADUFA 105 in 2008, which amended section 512 of the FD&C Act to require that sponsors of approved or conditionally approved applications for new animal drugs containing an antimicrobial active ingredient submit an annual report to FDA on the amount of each such ingredient in the drug that is sold or distributed for use in food-producing animals.

Each report must specify: (1) The amount of each antimicrobial active ingredient by container size, strength, and dosage form; (2) quantities distributed domestically and quantities exported; and (3) a listing of the target animals, indications, and production classes that are specified on the approved label of the product. The report must cover the period of the preceding calendar year and include separate information for each month of the calendar year.

ADUFA 105 also requires FDA to publish annual summary reports of the data it receives.

In accordance with the new law, sponsors of the affected antimicrobial new animal drug products have submitted their sales and distribution data to FDA, and FDA has published

summaries of such data, for each calendar year since 2009.

The proposed rule, if finalized, will amend the records and reports regulation in part 514 to include the following:

- Procedures relating to the submission to FDA of annual sales and distribution data reports by sponsors of approved new animal drug products sold or distributed for use in food-producing animals. The proposal includes specific reporting criteria, including the requirement that sponsors submit species-specific estimates of product sales as a percentage of total sales.

- Procedures applicable to FDA's preparation and publication of summary reports on an annual basis based on the sales and distribution data it receives from sponsors of approved antimicrobial new animal drug products. The proposal includes specific parameters for the content of the annual summary reports as well as provisions intended to protect confidential business information and national security, consistent with ADUFA 105.

- Provisions that will give sponsors of approved new animal drug products containing antimicrobial active ingredients that are sold or distributed for use in food-producing animals the opportunity to avoid duplicative reporting of product sales and distribution data to FDA under part 514.

Description of Respondents: Animal Drug Manufacturers (Sponsors).

This proposed rule would, among other things, revise existing OMB control number 0910–0659 (expiration date November 30, 2016) for antimicrobial drug products under ADUFA 105 by codifying statutory provisions. Many of the provisions of the information collection will not be affected by the proposed rule, if finalized. Therefore, this PRA section will concentrate on the changes being proposed in this rulemaking and will describe how the paperwork reduction implications will be affected.

FDA estimates the burden of this collection of information as follows:

Proposed Reporting Requirement—One-Time Reporting Burden and Costs

Because the information collection requirements of ADUFA 105 have been in effect for some time (the first report sponsors submitted was for calendar year 2009), one-time capital costs for the design of the report by firms have already occurred and need not be reported here.

In addition, the paper Form FDA 3744, the e-Form FDA 3744a, and

¹ It should also be noted that the Trade Secrets Act, 18 U.S.C. 1905, a broadly worded criminal statute, also imposes obligations on the Agency to protect confidential business information, including that obtained from the drug sponsors. A violation of the Trade Secrets Act can carry criminal penalties.

reporting via the Electronic Submission Gateway are provided by FDA at no cost. Thus, there is no one-time capital cost for report design or forms under the provisions of the proposed rule, and FDA considers the possession of computers and Internet accessibility to be usual and customary business practices.

Table 1 provides the one-time costs for the proposed rule, if finalized, which is estimated at \$138,800, about one-half of which is the unavoidable cost of reviewing the rule and developing a compliance plan. Current sponsors of approved or conditionally approved applications for antimicrobial new animal drugs sold or distributed for use in food-producing animals would need to review the rule; however, since the proposed rule would mostly codify current practices, sponsors would not require significant review time. FDA estimates that there are 34 sponsors total, 23 sponsors with active (*i.e.*, currently marketed) applications and 11 sponsors with only inactive applications, respectively, that would need to review the rule. This would require 24 hours each for the 23 active sponsors and 1 hour each for the 11 inactive sponsors. The sponsors with inactive applications would require less time to perform the review and would not need to develop the compliance plan. FDA estimates that one-half of the active sponsors would use personnel at the general and operations manager level (\$134 per hour times 24 hours times 11.5 equals approximately \$36,900). The other half of active sponsors would use an industrial production manager (\$109 per hour times 11.5 times 24 hours equals approximately \$30,100). (Please note that both estimates are rounded to be in accordance with the PRIA.) The total cost for review by sponsors of active approved applications is estimated at about \$67,000.

For the one-time, 1-hour review of the rule for the 11 sponsors of inactive approved applications, FDA assigns one-half, or 5.5 hours, at the \$134 per

hour adjusted rate for general and operations managers, while one-half, or 5.5 hours, is assigned at the \$109 adjusted rate for industrial production managers. The total cost for the review by sponsors of inactive approved applications is estimated at about \$1,300 (rounded to be in accordance with the PRIA).

FDA estimates that the total administrative costs for rule review and compliance plan development to be about \$68,300 (\$67,000 + \$1,300).

Benefits of Proposed § 514.87

The proposed rule would allow applicants submitting annual sales and distribution reports for antimicrobial new animal drug products under § 514.87 the option to not report distribution data under § 514.80(b)(4)(i)(A) for the approved applications that include these same products, but only provided certain conditions are met. One condition is that sponsors must ensure that the beginning of the reporting period for the annual periodic drug experience reports for such applications is January 1. For applications that currently have a reporting period that begins on a date other than January 1, applicants must request a change in reporting submission date for their annual periodic drug experience report such that the reporting period begins on January 1 and ends on December 31, as described in § 514.80(b)(4). A second, and related, condition, is that applicants that change their reporting submission date must also, on a one-time basis, submit a special drug experience report, as described in current § 514.80(b)(5)(i), that addresses any gaps in distribution data caused by the change in reporting periods.

FDA estimates that 90 percent of the sponsors currently marketing approved new animal drugs containing an antimicrobial active ingredient for use in food-producing animals would make the request to change the submission date such that the reporting period begins on January 1 and ends on

December 31. There are 23 sponsors of 153 approved applications. Ninety percent of 153 applications equates to about 138 applications held by 21 sponsors. FDA estimates that it would take approximately 2 hours for personnel to meet the first two conditions, making the change of date request for each application and preparing the one-time special drug experience report for each application. This results in approximately 276 hours. At the overhead and other benefits-adjusted wage rate of about \$134 per hour for general and operations managers for one-half of the hours, and at \$109 per hour for industrial production managers for the other one-half of the hours, the one-time cost would be about \$33,400 (rounded to be in accordance with the PRIA).

Costs of Proposed § 514.87

Proposed § 514.87(c) would require that each report containing the amount of antimicrobial ingredient that is sold or distributed contain a species-specific estimate of the percentage of each product that was sold or distributed domestically in the reporting year for use in any of the following animal species categories, but only for such species that appear on the approved label: Cattle, swine, chickens, turkeys. The total of the species-specific percentages reported for each product must account for 100 percent of its sales and distribution; therefore, a fifth category of “other species/unknown” must also be reported.

FDA estimates that an individual would spend about 5 hours complying with this requirement in the first year. (Subsequent years are estimated to require about 3 hours to comply.) The additional 2 hours in the first year is a one-time cost incurred as individual company personnel discuss and settle upon a method to calculate these species-specific estimates. With the labor split evenly over the two wage rates, these 2 hours amount to a one-time cost of about \$37,100 for the 153 active applications.

TABLE 1—ESTIMATED ONE-TIME REPORTING BURDEN ¹

21 U.S.C. 360b(b)(1)	Number of respondents	Number of responses per respondent	Total responses	Average burden per response	Total hours
Administrative Review of the Rule: Sponsors with Active Applications	23	1	23	24	552
Administrative Review of the Rule: Sponsors with Inactive Applications	11	1	11	1	11
Requesting a Change of Date and Submit Special Drug Experience Report to Avoid Duplicative Reporting	21	6.57	138	2	² 275
Report Species-Specific Estimate of Percent of Products Distributed Domestically	23	6.65	153	2	306

TABLE 1—ESTIMATED ONE-TIME REPORTING BURDEN ¹—Continued

21 U.S.C. 360b(b)(1)	Number of respondents	Number of responses per respondent	Total responses	Average burden per response	Total hours
Total	1,144

¹ There are no capital costs or operating and maintenance costs associated with this information collection.
² Hourly burden estimate adjusted to be in accordance with the PRIA.

Proposed Reporting Requirements—Annual Hourly Burden and Costs Benefits of Proposed § 514.87

A benefit of the proposed rule is to provide some flexibility in which new animal drug sponsors report the sales and distribution data under both § 514.80 and proposed § 514.87 by allowing sponsors to meet two separate reporting obligations under part 514 with one set of report submissions under certain circumstances. FDA estimates that 90 percent of the sponsors currently marketing approved new animal drugs containing an antimicrobial active ingredient for use in food-producing animals would make the request to change the submission date such that the reporting period begins on January 1 and ends on December 31, as provided in proposed § 514.87. These 138 approved applications (90 percent of 152) would still have to account for the costs of data collection and preparation, but they would no longer be required to include distribution data along with the other information required in the Drug Experience Report (DER) under § 514.80(b)(4)(i). FDA estimates that the time saved per application from the removal of the requirement for the distribution data in the DER could be as much as 6 hours per application. Using the same adjusted wage rates and distribution of hours by adjusted wage rates (one-half of the total hours at each rate), the annual benefit of the reduction of 138 hours times an average of \$121 per hour is about \$100,200.²

Another benefit of this proposed rule would be the cost savings associated with reporting monthly product sales and distribution data to FDA rather than calculating the amount of antimicrobial active ingredients associated with these monthly product sales and distribution data. Proposed § 514.87, if finalized, would eliminate the need for sponsors to perform and report calculations of the amount of antimicrobial active ingredients associated with monthly product sales and distribution data. These data have shown a wide variability in accuracy, causing

additional verification efforts for FDA personnel. Therefore, it would be more efficient for sponsors (and for FDA) if sponsors were to limit their annual reporting to product sales and distribution data. This would allow FDA to calculate the exact amounts of antimicrobial active ingredients associated with those product sales. FDA estimates that this would reduce the industry reporting effort by 1 hour per application. FDA estimates that 153 approved applications for antimicrobial new animal drugs that are currently marketed would be affected by this change in policy, resulting in 153 fewer compliance hours annually. At the overhead and other benefits-adjusted wage rate of about \$134 per hour for general and operations manager for one-half of the hours, and at \$109 per hour for industrial production managers for the other one-half of the hours, the annual cost saving would be about \$18,600 (rounded to be in accordance with the PRIA).

FDA estimates total annual benefits of this proposed rule, if finalized, at about \$118,800.

Costs of Proposed § 514.87

As stated previously, proposed § 514.87(c) would require that each report containing the amount of antimicrobial ingredient that is sold or distributed contain a species-specific estimate of the percentage of each product that was sold or distributed domestically in the reporting year for use in any of the following animal species categories, but only for such species that appear on the approved label: Cattle, swine, chickens, turkeys. The total of the species-specific percentages reported for each product must account for 100 percent of its sales and distribution; therefore, a fifth category of “other species/unknown” must also be reported. FDA estimates that affected sponsors will require about 3 hours to comply with this provision annually. FDA estimates that 153 approved, currently marketed applications containing antimicrobial drugs as active ingredients would be affected by this change in policy, resulting in 459 additional compliance hours annually. At the overhead and

other benefits-adjusted wage rate of about \$134 per hour for general and operations managers for one-half of the hours, and at \$109 per hour for industrial production managers for the other one-half of the hours, the additional 459 hours results in an additional annual cost of approximately \$55,700 (rounded to be in accordance with the PRIA).

Data for 2012 was submitted by 23 sponsors of 153 active applications for antimicrobial new animal drug products sold or distributed for use in food-producing animals. FDA estimates that 60 hours are currently required to collect the necessary data and prepare the submission to FDA for each of the estimated one-half of active applications for which data is submitted on a paper Form FDA 3744, for a total of 4,590 hours. FDA estimates that 50 hours are required to collect the necessary data and prepare the submission to FDA for each of the estimated one-half of active applications for which data is submitted on e-Form FDA 3744a, for a total of 3,825 hours. Thus, FDA estimates a total of 8,415 burden hours are currently needed for the 23 sponsors of 153 active applications to report to FDA. At the overhead and other benefits-adjusted wage rate of about \$134 per hour for general and operations managers for one-half of the hours, and at \$109 per hour for industrial production managers for the other one-half of the hours, the annual cost of reporting to FDA is currently approximately \$1.02 million.

FDA estimates that under the proposed rule, if finalized, affected sponsors would need 62 hours to report the necessary data on a paper Form FDA 3744 and 52 hours to report via e-Form FDA 3744a (3 additional hours for the species-specific reporting requirement minus 1 hour for cessation of the requirement to calculate the amount of antimicrobial ingredients associated with monthly product sales and distribution data). The total annual burden hours for the 23 sponsors of the 153 active applications to report under the proposed rule, if finalized would be 8,721 hours (4,743 hours for one-half of the industry using paper Form FDA 3744 and 3,978 hours for one-half of the industry using e-Form FDA 3744a), an

² OMB control numbers 0910-0284 and 0910-0645.

additional 306 hours over the current hourly burden. At the overhead and other benefits-adjusted wage rate of about \$134 per hour for general and operations managers for one-half of the hours, and at \$109 per hour for industrial production managers for the other one-half of the hours, the total annual cost of reporting for the industry under the proposed rule, if finalized, would be approximately \$1.06 million.

The cost of the additional 306 hours needed to annually report under the proposed rule, if finalized, is approximately \$37,100 (rounded to be in accordance with the PRIA).

The 2012 data also show 11 sponsors with only inactive applications for antimicrobial new animal drug products for use in food-producing animals. FDA estimates that sponsors of these inactive applications for antimicrobial drug

products need 2 hours per application to prepare and submit a report stating that there were no products distributed for the year, a total of 196 inactive approved applications times 2 hours annually equals 392 hours. This burden estimate would not be affected by the proposed rule, if finalized, and thus is not included in the following table.

TABLE 2—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 U.S.C. 360b(b)(1)	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average additional burden per response ²	Total hours
Annual Reports for Sponsors With Active Applications	3744	23	6.65	153	2	306

¹ There are no capital costs and no operating and maintenance costs associated with this information collection.

² Average additional burden per response in hours is the marginal difference between the current burden of OMB control number 0910–0659 and the additional burden per response resulting from this proposed rule.

Current Recordkeeping Burden

FDA will not address the recordkeeping provisions of all affected sponsors (34), who prepare 1 report per year and spend 2 hours annually maintaining those records (68 hours total), because the number of burden hours would not be affected by the proposed rule, if finalized.

To ensure that comments on information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the title “Animal Drug User Fee Amendments (ADUFA 105) Regulation Information Collection.”

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3407(d)), the Agency has submitted the information collection provisions of this proposed rule to OMB for review. These requirements will not be effective until FDA obtains OMB approval. FDA will publish a notice concerning OMB approval of these requirements in the **Federal Register**.

VI. Environmental Impact

The Agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

VII. Federalism

FDA has analyzed this proposed rule in accordance with the principles set

forth in Executive Order 13132. FDA has determined that the proposed rule, if finalized, would not contain policies that would 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. Accordingly, the Agency tentatively concludes that the proposed rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

VIII. 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. 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>.

List of Subjects in 21 CFR Part 514

Administrative practice and procedure, Animal drugs, Confidential business information, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 514 be amended as follows:

PART 514—NEW ANIMAL DRUG APPLICATIONS

■ 1. The authority citation for 21 CFR part 514 is revised to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 354, 356a, 360b, 360ccc, 371, 379e, 381.

■ 2. Amend § 514.80 by revising the fifth sentence of paragraph (b)(4) and by revising paragraph (b)(4)(i) to read as follows:

§ 514.80 Records and reports concerning experience with approved new animal drugs.

* * * * *

(b) * * *

(4) * * * The yearly periodic drug experience reports must be submitted within 90 days of the anniversary date of the approval of the NADA or ANADA. * * *

(i) *Distribution data.*

(A) Information about the distribution of each new animal drug product, including information on any distributor-labeled product. This information must include the total number of distributed units of each size, strength, or potency (e.g., 100,000 bottles of 100 5-milligram tablets; 50,000 10-milliliter vials of 5-percent solution). This information must be presented in two categories: Quantities distributed domestically and quantities exported.

(B) Applicants submitting annual sales and distribution reports for antimicrobial new animal drug products under § 514.87 have the option not to report distribution data under paragraph (b)(4)(i)(A) of this section for the approved applications that include these same products, but only provided

each of the following conditions are met:

(1) Applicants must have submitted complete periodic drug experience reports under this section for such applications for at least 2 full years after the date of their initial approval.

(2) Applicants must assure that the beginning of the reporting period for the annual periodic drug experience reports for such applications is January 1. For applications that currently have a reporting period that begins on a date other than January 1, applicants must request a change in reporting submission date such that the reporting period begins on January 1 and ends on December 31, as described in paragraph (b)(4) of this section.

(3) Applicants that change their reporting submission date must also submit a special drug experience report, as described in paragraph (b)(5)(i) of this section, that addresses any gaps in distribution data caused by the change in date of submission.

(4) Applicants who choose not to report under paragraph (b)(4)(i)(A) of this section must assure that full sales and distribution data for each product approved under such applications are alternatively reported under § 514.87, including products that are labeled for use only in nonfood-producing animals.

* * * * *

■ 3. Add § 514.87 to read as follows:

§ 514.87 Annual reports for antimicrobial animal drug sales and distribution.

(a) The applicant for each new animal drug product approved under section 512 of the Federal Food, Drug, and Cosmetic Act, or conditionally approved under section 571 of the Federal Food, Drug, and Cosmetic Act, and containing an antimicrobial active ingredient, must submit an annual report to FDA on the amount of each such antimicrobial active ingredient in the drug that is sold or distributed in the reporting year for use in food-producing animal species, including information on any distributor-labeled product.

(b) This report must identify the approved or conditionally approved application and must include the following information for each new animal drug product described in paragraph (a) of this section:

(1) A listing of each antimicrobial active ingredient contained in the product;

(2) A description of each product sold or distributed by unit, including the container size, strength, and dosage form of such product units;

(3) For each such product, a listing of the target animal species, indications,

and production classes that are specified on the approved label;

(4) For each such product, the number of units sold or distributed in the United States (*i.e.*, domestic sales) for each month of the reporting year; and

(5) For each such product, the number of units sold or distributed outside the United States (*i.e.*, quantities exported) for each month of the reporting year.

(c) Each report must also provide a species-specific estimate of the percentage of each product described in paragraph (b)(2) of this section that was sold or distributed domestically in the reporting year for use in any of the following animal species categories, but only for such species that appear on the approved label: Cattle, swine, chickens, turkeys. The total of the species-specific percentages reported for each product must account for 100 percent of its sales and distribution; therefore, a fifth category of “other species/unknown” must also be reported.

(d) Each report must:

(1) Be submitted not later than March 31 each year;

(2) Cover the period of the preceding calendar year; and

(3) Be submitted using Form FDA 3744, “Antimicrobial Animal Drug Distribution Report.”

(e) Sales and distribution data and information reported under this section will be considered to fall within the exemption for confidential commercial information established in § 20.61 of this chapter and will not be publicly disclosed, except that summary reports of such information aggregated in such a way that does not reveal information which is not available for public disclosure under this provision will be prepared by FDA and made available to the public as provided in paragraph (f) of this section.

(f) FDA will publish an annual summary report of the data and information it receives under this section for each calendar year by December 31 of the following year. Such annual reports must include a summary of sales and distribution data and information by antimicrobial drug class and may include additional summary data and information as determined by FDA. In order to protect confidential commercial information, each individual datum appearing in the summary report must:

(1) Reflect combined product sales and distribution data and information obtained from three or more distinct sponsors of approved products that were actively sold or distributed that reporting year, and

(2) Be reported in a manner consistent with protecting both national security

and confidential commercial information.

Dated: May 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–12081 Filed 5–19–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–140991–09]

RIN 1545–BJ08

Guidance Regarding the Treatment of Transactions in Which Federal Financial Assistance Is Provided

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains proposed regulations under section 597 of the Internal Revenue Code (the “Code”). The proposed regulations, which will apply to banks and domestic building and loan associations (and related parties) that receive Federal financial assistance (“FFA”), will modify and clarify the treatment of transactions in which FFA is provided to such institutions. This document also invites comments from the public and requests for a public hearing regarding these proposed regulations.

DATES: Written or electronic comments and requests for a public hearing must be received by August 18, 2015.

ADDRESSES: Send submissions to: CC:PA:LPD:PR (REG–140991–09), room 5203, Internal Revenue Service, P.O. Box 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand-delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:LPD:PR (REG–140991–09), Courier’s Desk, Internal Revenue Service, 1111 Constitution Avenue NW., Washington, DC, or sent electronically via the Federal eRulemaking Portal at <http://www.regulations.gov/> (IRS REG–140991–09).

FOR FURTHER INFORMATION CONTACT:

Concerning the proposed regulations, Russell G. Jones, (202) 317–5357, or Ken Cohen, (202) 317–5367; concerning the submission of comments or to request a public hearing, Oluwafunmilayo (Funmi) P. Taylor, (202) 317–6901 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking has been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of Treasury, Office of Information and Regulatory Affairs, Washington, DC 20224. Comments on the collection of information should be received by July 20, 2015.

The Treasury Department and the IRS previously issued a comprehensive set of regulations providing guidance to banks and domestic building and loan associations (and related parties) that receive FFA. These regulations (see TD 8641) were previously approved under control number 1545-1300.

The collections of information in this proposed regulation are in §§ 1.597-2(c)(4), 1.597-4(g)(5), 1.597-6(c), and 1.597-7(c)(3). The collections of information in these regulations are necessary for the proper performance of the function of the IRS by providing relevant information concerning the deferred FFA account and the amount of income tax potentially not subject to collection. The collections also inform the IRS and certain financial institutions that certain elections in these regulations have been made. The likely recordkeepers will be banks and domestic building and loan associations (and related parties) that receive FFA.

The estimated burden is as follows:

Estimated total annual reporting and/or recordkeeping burden: 2,200 hours.

Estimated average annual burden per respondent: 4.4 hours.

Estimated number of respondents: 500.

Estimated annual frequency of responses: Once.

Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be directed to the Office of Management and Budget, Attn: Desk Officer for the Department of Treasury, Office of Information and Regulatory Affairs, Washington DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, SE:W:CAR:MP:T:T:SP, Washington, DC 20224. Any such comments should be submitted not later than July 20, 2015. Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the Internal Revenue

Service, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information;

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of service to provide information.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid control number assigned by the Office of Management and Budget.

Books or records relating to a collection of information must be retained as long as their contents may become material in the administration of any internal revenue law. Generally, tax returns and tax return information are confidential, as required by section 6103.

Background

Overview of Legislative History and Current Regulations

Section 597 was enacted as part of the Economic Recovery Tax Act of 1981 (Pub. L. 97-34, 95 Stat 172 (1981)) in response to the emerging savings and loan crisis. As originally enacted, section 597 provided that money or other property provided to a domestic building and loan association by the Federal Savings and Loan Insurance Corporation (“FSLIC”) was excluded from the recipient’s gross income, and that such recipient was not required to make a downward adjustment to the basis of its assets.

The Technical and Miscellaneous Revenue Act of 1988 (Pub. L. 100-647, 102 Stat 3342 (1988)) modified section 597 by requiring taxpayers to reduce certain tax attributes by one-half of the amount of financial assistance received from the FSLIC or the Federal Deposit Insurance Corporation (“FDIC”). Yet troubled financial institutions still could receive half of such financial assistance without any corresponding reduction in tax attributes. These rules thus continued to allow the FSLIC and the FDIC to arrange acquisitions of troubled financial institutions by healthy financial institutions at a tax-subsidized cost. Notice 89-102 (1989-2 CB 436).

Section 1401 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (Pub. L. 101-73, 103 Stat 183 (1989)) (“FIRREA”) further amended section 597 to provide that FFA generally is treated as taxable income. Congress believed that the tax subsidy provided to troubled financial institutions was an inefficient way to provide assistance to such institutions. See H.R. Rep. No. 101-54, pt. 2, at 25 (1989). Moreover, Congress believed that a tax subsidy no longer was necessary because the provisions of FIRREA that deem FFA to be included in the troubled financial institution’s income at the time the institution’s assets are sold or transferred generally would cause the FFA inclusion to be offset by the institution’s losses. Id. at 27.

In 1995, the Treasury Department and the IRS issued a comprehensive set of regulations (the “current regulations”) providing guidance for banks and domestic building and loan associations (“Institutions”) and their affiliates for transactions occurring in connection with the receipt of FFA. See TD 8641 (1996-1 CB 103). For these purposes, the term “Institution” includes not only a troubled financial institution, but also a financial institution that acquires the troubled institution’s assets and liabilities in a transaction facilitated by “Agency” (the Resolution Trust Corporation, the FDIC, any similar instrumentality of the U.S. government, and any predecessor or successor of the foregoing (including the FSLIC)).

The current regulations reflect certain principles derived from the legislative history of FIRREA. First, FFA generally is treated as ordinary income of the troubled Institution that is being compensated for its losses through the provision of assistance. Second, an Institution should not get the tax benefit of losses for which it has been compensated with FFA. Third, the timing of the inclusion of FFA should, where feasible, match the recognition of the Institution’s losses. Finally, the income tax consequences of the receipt of FFA as part of a transaction in which a healthy Institution acquires a troubled Institution should not depend on the form of the acquisition (for example, the income tax consequences should not differ depending on whether the stock or the assets of a troubled Institution are acquired).

Definitions

As provided in section 597(c) and current § 1.597-1(b), “FFA” means any money or property provided by Agency to an Institution or to a direct or indirect owner of stock in an Institution under

section 406(f) of the National Housing Act (12 U.S.C. 1729(f), prior to its repeal by Pub. L. 101-73), section 21A(b)(4) of the Federal Home Loan Bank Act (12 U.S.C. 1441a(b)(4), prior to its repeal by Pub. L. 111-203, 124 Stat 1376 (2010)), section 11(f) or 13(c) of the Federal Deposit Insurance Act (12 U.S.C. 1821(f), 1823(c)), or any similar provision of law.

The amount of FFA received or accrued is the amount of any money, the fair market value of any property (other than an Agency Obligation), and the issue price of any Agency Obligation. An "Agency Obligation" is a debt instrument that Agency issues to an Institution or to a direct or indirect owner thereof.

FFA includes "Loss Guarantee" payments, "Net Worth Assistance," and certain other types of payments. A "Loss Guarantee" is an agreement pursuant to which Agency (or an entity under "Agency Control") guarantees or agrees to pay an Institution a specified amount upon the disposition or charge-off (in whole or in part) of specific assets, an agreement pursuant to which an Institution has a right to put assets to Agency (or to an entity under "Agency Control") at a specified price, or a similar arrangement. An Institution or entity is under "Agency Control" if Agency is conservator or receiver of the Institution or entity or if Agency has the right to appoint any of the Institution's or entity's directors. "Net Worth Assistance" is money or property that Agency provides as an integral part of certain actual or deemed transfers of assets or deposit liabilities, other than FFA that accrues after the date of the transfer (Net Worth Assistance thus does not include Loss Guarantee payments).

Other terms are defined in current §§ 1.597-1(b) or 1.597-5(a)(1). "Taxable Transfers" generally include (i) transfers of deposit liabilities (if FFA is provided) or of any asset for which Agency or an entity under Agency Control has any financial obligation (for example, pursuant to a Loss Guarantee), and (ii) certain deemed asset transfers. "Acquiring" refers to a corporation that is a transferee of the assets and liabilities of a troubled Institution in a Taxable Transfer (other than a deemed transferee in a Taxable Transfer described in current § 1.597-5(b)). A "New Entity" is the new corporation that is treated as purchasing all the assets of a troubled Institution in a Taxable Transfer described in § 1.597-5(b)). A "Consolidated Subsidiary" is a member of the consolidated group of which an Institution is a member that bears the same relationship to the

Institution that the members of a consolidated group bear to their common parent under section 1504(a)(1). For additional terms not otherwise defined herein, *see* generally § 1.597-1(b).

Inclusion of FFA in Income

Under the current regulations, FFA generally is includible as ordinary income to the recipient at the time the FFA is received or accrued in accordance with the recipient's method of accounting. Section 1.597-2(a)(1). There are three exceptions to this general rule, however. First, if Net Worth Assistance is provided to Acquiring or a New Entity, the troubled Institution is treated as having directly received such FFA immediately before the transfer, and the Net Worth Assistance is treated as an asset that is sold in the Taxable Transfer. Section 1.597-5(c)(1). The inclusion of Net Worth Assistance in the troubled Institution's income generally will be offset by the Institution's net operating losses and other losses. Second, § 1.597-2(c) limits the amount of FFA an Institution currently must include in income under certain circumstances (for example, if the Institution has insufficient net operating losses and other losses to offset the inclusion of Net Worth Assistance in income) and provides rules for the deferred inclusion in income of amounts in excess of those limits. This provision results in matching the inclusion of FFA in income with the recognition of an Institution's built-in losses. Third, under § 1.597-2(d)(2), certain amounts received pursuant to a Loss Guarantee are included in the amount realized by Acquiring with respect to an asset subject to the Loss Guarantee rather than being included directly in gross income.

The typical Agency-assisted transaction involves the sale by Agency (in its capacity as receiver) of the troubled Institution's assets and the provision of FFA to Acquiring, which agrees to assume the troubled Institution's deposit liabilities. If, instead, an Agency-assisted transaction were structured as a stock purchase, the current regulations would treat the transaction as an asset transfer under certain circumstances. A deemed asset transfer occurs if a transaction structured as a transfer of Institution or Consolidated Subsidiary stock causes an Institution or its Consolidated Subsidiary to enter or leave a consolidated group (other than pursuant to an election under § 1.597-4(g)), or if the Institution or its Consolidated Subsidiary issues sufficient stock to

cause an ownership change of at least 50 percent (*see* § 1.597-5(b)). The foregoing rules are intended to treat an Agency-assisted acquisition of a troubled Institution as a taxable asset acquisition regardless of how the acquisition is structured. The treatment of certain stock transfers as asset transfers also fosters the matching of FFA income with a troubled Institution's losses by triggering the Institution's built-in losses.

If an Agency-assisted transaction involves an actual asset transfer, the amount realized by the transferor Institution is determined under section 1001(b) by reference to the consideration paid by Acquiring. If the transaction involves a deemed asset transfer instead, the amount realized is the grossed-up basis in the acquired stock plus the amount of liabilities assumed (plus certain other items). Section 1.597-5(c)(2).

Section 1.597-5(d)(2)(i) of the current regulations provides that the purchase price for assets acquired in a Taxable Transfer generally is allocated among the assets in the same manner as amounts are allocated among assets under § 1.338-6(b), (c)(1), and (c)(2). This means that the purchase price first is allocated to the Class I assets; then, to the extent the purchase price exceeds the value of the Class I assets, the remaining purchase price is allocated among the Class II assets in proportion to their fair market value. Any remaining purchase price after allocation to the Class II assets is then allocated in a similar method among the Class III, IV, V, VI, and VII assets *seriatim*.

The current regulations modify certain aspects of the section 338 allocation rules. Section 1.597-5(c)(3)(ii) treats an asset subject to a Loss Guarantee as a Class II asset with a fair market value that cannot be less than its highest guaranteed value or the highest price at which it can be put. Further, § 1.597-5(d)(2)(iii) provides that if the fair market value of the Class I and Class II assets acquired in a Taxable Transfer is greater than Acquiring's or a New Entity's purchase price for the acquired assets, then the basis of the Class I and Class II assets equals their fair market value (which, in the case of an asset subject to a Loss Guarantee, cannot be less than its highest guaranteed value or the highest price at which it can be put). The amount by which the assets' fair market value exceeds the purchase price is included ratably as ordinary income by Acquiring or a New Entity over a six-year period beginning in the year of the Taxable Transfer.

In certain situations, Agency may organize a “Bridge Bank” to hold the deposit liabilities and assets of a troubled Institution and continue its operations pending its acquisition or liquidation. In general, a Bridge Bank and its associated “Residual Entity” (the entity that remains after the troubled Institution transfers its deposit liabilities to the Bridge Bank) are treated as a single entity for income tax purposes and are treated together as the successor to the troubled Institution. Thus, for example, the transferring Institution recognizes no gain or loss on the transfer of deposit liabilities to a Bridge Bank, and the Bridge Bank succeeds to the transferring Institution’s basis in any transferred assets, its other tax attributes, its Taxpayer Identification Number (“TIN”), its taxable year, and its status as a member of a consolidated group. The Bridge Bank also is responsible for filing all income tax returns and statements for this single entity and is the agent for the Residual Entity (which effectively is treated as a division of the Bridge Bank). Section 1.597–4(d) and (e).

To ensure that FFA is included in the income of the transferor Institution or its consolidated group, current § 1.597–4(f) provides that the Institution remains a member of its consolidated group regardless of its placement under Agency Control or the transfer of its deposit liabilities to a Bridge Bank, unless an election is made under § 1.597–4(g) to disaffiliate the Institution. Under § 1.597–4(g), a consolidated group may elect to exclude from the group a subsidiary member that is an Institution in Agency receivership. The election is irrevocable and requires the inclusion of a “toll charge” in the group’s income (the toll charge is intended to reflect the amount the group would include in income if Agency were to provide the entire amount of FFA necessary to restore the Institution’s solvency at the time of the event permitting disaffiliation). Section § 1.597–4(g)(6) further imposes a deemed election (subject to the toll charge) if members of a consolidated group deconsolidate a subsidiary Institution in contemplation of Agency Control or the receipt of FFA. After any affirmative or deemed election to disaffiliate, an Institution generally is treated as a new unaffiliated corporation that received its assets and liabilities in a section 351 transaction (and thus has no net operating or capital loss carryforwards) and that holds an account receivable for future FFA with a basis equal to the toll charge (to offset the inclusion of future FFA). Section

1.597–4(g)(4)(i). The regulations under section 597 take precedence over any conflicting provisions in the regulations under section 1502. Section 1.597–4(f)(3).

Explanation of Provisions

The Treasury Department and the IRS received many comments suggesting that changes be made to the current regulations under section 597. These proposed regulations address many of these comments as well as additional concerns not raised in comments. Not all comments resulted in proposed modifications to the regulations. For example, as discussed in sections 9, 10, and 11 of this preamble, the proposed regulations generally have not been modified to match non-tax accounting treatment. This preamble describes the proposed changes and also addresses certain areas in which commenters requested changes but no changes are proposed.

These regulations propose to modify and clarify the treatment of certain transactions in which FFA is provided to Institutions (and related persons). The proposed regulations remove all references to “highest guaranteed value” and provide guidance relating to the determination of assets’ fair market value. In addition, the proposed regulations provide guidance regarding the transfer of property to Agency by a non-consolidated affiliate of an Institution, the ownership of assets subject to a Loss Guarantee (“Covered Assets”), and the determination of Acquiring’s purchase price when it has an option to purchase additional assets. The proposed regulations also make changes to facilitate e-filing, remove the reference to former § 1.1502–76(b)(5)(ii) (which allowed a subsidiary that was a consolidated group member for 30 days or less during the group’s taxable year to elect not to be included as a group member for that year), make a non-substantive change to the terminology used in § 1.597–5(b)(1) and (2) to clarify that the events resulting in a deemed acquisition of assets must occur to an Institution or a Consolidated Subsidiary of an Institution, and make a non-substantive change to the definition of Consolidated Subsidiary. In addition, there are numerous non-substantive changes that pervade all sections of the current regulations. Thus, the proposed regulations amend and restate all of §§ 1.597–1 through 1.597–7 in order to make the reading of the regulations more user-friendly. The proposed regulations make no changes to § 1.597–8.

1. Removal of References to Highest Guaranteed Value

It is common practice for Agency to provide a Loss Guarantee that does not provide for payment of a specific amount with respect to a Covered Asset, but that instead provides for reimbursement to an Institution for a percentage of its losses on Covered Assets, with the reimbursement percentage changing if a certain threshold of losses is met (a “Loss Share Agreement”). For example, assume that a guaranteed party has a pool of loans with an unpaid principal balance of \$90 million and owns real estate with a book value of \$10 million, and that Agency enters into a Loss Share Agreement whereby Agency will reimburse the guaranteed party zero percent of the first \$20 million of losses (the “first loss tranche”) on the Covered Assets (the pool of loans and the real estate) and 80 percent of any additional losses (the “second loss tranche”) on the Covered Assets. Losses generally are determined by reference to the unpaid principal balance of a loan or the book value of an asset, not by reference to tax basis.

The Treasury Department and the IRS have received comments and inquiries from taxpayer groups asking how to calculate a Covered Asset’s “highest guaranteed value” under a Loss Share Agreement. This term, which appears in §§ 1.597–3(f), 1.597–5(c)(3)(ii), and 1.597–5(f) (Example 4) of the current regulations, is not presently defined, and the Treasury Department and the IRS understand that there may be uncertainty in determining how to calculate highest guaranteed value in the absence of guidance. Moreover, commenters have observed that reliance on certain measures of highest guaranteed value may cause basis to be allocated to assets in amounts that exceed the total principal collections and Agency reimbursements that Acquiring reasonably can expect to receive.

To alleviate confusion and possible distortions created by use of the term “highest guaranteed value,” and because of the clarification of the meaning of “fair market value” (as discussed in the paragraphs that follow), the Treasury Department and the IRS have removed all references to “highest guaranteed value” from the regulations.

2. Determination of Fair Market Value of Covered Assets

Taxpayers have asked whether potential Agency payments pursuant to a Loss Guarantee are included in determining the fair market value of a Covered Asset. Legislative history

provides that Congress intended “that basis be allocated to the specified assets (or pool of assets) in an amount equal to their fair market value *as adjusted to reflect the capital loss guarantee and income maintenance agreements applicable to those assets.*” H.R. Rep. No. 101–54, pt. 2, at 28 (1989) (emphasis added). Accordingly, the proposed regulations provide that, in determining the fair market value of a Covered Asset, potential Loss Guarantee payments from Agency are included.

More specifically, the fair market value of a Covered Asset equals its “Expected Value”—the sum of (i) the amount a third party would pay for the asset absent the existence of a Loss Guarantee (the “Third-Party Price” or “TPP”), and (ii) the amount Agency would pay if the asset actually were sold for the Third-Party Price. If the amount Agency agrees to reimburse the guaranteed party is determined by a Loss Share Agreement, then for purposes of calculating the Expected Value, the amount that Agency would pay is determined by multiplying the loss (as determined under the terms of the Loss Share Agreement) that would be realized if the asset were disposed of at the Third-Party Price by the “Average Reimbursement Rate” (or “ARR”). In turn, the Average Reimbursement Rate is the percentage of losses under a Loss Share Agreement that would be reimbursed if every Covered Asset were disposed of for the Third-Party Price at the time of the Taxable Transfer. In effect, the ARR converts a multiple-tranche reimbursement into a single rate that covers all losses.

For example, assume that a guaranteed party has a pool of loans with an unpaid principal balance of \$90 million and owns real estate with a book value of \$10 million, and that Agency enters into a Loss Share Agreement whereby Agency will reimburse the guaranteed party zero percent of the first \$20 million of losses on the pool of loans and the real estate and 80 percent of any additional losses on these Covered Assets. Further assume that the Third-Party Price is \$46 million for the pool of loans and \$4 million for the real estate. If all of these assets were disposed of for the \$50 million Third-Party Price, the guaranteed party would have a total realized loss of \$50 million (\$100 million – \$50 million), and Agency would reimburse the guaranteed party a total of \$24 million (((\$20 million realized loss × 0%) + (\$30 million realized loss × 80%)). Therefore, the Average Reimbursement Rate would equal 48 percent (\$24 million reimbursement/\$50 million realized loss). The Expected Value of the pool of

loans thus would equal \$67.12 million (\$46 million TPP plus \$21.12 million from Agency (\$44 million realized loss × 48% ARR)), and the Expected Value of the real estate would equal \$6.88 million (\$4 million TPP plus \$2.88 million from Agency (\$6 million realized loss × 48% ARR)).

The Treasury Department and the IRS believe this definition of a Covered Asset’s fair market value furthers Congress’s intent and correctly represents the true economic value of a Covered Asset. Whether an Institution receives an amount on the disposition of an asset entirely from either the purchaser or from Agency, or whether the Institution instead receives a portion of the amount from the purchaser and the remainder from Agency, the asset is worth the same amount from the Institution’s perspective. To simplify the administration of these regulations, however, the Average Reimbursement Rate is determined at the time of the Taxable Transfer and is not adjusted for any changes in Third-Party Price over the life of any asset subject to a Loss Share Agreement or the prior disposition of any asset subject to a Loss Share Agreement.

For purposes of the foregoing example, the pool of loans has been treated as if it were a single asset. However, in applying the proposed regulations, the fair market value, Third-Party Price, and Expected Value of each loan within a pool must be determined separately. The Treasury Department and the IRS request comments as to whether an Institution that holds assets subject to a Loss Guarantee should be permitted or required to “pool” those assets for valuation purposes rather than value each asset separately. The Treasury Department and the IRS also request comments about how such a pooling approach should be implemented and about valuation and other issues that may arise from pooling assets.

3. Transfers of Property to Agency by a Non-Consolidated Affiliate of an Institution

Under current § 1.597–2(c)(4), an Institution must establish and maintain a deferred FFA account if any FFA received by the Institution is not currently included in its income. In general terms, a deferred FFA account is necessary if an Institution has insufficient net operating losses and other losses to fully offset an FFA inclusion. For example, assume that, at the beginning of the taxable year, Institution A has assets with a value of \$750 and a basis of \$800 (written down from \$1,000) and liabilities of \$1,000. A

has a \$200 net operating loss from writing down its assets. Further assume that Agency provides \$250 of Net Worth Assistance to Institution B in connection with B’s acquisition of A’s assets and liabilities. Under these circumstances, A would currently include \$200 of the Net Worth Assistance in income, and A would establish a deferred FFA account for the remaining \$50. As A recognizes built-in losses upon the sale of its assets, a corresponding amount of the \$50 of deferred FFA (which would be offset by these losses) would be taken into account. See § 1.597–2(c)(2).

Under current § 1.597–2(d)(4)(i), if an Institution transfers money or property to Agency, the amount of money and the fair market value of the property will decrease the balance in its deferred FFA account to the extent the amount transferred exceeds the amount Agency provides in the exchange. For purposes of the foregoing rules, an Institution is treated under § 1.597–2(d)(4)(iv) as having made any transfer to Agency that was made by any other member of its consolidated group, and appropriate investment basis adjustments must be made. However, there is no corresponding provision for transfers made by a person other than the Institution if the Institution is not a member of a consolidated group.

For example, assume that Corporation X (an includible corporation within the meaning of section 1504(b)) owns all of the outstanding stock of an Institution, but X and the Institution do not join in filing a consolidated return. Further assume that Agency provides \$10 million of FFA to the Institution in 2015 in exchange for a debt instrument of X (which, under § 1.597–3(b), is not treated as debt for any purposes of the Code while held by Agency); that the Institution has a deferred FFA account of \$5 million at the beginning of 2016; and that, during 2016, X makes a \$1 million payment on the debt instrument to Agency. Because X and the Institution do not join in filing a consolidated return, the Institution would not be able to reduce its FFA account to reflect X’s payment. Moreover, because the debt instrument is not treated as debt while held by Agency, X would not be allowed a deduction for any portion of the payment to Agency.

The proposed regulations expand § 1.597–2(d)(4)(iv) by providing that an Institution is treated as having made any transfer to Agency that was made by any other member of its affiliated group, regardless of whether a consolidated return is filed. Because the affiliate is transferring property to Agency to

reimburse Agency for FFA provided to the Institution, the Treasury Department and the IRS believe it is appropriate that the recipient of the FFA (in this case, the Institution) take such transfer into account in determining adjustments to its deferred FFA account, regardless of whether a consolidated return is filed. Economically, the reason for the transfer by the Institution's affiliate is the same. Appropriate adjustments must be made to reflect the affiliate's payment with respect to the Institution's FFA account.

4. Covered Assets Not Owned by an Institution

Section 1.597-3(a) of the current regulations provides that, for all Federal income tax purposes, an Institution is treated as the owner of all Covered Assets, regardless of whether Agency otherwise would be treated as the owner under general principles of income taxation. The Treasury Department and the IRS have become aware of certain instances in which Agency has provided Loss Guarantees to an Institution for assets held by a subsidiary of the Institution that is not a member of the Institution's consolidated group (for example, a real estate investment trust ("REIT")).

The intent behind § 1.597-3(a) of the current regulations was to prevent Agency from being considered the owner of Covered Assets even though Agency might have significant indicia of tax ownership with respect to such assets. The question of whether the Institution or its non-consolidated subsidiary should be treated as the owner of a Covered Asset was not considered because that scenario was not envisioned at the time the current regulations were promulgated. The proposed regulations modify this rule to clarify that the entity that actually holds the Covered Asset will be treated as the owner of such asset. Pursuant to proposed regulation § 1.597-2(d)(2)(ii), appropriate basis adjustments must be made to reflect the receipt of FFA by the Institution when the Covered Asset is disposed of or charged off by the asset's owner. The proposed regulations also provide that the deemed transfer of FFA by a regulated investment company ("RIC") or a REIT to the Institution, if a deemed distribution, will not be treated as a preferential dividend for purposes of sections 561, 562, 852, or 857.

5. Determination of Purchase Price When Acquiring Has Option To Purchase Additional Assets

Some taxpayers have questioned how the purchase price for assets is determined when the purchase

agreement provides Acquiring an option period (for example, 90 days) to decide whether it also wants to acquire the troubled Institution's physical assets (for example, branch buildings). The Treasury Department and the IRS believe that, in accord with general principles of tax law and the intent of the current regulations, the amount paid for assets subsequently acquired under an option should be integrated into the overall purchase price because the purchase of those assets relates back to, and is part of, the overall purchase agreement. The proposed regulations clarify the current regulations and update the citation in § 1.597-5(d)(1) to the final regulations under section 1060.

6. E-Filing

The proposed regulations make two changes to facilitate e-filing. First, the proposed regulations replace the requirement in current § 1.597-4(g)(5)(i)(A) that a consolidated group attach a copy of any election statement mailed to an affected Institution and the accompanying certified mail receipt to its income tax return with the requirement that the consolidated group include an election statement with its income tax return and retain a copy of certain documents in its records. Second, if an Institution without Continuing Equity (in other words, an Institution that is a Bridge Bank, in Agency receivership, or treated as a New Entity on the last day of the taxable year) is liable for income tax that is potentially not subject to collection because it would be borne by Agency, the proposed regulations replace the requirement in current § 1.597-6(c) that a consolidated group make a notation of such amount directly on the front page of its tax return with the requirement that a consolidated group include a statement providing such amount on its income tax return.

7. Removal of Outdated Provision

The proposed regulations remove paragraph § 1.597-4(f)(2) of the current regulations relating to a 30-day election to be excluded from the consolidated group. The 30-day election was eliminated for subsidiary members of a consolidated group that became or ceased to be members of the consolidated group on or after January 1, 1995. Therefore, the reference to such election is no longer necessary.

8. Consolidated Subsidiary

As noted previously, § 1.597-1(b) of the current regulations defines "Consolidated Subsidiary" to mean a member of the consolidated group of which an Institution is a member that

bears the same relationship to the Institution that the members of a consolidated group bear to their common parent under section 1504(a)(1). These proposed regulations modify this definition to provide that a "Consolidated Subsidiary" is a corporation that both (i) is a member of the same consolidated group as an Institution, and (ii) would be a member of the affiliated group that would be determined under section 1504(a) if the Institution were the common parent thereof. This change is intended merely to clarify the meaning of "Consolidated Subsidiary" and is not intended to be a substantive change.

The Treasury Department and the IRS request comments as to whether the rules in these proposed regulations concerning Consolidated Subsidiaries should be expanded to apply either to (i) an Institution's subsidiaries that are "includible corporations" (within the meaning of section 1504(b)) but that are not members of the Institution's consolidated group (such as affiliated but non-consolidated subsidiaries of an Institution or subsidiaries of an Institution that is an S corporation), or (ii) an Institution's subsidiaries that are not "includible corporations" (such as REITs). Any such comments should explain which (if any) provisions in the regulations should be changed and which provisions should continue to apply solely to Consolidated Subsidiaries (as defined in the proposed regulations). Such comments also should describe the reasons for the recommended change (or for making no change). Final regulations issued pursuant to this notice of proposed rulemaking may contain a broader rule than these proposed regulations.

9. Basis-Step-Up and Six-Year-Inclusion Rules

As noted previously, certain Taxable Transfers can result in the fair market value of Class I and Class II assets exceeding their purchase price and the inclusion of the excess in income by Acquiring or a New Entity over a six-year period. See § 1.597-5(d)(2)(iii). For example, assume that Acquiring assumes \$150,000 of a troubled Institution's deposit liabilities in Year 1 in exchange for Institution's Assets 1 and 2 (which have a 10-year weighted average life) and Agency's provision of an \$80,000 Loss Guarantee with respect to Asset 1 and a \$100,000 Loss Guarantee with respect to Asset 2. (These Loss Guarantees are not Loss Share Agreements.) Further assume that the Third-Party Price for Assets 1 and 2 is \$70,000 and \$95,000, respectively. Under the current regulations, the fair

market value of Assets 1 and 2 equals \$80,000 and \$100,000, respectively—each asset's highest guaranteed value. Under the proposed regulations, the fair market value of Assets 1 and 2 also equals \$80,000 and \$100,000, respectively—each asset's Expected Value. The aggregate fair market value of Assets 1 and 2 (\$180,000) thus exceeds their purchase price (\$150,000). At the end of Year 2, Acquiring wholly charges off Assets 1 and 2 and receives \$180,000 from Agency. Under the basis-step-up and six-year-inclusion rules in § 1.597-5(d)(2)(iii), Acquiring's aggregate basis in Assets 1 and 2 upon their acquisition equals their fair market value (\$180,000). Even though Assets 1 and 2 have a 10-year weighted average life, Acquiring may not depreciate these assets below \$180,000 because Agency guarantees Acquiring \$180,000 on the disposition of the assets. See § 1.597-3(f). Acquiring thus recognizes no gain or loss with respect to the charge-off of these assets in Year 2. Instead, Acquiring includes \$5,000 in income for each of Years 1–6 (\$30,000 excess of fair market value over purchase price/6 years).

One commenter suggested that the current rules may create a mismatch in the timing of a taxpayer's economic and taxable income that results in a timing benefit for, or a timing detriment to, either the taxpayer or the government, depending on the expected life of the purchased assets. For instance, in the foregoing example, Acquiring must include amounts in income over a six-year period even though Assets 1 and 2 have a 10-year weighted average life; consequently, this mismatch results in a detriment to the taxpayer. The commenter thus would eliminate the basis-step-up and six-year-inclusion rules, have Acquiring take an initial basis in the Class I and Class II assets equal to their purchase price, and then have Acquiring either (a) recognize gain upon the disposition of the assets, or (b) accrue income (and increase basis) in each year based on the weighted average life of the assets (rather than over a six-year period).

Under the commenter's first proposed approach, Acquiring's aggregate asset basis in the foregoing example would be \$150,000 (the amount of liabilities assumed) rather than \$180,000, and Acquiring would recognize \$30,000 of gain at the end of Year 2. Under the commenter's second proposed approach, the \$30,000 would be spread over 10 years; thus, Acquiring's economic and taxable income would be matched.

After consideration of the comment, these proposed regulations retain the

current basis-step-up and six-year-inclusion rules. The basis-step-up and six-year-inclusion rules prevent the realization of income from being a factor in the acquirer's decision whether to retain or dispose of Covered Assets. Furthermore, these rules lock in the tax cost of the purchase, which reduces the cost of uncertainties ultimately borne by Agency.

The Treasury Department and the IRS believe that, although the current rules may be imperfect (in that sometimes there will be a benefit and other times a detriment), they are administratively efficient and they satisfy the intent of the current regulations. Accordingly, these proposed regulations retain the current rules.

10. Treatment of Debt or Equity Issued to Agency

Section 1.597-3(b) of the current regulations disregards any debt or equity interests in the Institution (or any affiliates) that Agency receives in connection with a transaction in which FFA is provided while such debt or equity interests are held by Agency. One commenter supported eliminating the current rule (resulting in an Institution's debt or equity issued to Agency being included in Acquiring's purchase price) and replacing it with anti-abuse rules to address any concerns.

After consideration of the comment, these proposed regulations retain the current rules. The Treasury Department and the IRS believe that treating debt or equity interests in an Institution as having value would be inconsistent with section 597(c), which provides that all amounts provided by Agency are FFA regardless of whether Agency takes back an instrument in exchange therefor. Further, the current rule eliminates any issues for Agency and the IRS relating to valuation of the debt or equity interests.

11. Tax Treatment of Agency Payments Under Loss Share Agreements

The current regulations integrate the treatment of Loss Guarantee payments with other proceeds received with respect to Covered Assets, whereas under non-tax accounting principles a Loss Guarantee is treated as a separate asset and source of income. Commenters suggested that the tax treatment of Loss Guarantees and payments thereunder be conformed to the non-tax accounting treatment thereof. After consideration of these comments, these proposed regulations retain the current rules. The Treasury Department and the IRS believe the treatment of Loss Guarantee payments in the current and proposed regulations comports better with general

income tax principles (for example, treating Loss Guarantee payments as part of the consideration received with respect to a Covered Asset is analogous to the tax treatment of insurance proceeds received with respect to other losses).

12. Effective/Applicability Date

The proposed regulations will be effective on the date of publication of the Treasury decision adopting these proposed rules as final regulations in the **Federal Register**, except with respect to FFA provided pursuant to an agreement entered into before such date. In the latter case, the current regulations will continue to apply unless the taxpayer elects to apply the final regulations on a retroactive basis. However, the election to apply the final regulations on a retroactive basis cannot be made if the period for assessment and collection of tax has expired under the rules of section 6501 for any taxable year in which §§ 1.597-1 through 1.597-6 would affect the determination of the electing entity's or group's income, deductions, gain, loss, basis, or other items.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866, as supplemented by Executive Order 13563. Therefore, a regulatory assessment is not required. It also has been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) does not apply to these regulations. It is hereby certified that these regulations will not have a significant economic impact on a substantial number of small entities. This certification is based on the fact that the regulations apply only to transactions involving banks or domestic building and loan associations, which tend to be larger businesses. Accordingly, a Regulatory Flexibility Analysis under the Regulatory Flexibility Act (5 U.S.C. chapter 6) is not required. Pursuant to section 7805(f) of the Code, these regulations have been submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small business.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written comments (a signed original and eight (8) copies) or electronic comments that are submitted timely to the IRS. In addition to the specific requests for

comments made elsewhere in this preamble, the Treasury Department and the IRS request comments on all aspects of the proposed rules. All comments will be available for public inspection and copying. A public hearing may be scheduled if requested in writing by any person who timely submits written comments. If a public hearing is scheduled, notice of the date, time, and place of the hearing will be published in the **Federal Register**.

Drafting Information

The principal author of these proposed regulations is Russell G. Jones of the Office of Associate Chief Counsel (Corporate). However, other personnel from the Treasury Department and the IRS participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

■ **Paragraph 1.** The authority citation for part 1 continues to read in part as follows:

Authority: 26 U.S.C. 7805, unless otherwise noted. * * *

■ **Par. 2.** Section 1.597–1 is revised to read as follows:

§ 1.597–1 Definitions.

For purposes of the regulations under section 597—

(a) Unless the context otherwise requires, the terms *consolidated group*, *member*, and *subsidiary* have the meanings provided in § 1.1502–1; and

(b) The following terms have the meanings provided below:

Acquiring. The term *Acquiring* means a corporation that is a transferee in a Taxable Transfer, other than a deemed transferee in a Taxable Transfer described in § 1.597–5(b).

Agency. The term *Agency* means the Resolution Trust Corporation, the Federal Deposit Insurance Corporation, any similar instrumentality of the United States government, and any predecessor or successor of the foregoing (including the Federal Savings and Loan Insurance Corporation).

Agency Control. An Institution or entity is under *Agency Control* if Agency is conservator or receiver of the Institution or entity, or if Agency has the right to appoint any of the Institution's or entity's directors.

Agency Obligation. The term *Agency Obligation* means a debt instrument that

Agency issues to an Institution or to a direct or indirect owner of an Institution.

Average Reimbursement Rate. The term *Average Reimbursement Rate* means the percentage of losses (as determined under the terms of the Loss Share Agreement) that would be reimbursed by Agency or a Controlled Entity if every asset subject to a Loss Share Agreement were disposed of for the Third-Party Price. The Average Reimbursement Rate is determined at the time of the Taxable Transfer and is not adjusted for any changes in Third-Party Price over the life of any asset subject to the Loss Share Agreement or the prior disposition of any asset subject to the Loss Share Agreement.

Bridge Bank. The term *Bridge Bank* means an Institution that is organized by Agency to hold assets and liabilities of another Institution and that continues the operation of the other Institution's business pending its acquisition or liquidation, and that is any of the following:

(1) A national bank chartered by the Comptroller of the Currency under section 11(n) of the Federal Deposit Insurance Act (12 U.S.C. 1821(n)) or section 21A(b)(10)(A) of the Federal Home Loan Bank Act (12 U.S.C. 1441a(b)(10)(A), prior to its repeal by Pub. L. 111–203), or under any successor sections;

(2) A Federal savings association chartered by the Director of the Office of Thrift Supervision under section 21A(b)(10)(A) of the Federal Home Loan Bank Act (12 U.S.C. 1441a(b)(10)(A), prior to its repeal by Pub. L. 111–203) or any successor section; or

(3) A similar Institution chartered under any other statutory provisions.

Consolidated Subsidiary. The term *Consolidated Subsidiary* means a corporation that both:

(1) Is a member of the same consolidated group as an Institution; and

(2) Would be a member of the affiliated group that would be determined under section 1504(a) if the Institution were the common parent thereof.

Continuing Equity. An Institution has *Continuing Equity* for any taxable year if, on the last day of the taxable year, the Institution is not a Bridge Bank, in Agency receivership, or treated as a New Entity.

Controlled Entity. The term *Controlled Entity* means an entity under Agency Control.

Covered Asset. The term *Covered Asset* means an asset subject to a Loss Guarantee. The fair market value of a

Covered Asset equals the asset's Expected Value.

Expected Value. The term *Expected Value* means the sum of the Third-Party Price for a Covered Asset and the amount that Agency or a Controlled Entity would pay under the Loss Guarantee if the asset actually were sold for the Third-Party Price. For purposes of the preceding sentence, if an asset is subject to a Loss Share Agreement, the amount that Agency or a Controlled Entity would pay under a Loss Guarantee with respect to the asset is determined by multiplying the amount of loss that would be realized under the terms of the Loss Share Agreement if the asset were disposed of at the Third-Party Price by the Average Reimbursement Rate.

Federal Financial Assistance. The term *Federal Financial Assistance* (FFA), as defined by section 597(c), means any money or property provided by Agency to an Institution or to a direct or indirect owner of stock in an Institution under section 406(f) of the National Housing Act (12 U.S.C. 1729(f), prior to its repeal by Pub. L. 101–73), section 21A(b)(4) of the Federal Home Loan Bank Act (12 U.S.C. 1441a(b)(4), prior to its repeal by Pub. L. 111–203), section 11(f) or 13(c) of the Federal Deposit Insurance Act (12 U.S.C. 1821(f), 1823(c)), or any similar provision of law. Any such money or property is FFA, regardless of whether the Institution or any of its affiliates issues Agency a note or other obligation, stock, warrants, or other rights to acquire stock in connection with Agency's provision of the money or property. FFA includes Net Worth Assistance, Loss Guarantee payments, yield maintenance payments, cost to carry or cost of funds reimbursement payments, expense reimbursement or indemnity payments, and interest (including original issue discount) on an Agency Obligation.

Institution. The term *Institution* means an entity that is, or immediately before being placed under Agency Control was, a bank or domestic building and loan association within the meaning of section 597 (including a Bridge Bank). Except as otherwise provided in the regulations under section 597, the term Institution includes a New Entity or Acquiring that is a bank or domestic building and loan association within the meaning of section 597.

Loss Guarantee. The term *Loss Guarantee* means an agreement pursuant to which Agency or a Controlled Entity guarantees or agrees to pay an Institution a specified amount upon the disposition or charge-off (in

whole or in part) of specific assets, an agreement pursuant to which an Institution has a right to put assets to Agency or a Controlled Entity at a specified price, a Loss Share Agreement, or a similar arrangement.

Loss Share Agreement. The term *Loss Share Agreement* means an agreement pursuant to which Agency or a Controlled Entity agrees to reimburse the guaranteed party a percentage of losses realized.

Net Worth Assistance. The term *Net Worth Assistance* means money or property (including an Agency Obligation to the extent it has a fixed principal amount) that Agency provides as an integral part of a Taxable Transfer, other than FFA that accrues after the date of the Taxable Transfer. For example, Net Worth Assistance does not include Loss Guarantee payments, yield maintenance payments, cost to carry or cost of funds reimbursement payments, or expense reimbursement or indemnity payments. An Agency Obligation is considered to have a fixed principal amount notwithstanding an agreement providing for its adjustment after issuance to reflect a more accurate determination of the condition of the Institution at the time of the acquisition.

New Entity. The term *New Entity* means the new corporation that is treated as purchasing all of the assets of an Old Entity in a Taxable Transfer described in § 1.597–5(b).

Old Entity. The term *Old Entity* means the Institution or Consolidated Subsidiary that is treated as selling all of its assets in a Taxable Transfer described in § 1.597–5(b).

Residual Entity. The term *Residual Entity* means the entity that remains after an Institution transfers deposit liabilities to a Bridge Bank.

Taxable Transfer. The term *Taxable Transfer* has the meaning provided in § 1.597–5(a)(1).

Third-Party Price. The term *Third-Party Price* means the amount that a third party would pay for an asset absent the existence of a Loss Guarantee.

■ **Par. 3.** Section 1.597–2 is revised to read as follows:

§ 1.597–2 Taxation of Federal financial assistance.

(a) *Inclusion in income*—(1) *In general.* Except as otherwise provided in the regulations under section 597, all FFA is includible as ordinary income to the recipient at the time the FFA is received or accrued in accordance with the recipient's method of accounting. The amount of FFA received or accrued is the amount of any money, the fair market value of any property (other than

an Agency Obligation), and the issue price of any Agency Obligation (determined under § 1.597–3(c)(2)). An Institution (and not the nominal recipient) is treated as receiving directly any FFA that Agency provides in a taxable year to a direct or indirect shareholder of the Institution, to the extent the money or property is transferred to the Institution pursuant to an agreement with Agency.

(2) *Cross references.* See paragraph (c) of this section for rules regarding the timing of inclusion of certain FFA. See paragraph (d) of this section for additional rules regarding the treatment of FFA received in connection with transfers of money or property to Agency or a Controlled Entity, or paid pursuant to a Loss Guarantee. See § 1.597–5(c)(1) for additional rules regarding the inclusion of Net Worth Assistance in the income of an Institution.

(b) *Basis of property that is FFA.* If FFA consists of property, the Institution's basis in the property equals the fair market value of the property (other than an Agency Obligation) or the issue price of the Agency Obligation (as determined under § 1.597–3(c)(2)).

(c) *Timing of inclusion of certain FFA*—(1) *Scope.* This paragraph (c) limits the amount of FFA an Institution must include in income currently under certain circumstances and provides rules for the deferred inclusion in income of amounts in excess of those limits. This paragraph (c) does not apply to a New Entity or Acquiring.

(2) *Amount currently included in income by an Institution without Continuing Equity.* The amount of FFA an Institution without Continuing Equity must include in income in a taxable year under paragraph (a)(1) of this section is limited to the sum of—

(i) The excess at the beginning of the taxable year of the Institution's liabilities over the adjusted bases of the Institution's assets; and

(ii) The amount by which the excess for the taxable year of the Institution's deductions allowed by chapter 1 of the Internal Revenue Code (other than net operating and capital loss carryovers) over its gross income (determined without regard to FFA) is greater than the excess at the beginning of the taxable year of the adjusted bases of the Institution's assets over the Institution's liabilities.

(3) *Amount currently included in income by an Institution with Continuing Equity.* The amount of FFA an Institution with Continuing Equity must include in income in a taxable year under paragraph (a)(1) of this section is limited to the sum of—

(i) The excess at the beginning of the taxable year of the Institution's liabilities over the adjusted bases of the Institution's assets;

(ii) The greater of—

(A) The excess for the taxable year of the Institution's deductions allowed by chapter 1 of the Internal Revenue Code (other than net operating and capital loss carryovers) over its gross income (determined without regard to FFA); or

(B) The excess for the taxable year of the deductions allowed by chapter 1 of the Internal Revenue Code (other than net operating and capital loss carryovers) of the consolidated group of which the Institution is a member on the last day of the Institution's taxable year over the group's gross income (determined without regard to FFA); and

(iii) The excess of the amount of any net operating loss carryover of the Institution (or in the case of a carryover from a consolidated return year of the Institution's current consolidated group, the net operating loss carryover of the group) to the taxable year over the amount described in paragraph (c)(3)(i) of this section.

(4) *Deferred FFA*—(i) *Maintenance of account.* An Institution must establish a deferred FFA account commencing in the first taxable year in which it receives FFA that is not currently included in income under paragraph (c)(2) or (c)(3) of this section, and must maintain that account in accordance with the requirements of this paragraph (c)(4). The Institution must add the amount of any FFA that is not currently included in income under paragraph (c)(2) or (c)(3) of this section to its deferred FFA account. The Institution must decrease the balance of its deferred FFA account by the amount of deferred FFA included in income under paragraphs (c)(4)(ii), (iv), and (v) of this section. (See also paragraphs (d)(4) and (d)(5)(i)(B) of this section for other adjustments that decrease the deferred FFA account.) If, under paragraph (c)(3) of this section, FFA is not currently included in income in a taxable year, the Institution thereafter must maintain its deferred FFA account on a FIFO (first in, first out) basis (for example, for purposes of the first sentence of paragraph (c)(4)(iv) of this section).

(ii) *Deferred FFA recapture.* In any taxable year in which an Institution has a balance in its deferred FFA account, it must include in income an amount equal to the lesser of the amount described in paragraph (c)(4)(iii) of this section or the balance in its deferred FFA account.

(iii) *Annual recapture amount*—(A) *Institutions without Continuing Equity*—

(1) *In general.* In the case of an Institution without Continuing Equity, the amount described in this paragraph (c)(4)(iii) is the amount by which—

(i) The excess for the taxable year of the Institution's deductions allowed by chapter 1 of the Internal Revenue Code (other than net operating and capital loss carryovers) over its gross income (taking into account FFA included in income under paragraph (c)(2) of this section) is greater than

(ii) The Institution's remaining equity as of the beginning of the taxable year.

(2) *Remaining equity.* The Institution's remaining equity is—

(i) The amount at the beginning of the taxable year in which the deferred FFA account was established equal to the adjusted bases of the Institution's assets minus the Institution's liabilities (which amount may be positive or negative); plus

(ii) The Institution's taxable income (computed without regard to any carryover from any other year) in any subsequent taxable year or years; minus

(iii) The excess in any subsequent taxable year or years of the Institution's deductions allowed by chapter 1 of the Internal Revenue Code (other than net operating and capital loss carryovers) over its gross income.

(B) *Institutions with Continuing Equity.* In the case of an Institution with Continuing Equity, the amount described in this paragraph (c)(4)(iii) is the amount by which the Institution's deductions allowed by chapter 1 of the Internal Revenue Code (other than net operating and capital loss carryovers) exceed its gross income (taking into account FFA included in income under paragraph (c)(3) of this section).

(iv) *Additional deferred FFA recapture by an Institution with Continuing Equity.* To the extent that, as of the end of a taxable year, the cumulative amount of FFA deferred under paragraph (c)(3) of this section that an Institution with Continuing Equity has recaptured under this paragraph (c)(4) is less than the cumulative amount of FFA deferred under paragraph (c)(3) of this section that the Institution would have recaptured if that FFA had been included in income ratably over the six taxable years immediately following the taxable year of deferral, the Institution must include that difference in income for the taxable year. An Institution with Continuing Equity must include in income the balance of its deferred FFA account in the taxable year in which it liquidates, ceases to do business, transfers (other than to a Bridge Bank) substantially all of its assets and

liabilities, or is deemed to transfer all of its assets under § 1.597-5(b).

(v) *Optional accelerated recapture of deferred FFA.* An Institution that has a deferred FFA account may include in income the balance of its deferred FFA account on its timely filed (including extensions) original income tax return for any taxable year that it is not under Agency Control. The balance of its deferred FFA account is income on the last day of that year.

(5) *Exceptions to limitations on use of losses.* In computing an Institution's taxable income or alternative minimum taxable income for a taxable year, sections 56(d)(1), 382, and 383 and §§ 1.1502-15, 1.1502-21, and 1.1502-22 (or §§ 1.1502-15A, 1.1502-21A, and 1.1502-22A, as appropriate) do not limit the use of the attributes of the Institution to the extent, if any, that the inclusion of FFA (including recaptured FFA) in income results in taxable income or alternative minimum taxable income (determined without regard to this paragraph (c)(5)) for the taxable year. This paragraph (c)(5) does not apply to any limitation under section 382 or 383 or §§ 1.1502-15, 1.1502-21, or 1.1502-22 (or §§ 1.1502-15A, 1.1502-21A, or 1.1502-22A, as appropriate) that arose in connection with or prior to a corporation becoming a Consolidated Subsidiary of the Institution.

(6) *Operating rules—(i) Bad debt reserves.* For purposes of paragraphs (c)(2), (c)(3), and (c)(4) of this section, the adjusted bases of an Institution's assets are reduced by the amount of the Institution's reserves for bad debts under section 585 or 593, other than supplemental reserves under section 593.

(ii) *Aggregation of Consolidated Subsidiaries.* For purposes of this paragraph (c), an Institution is treated as a single entity that includes the income, expenses, assets, liabilities, and attributes of its Consolidated Subsidiaries, with appropriate adjustments to prevent duplication.

(iii) *Alternative minimum tax.* To compute the alternative minimum taxable income attributable to FFA of an Institution for any taxable year under section 55, the rules of this section, and related rules, are applied by using alternative minimum tax basis, deductions, and all other items required to be taken into account. All other alternative minimum tax provisions continue to apply.

(7) *Earnings and profits.* FFA that is not currently included in income under this paragraph (c) is included in earnings and profits for all purposes of the Internal Revenue Code to the extent

and at the time it is included in income under this paragraph (c).

(d) *Transfers of money or property to Agency, and Covered Assets—(1) Transfers of property to Agency.* Except as provided in paragraph (d)(4)(iii) of this section, the transfer of property to Agency or a Controlled Entity is a taxable sale or exchange in which the Institution is treated as realizing an amount equal to the property's fair market value.

(2) *FFA with respect to Covered Assets other than on transfer to Agency—(i)* FFA provided pursuant to a Loss Guarantee with respect to a Covered Asset is included in the amount realized with respect to the Covered Asset.

(ii) If Agency makes a payment to an Institution pursuant to a Loss Guarantee with respect to a Covered Asset owned by an entity other than the Institution, the payment will be treated as made directly to the owner of the Covered Asset and included in the amount realized with respect to the Covered Asset when the Covered Asset is sold or charged off. The payment will be treated as further transferred through chains of ownership to the extent necessary to reflect the actual receipt of such payment. Any such transfer, if a deemed distribution, will not be a preferential dividend for purposes of sections 561, 562, 852, or 857.

(iii) For the purposes of this paragraph (d)(2), references to an amount realized include amounts obtained in whole or partial satisfaction of loans, amounts obtained by virtue of charging off or marking to market a Covered Asset, and other amounts similarly related to property, whether or not disposed of.

(3) *Treatment of FFA received in exchange for property.* FFA included in the amount realized for property under this paragraph (d) is not includible in income under paragraph (a)(1) of this section. The amount realized is treated in the same manner as if realized from a person other than Agency or a Controlled Entity. For example, gain attributable to FFA received with respect to a capital asset retains its character as capital gain. Similarly, FFA received with respect to property that has been charged off for income tax purposes is treated as a recovery to the extent of the amount previously charged off. Any FFA provided in excess of the amount realized under this paragraph (d) is includible in income under paragraph (a)(1) of this section.

(4) *Adjustment to FFA—(i) In general.* If an Institution pays or transfers money or property to Agency or a Controlled Entity, the amount of money and the fair market value of the property is an

adjustment to its FFA to the extent the amount paid and transferred exceeds the amount of money and the fair market value of any property that Agency or a Controlled Entity provides in exchange.

(ii) *Deposit insurance.* This paragraph (d)(4) does not apply to amounts paid to Agency with respect to deposit insurance.

(iii) *Treatment of an interest held by Agency or a Controlled Entity—(A) In general.* For purposes of this paragraph (d), an interest described in § 1.597–3(b) is not treated as property when transferred by the issuer to Agency or a Controlled Entity nor when acquired from Agency or a Controlled Entity by the issuer.

(B) *Dispositions to persons other than issuer.* On the date Agency or a Controlled Entity transfers an interest described in § 1.597–3(b) to a holder other than the issuer, Agency, or a Controlled Entity, the issuer is treated for purposes of this paragraph (d)(4) as having transferred to Agency an amount of money equal to the sum of the amount of money and the fair market value of property that was paid by the new holder as consideration for the interest.

(iv) *Affiliated groups.* For purposes of this paragraph (d), an Institution is treated as having made any transfer to Agency or a Controlled Entity that was made by any other member of its affiliated group. The affiliated group must make appropriate basis adjustments or other adjustments to the extent the member transferring money or other property is not the member that received FFA.

(5) *Manner of making adjustments to FFA—(i) Reduction of FFA and deferred FFA.* An Institution adjusts its FFA under paragraph (d)(4) of this section by reducing in the following order and in an aggregate amount not greater than the adjustment—

(A) The amount of any FFA that is otherwise includible in income for the taxable year (before application of paragraph (c) of this section); and

(B) The balance (but not below zero) in the deferred FFA account, if any, maintained under paragraph (c)(4) of this section.

(ii) *Deduction of excess amounts.* If the amount of the adjustment exceeds the sum of the amounts described in paragraph (d)(5)(i) of this section, the Institution may deduct the excess to the extent the deduction does not exceed the amount of FFA included in income for prior taxable years reduced by the amount of deductions allowable under this paragraph (d)(5)(ii) in prior taxable years.

(iii) *Additional adjustments.* Any adjustment to FFA in excess of the sum of the amounts described in paragraphs (d)(5)(i) and (ii) of this section is treated—

(A) By an Institution other than a New Entity or Acquiring, as a deduction of the amount in excess of FFA received that is required to be transferred to Agency under section 11(g) of the Federal Deposit Insurance Act (12 U.S.C. 1821(g)); or

(B) By a New Entity or Acquiring, as an adjustment to the purchase price paid in the Taxable Transfer (see § 1.338–7).

(e) *Examples.* The following examples illustrate the provisions of this section:

Example 1. Timing of inclusion of FFA in income. (i) Institution M, a calendar-year taxpayer without Continuing Equity because it is in Agency receivership, is not a member of a consolidated group and has not been acquired in a Taxable Transfer. On January 1, 2016, M has assets with a total adjusted basis of \$100 million and total liabilities of \$120 million. M's deductions do not exceed its gross income (determined without regard to FFA) for 2016. Agency provides \$30 million of FFA to M in 2016. The amount of this FFA that M must include in income in 2016 is limited by paragraph (c)(2) of this section to \$20 million, the amount by which M's liabilities (\$120 million) exceed the total adjusted basis of its assets (\$100 million) at the beginning of the taxable year. Pursuant to paragraph (c)(4)(i) of this section, M must establish a deferred FFA account for the remaining \$10 million.

(ii) If Agency instead lends M the \$30 million, M's indebtedness to Agency is disregarded and the results are the same as in paragraph (i) of this *Example 1* under section 597(c), paragraph (b) of § 1.597–1, and paragraph (b) of § 1.597–3.

Example 2. Transfer of property to Agency.

(i) Institution M, a calendar-year taxpayer without Continuing Equity because it is in Agency receivership, is not a member of a consolidated group and has not been acquired in a Taxable Transfer. At the beginning of 2016, M's remaining equity is \$0 and M has a deferred FFA account of \$10 million. Agency does not provide any FFA to M in 2016. During the year, M transfers property not subject to a Loss Guarantee to Agency and does not receive any consideration. The property has an adjusted basis of \$5 million and a fair market value of \$1 million at the time of the transfer. M has no other taxable income or loss in 2016.

(ii) Under paragraph (d)(1) of this section, M is treated as selling the property for \$1 million, its fair market value, thus recognizing a \$4 million loss (\$5 million – \$1 million). In addition, because M did not receive any consideration from Agency, under paragraph (d)(4) of this section M has an adjustment to FFA of \$1 million, the amount by which the fair market value of the transferred property (\$1 million) exceeds the consideration M received from Agency (\$0). Because no FFA is provided to M in 2016, this adjustment reduces the balance of M's

deferred FFA account to \$9 million (\$10 million – \$1 million) under paragraph (d)(5)(i)(B) of this section. Because M's \$4 million loss causes M's deductions to exceed its gross income by \$4 million in 2016 and M has no remaining equity, under paragraph (c)(4)(iii)(A) of this section M must include \$4 million of deferred FFA in income and must decrease the remaining \$9 million balance of its deferred FFA account by the same amount, leaving a balance of \$5 million.

Example 3. Loss Guarantee. Institution Q, a calendar-year taxpayer, holds a Covered Asset (Asset Z). Q's adjusted basis in Asset Z is \$10,000. Q sells Asset Z to an unrelated third party for \$4,000. Pursuant to the Loss Guarantee, Agency pays Q \$6,000 (\$10,000 – \$4,000). Q's amount realized from the sale of Asset Z is \$10,000 (\$4,000 from the third party and \$6,000 from Agency) under paragraph (d)(2) of this section. Q realizes no gain or loss on the sale (\$10,000 – \$10,000 = \$0), and therefore includes none of the \$6,000 of FFA it receives pursuant to the Loss Guarantee in income under paragraph (d)(3) of this section.

■ **Par. 4.** Section 1.597–3 is revised to read as follows:

§ 1.597–3 Other rules.

(a) *Ownership of assets.* For all income tax purposes, Agency is not treated as the owner of assets subject to a Loss Guarantee, yield maintenance agreement, or cost to carry or cost of funds reimbursement agreement, regardless of whether it otherwise would be treated as the owner under general principles of income taxation.

(b) *Debt and equity interests received by Agency.* Debt instruments, stock, warrants, or other rights to acquire stock of an Institution (or any of its affiliates) that Agency or a Controlled Entity receives in connection with a transaction in which FFA is provided are not treated as debt, stock, or other equity interests of or in the issuer for any purpose of the Internal Revenue Code while held by Agency or a Controlled Entity. On the date Agency or a Controlled Entity transfers an interest described in this paragraph (b) to a holder other than Agency or a Controlled Entity, the interest is treated as having been newly issued by the issuer to the holder with an issue price equal to the sum of the amount of money and the fair market value of property paid by the new holder in exchange for the interest.

(c) *Agency Obligations—(1) In general.* Except as otherwise provided in this paragraph (c), the original issue discount rules of sections 1271 et. seq. apply to Agency Obligations.

(2) *Issue price of Agency Obligations provided as Net Worth Assistance.* The issue price of an Agency Obligation that is provided as Net Worth Assistance and

that bears interest at either a single fixed rate or a qualified floating rate (and provides for no contingent payments) is the lesser of the sum of the present values of all payments due under the obligation, discounted at a rate equal to the applicable Federal rate (within the meaning of section 1274(d)(1) and (3)) in effect for the date of issuance, or the stated principal amount of the obligation. The issue price of an Agency Obligation that bears a qualified floating rate of interest (within the meaning of § 1.1275-5(b)) is determined by treating the obligation as bearing a fixed rate of interest equal to the rate in effect on the date of issuance under the obligation.

(3) *Adjustments to principal amount.* Except as provided in § 1.597-5(d)(2)(iv), this paragraph (c)(3) applies if Agency modifies or exchanges an Agency Obligation provided as Net Worth Assistance (or a successor obligation). The issue price of the modified or new Agency Obligation is determined under paragraphs (c)(1) and (2) of this section. If the issue price is greater than the adjusted issue price of the existing Agency Obligation, the difference is treated as FFA. If the issue price is less than the adjusted issue price of the existing Agency Obligation, the difference is treated as an adjustment to FFA under § 1.597-2(d)(4).

(d) *Successors.* To the extent necessary to effectuate the purposes of the regulations under section 597, an entity's treatment under the regulations applies to its successor. A successor includes a transferee in a transaction to which section 381(a) applies or a Bridge Bank to which another Bridge Bank transfers deposit liabilities.

(e) [Reserved].

(f) *Losses and deductions with respect to Covered Assets.* Prior to the disposition of a Covered Asset, the asset cannot be charged off, marked to a market value, depreciated, amortized, or otherwise treated in a manner that supposes an actual or possible diminution of value below the asset's fair market value. See § 1.597-1(b).

(g) *Anti-abuse rule.* The regulations under section 597 must be applied in a manner consistent with the purposes of section 597. Accordingly, if, in structuring or engaging in any transaction, a principal purpose is to achieve a tax result that is inconsistent with the purposes of section 597 and the regulations thereunder, the Commissioner can make appropriate adjustments to income, deductions, and other items that would be consistent with those purposes.

■ **Par. 5.** Section 1.597-4 is revised to read as follows:

§ 1.597-4 Bridge Banks and Agency Control.

(a) *Scope.* This section provides rules that apply to a Bridge Bank or other Institution under Agency Control and to transactions in which an Institution transfers deposit liabilities (whether or not the Institution also transfers assets) to a Bridge Bank.

(b) *Status as taxpayer.* A Bridge Bank or other Institution under Agency Control is a corporation within the meaning of section 7701(a)(3) for all purposes of the Internal Revenue Code and is subject to all Internal Revenue Code provisions that generally apply to corporations, including those relating to methods of accounting and to requirements for filing returns, even if Agency owns stock of the Institution.

(c) *No section 382 ownership change.* The imposition of Agency Control, the cancellation of Institution stock by Agency, a transaction in which an Institution transfers deposit liabilities to a Bridge Bank, and an election under paragraph (g) of this section are disregarded in determining whether an ownership change has occurred within the meaning of section 382(g).

(d) *Transfers to Bridge Banks—(1) In general.* Except as otherwise provided in paragraph (g) of this section, the rules of this paragraph (d) apply to transfers to Bridge Banks. In general, a Bridge Bank and its associated Residual Entity are together treated as the successor entity to the transferring Institution. If an Institution transfers deposit liabilities to a Bridge Bank (whether or not it also transfers assets), the Institution recognizes no gain or loss on the transfer and the Bridge Bank succeeds to the transferring Institution's basis in any transferred assets. The associated Residual Entity retains its basis in any assets it continues to hold. Immediately after the transfer, the Bridge Bank succeeds to and takes into account the transferring Institution's items described in section 381(c) (subject to the conditions and limitations specified in section 381(c)), taxpayer identification number ("TIN"), deferred FFA account, and account receivable for future FFA as described in paragraph (g)(4)(ii) of this section. The Bridge Bank also succeeds to and continues the transferring Institution's taxable year.

(2) *Transfers to a Bridge Bank from multiple Institutions.* If two or more Institutions transfer deposit liabilities to the same Bridge Bank, the rules in paragraph (d)(1) of this section are modified to the extent provided in this paragraph (d)(2). The Bridge Bank succeeds to the TIN and continues the taxable year of the Institution that

transfers the largest amount of deposits. The taxable years of the other transferring Institutions close at the time of the transfer. If all the transferor Institutions are members of the same consolidated group, the Bridge Bank's carryback of losses to the Institution that transfers the largest amount of deposits is not limited by section 381(b)(3). The limitations of section 381(b)(3) do apply to the Bridge Bank's carrybacks of losses to all other transferor Institutions. If the transferor Institutions are not all members of the same consolidated group, the limitations of section 381(b)(3) apply with respect to all transferor Institutions. See paragraph (g)(6)(ii) of this section for additional rules that apply if two or more Institutions that are not members of the same consolidated group transfer deposit liabilities to the same Bridge Bank.

(e) *Treatment of Bridge Bank and Residual Entity as a single entity.* A Bridge Bank and its associated Residual Entity or Entities are treated as a single entity for income tax purposes and must file a single combined income tax return. The Bridge Bank is responsible for filing all income tax returns and statements for this single entity and is the agent of each associated Residual Entity to the same extent as if the Bridge Bank were the common parent of a consolidated group including the Residual Entity. The term Institution includes a Residual Entity that files a combined return with its associated Bridge Bank.

(f) *Rules applicable to members of consolidated groups—(1) Status as members.* Unless an election is made under paragraph (g) of this section, Agency Control of an Institution does not terminate the Institution's membership in a consolidated group. Stock of a subsidiary that is canceled by Agency is treated as held by the members of the consolidated group that held the stock prior to its cancellation. If an Institution is a member of a consolidated group immediately before it transfers deposit liabilities to a Bridge Bank, the Bridge Bank succeeds to the Institution's status as the common parent or, unless an election is made under paragraph (g) of this section, as a subsidiary of the group. If a Bridge Bank succeeds to an Institution's status as a subsidiary, its stock is treated as held by the shareholders of the transferring Institution, and the stock basis or excess loss account of the Institution carries over to the Bridge Bank. A Bridge Bank is treated as owning stock owned by its associated Residual Entities, including for purposes of determining membership in an affiliated group.

(2) *Coordination with consolidated return regulations.* The provisions of the regulations under section 597 take precedence over conflicting provisions in the regulations under section 1502.

(g) *Elective disaffiliation*—(1) *In general.* A consolidated group of which an Institution is a subsidiary may elect irrevocably not to include the Institution in its affiliated group if the Institution is placed in Agency receivership (whether or not assets or deposit liabilities of the Institution are transferred to a Bridge Bank). See paragraph (g)(6) of this section for circumstances under which a consolidated group is deemed to make this election.

(2) *Consequences of election.* If the election under this paragraph (g) is made with respect to an Institution, the following consequences occur immediately before the subsidiary Institution to which the election applies is placed in Agency receivership (or, in the case of a deemed election under paragraph (g)(6) of this section, immediately before the consolidated group is deemed to make the election) and in the following order—

(i) All adjustments of the Institution and its Consolidated Subsidiaries under section 481 are accelerated;

(ii) Deferred intercompany gains and losses and intercompany items with respect to the Institution and its Consolidated Subsidiaries are taken into account and the Institution and its Consolidated Subsidiaries take into account any other items required under the regulations under section 1502 for members that become nonmembers within the meaning of § 1.1502–32(d)(4);

(iii) The taxable year of the Institution and its Consolidated Subsidiaries closes and the Institution includes the amount described in paragraph (g)(3) of this section in income as ordinary income as its last item for that taxable year;

(iv) The members of the consolidated group owning the common stock of the Institution include in income any excess loss account with respect to the Institution's stock under § 1.1502–19 and any other items required under the regulations under section 1502 for members that own stock of corporations that become nonmembers within the meaning of § 1.1502–32(d)(4); and

(v) If the Institution's liabilities exceed the aggregate fair market value of its assets on the date the Institution is placed in Agency receivership (or, in the case of a deemed election under paragraph (g)(6) of this section, on the date the consolidated group is deemed to make the election), the members of the consolidated group treat their stock in the Institution as worthless. (See

§§ 1.337(d)-2, 1.1502–35(f), and 1.1502–36 for rules applicable when a member of a consolidated group is entitled to a worthless stock deduction with respect to stock of another member of the group.) In all other cases, the consolidated group will be treated as owning stock of a nonmember corporation until such stock is disposed of or becomes worthless under rules otherwise applicable.

(3) *Toll charge.* The amount described in this paragraph (g)(3) is the excess of the Institution's liabilities over the adjusted bases of its assets immediately before the Institution is placed in Agency receivership (or, in the case of a deemed election under paragraph (g)(6) of this section, immediately before the consolidated group is deemed to make the election). In computing this amount, the adjusted bases of an Institution's assets are reduced by the amount of the Institution's reserves for bad debts under section 585 or 593, other than supplemental reserves under section 593. For purposes of this paragraph (g)(3), an Institution is treated as a single entity that includes the assets and liabilities of its Consolidated Subsidiaries, with appropriate adjustments to prevent duplication. The amount described in this paragraph (g)(3) for alternative minimum tax purposes is determined using alternative minimum tax basis, deductions, and all other items required to be taken into account. In computing the increase in the group's taxable income or alternative minimum taxable income, sections 56(d)(1), 382, and 383 and §§ 1.1502–15, 1.1502–21, and 1.1502–22 (or §§ 1.1502–15A, 1.1502–21A, and 1.1502–22A, as appropriate) do not limit the use of the attributes of the Institution and its Consolidated Subsidiaries to the extent, if any, that the inclusion of the amount described in this paragraph (g)(3) in income would result in the group having taxable income or alternative minimum taxable income (determined without regard to this sentence) for the taxable year. The preceding sentence does not apply to any limitation under section 382 or 383 or §§ 1.1502–15, 1.1502–21, or 1.1502–22 (or §§ 1.1502–15A, 1.1502–21A, or 1.1502–22A, as appropriate) that arose in connection with or prior to a corporation becoming a Consolidated Subsidiary of the Institution.

(4) *Treatment of Institutions after disaffiliation*—(i) *In general.* If the election under this paragraph (g) is made with respect to an Institution, immediately after the Institution is placed in Agency receivership (or, in the case of a deemed election under paragraph (g)(6) of this section,

immediately after the consolidated group is deemed to make the election), the Institution and each of its Consolidated Subsidiaries are treated for income tax purposes as new corporations that are not members of the electing group's affiliated group. Each new corporation retains the TIN of the corresponding disaffiliated corporation and is treated as having received the assets and liabilities of the corresponding disaffiliated corporation in a transaction to which section 351 applies (and in which no gain was recognized under section 357(c) or otherwise). Thus, the new corporation has no net operating or capital loss carryforwards. An election under this paragraph (g) does not terminate the single entity treatment of a Bridge Bank and its Residual Entities provided in paragraph (e) of this section.

(ii) *FFA.* A new Institution is treated as having a non-interest bearing, nontransferable account receivable for future FFA with a basis equal to the amount described in paragraph (g)(3) of this section. If a disaffiliated Institution has a deferred FFA account at the time of its disaffiliation, the corresponding new Institution succeeds to and takes into account that deferred FFA account.

(iii) *Filing of consolidated returns.* If a disaffiliated Institution has Consolidated Subsidiaries at the time of its disaffiliation, the corresponding new Institution is required to file a consolidated income tax return with the subsidiaries in accordance with the regulations under section 1502.

(iv) *Status as Institution.* If an Institution is disaffiliated under this paragraph (g), the resulting new corporation is treated as an Institution for purposes of the regulations under section 597 regardless of whether it is a bank or domestic building and loan association within the meaning of section 597.

(v) *Loss carrybacks.* To the extent a carryback of losses would result in a refund being paid to a fiduciary under section 6402(k), an Institution or Consolidated Subsidiary with respect to which an election under this paragraph (g) (other than under paragraph (g)(6)(ii) of this section) applies is allowed to carry back losses as if the Institution or Consolidated Subsidiary had continued to be a member of the consolidated group that made the election.

(5) *Affirmative election*—(i) *Original Institution*—(A) *Manner of making election.* Except as otherwise provided in paragraph (g)(6) of this section, a consolidated group makes the election provided by this paragraph (g) by sending a written statement by certified mail to the affected Institution on or

before 120 days after its placement in Agency receivership. The statement must contain the following legend at the top of the page: "THIS IS AN ELECTION UNDER § 1.597-4(g) TO EXCLUDE THE BELOW-REFERENCED INSTITUTION AND CONSOLIDATED SUBSIDIARIES FROM THE AFFILIATED GROUP," and must include the names and taxpayer identification numbers of the common parent and of the Institution and Consolidated Subsidiaries to which the election applies, and the date on which the Institution was placed in Agency receivership. The consolidated group must send a similar statement to all subsidiary Institutions placed in Agency receivership during the consistency period described in paragraph (g)(5)(ii) of this section. (Failure to satisfy the requirement in the preceding sentence, however, does not invalidate the election with respect to any subsidiary Institution placed in Agency receivership during the consistency period described in paragraph (g)(5)(ii) of this section.) The consolidated group must retain a copy of the statement sent to any affected or subsidiary Institution (and the accompanying certified mail receipt) as proof that it mailed the statement to the affected Institution, and the consolidated group must make the statement and receipt available for inspection by the Commissioner upon request. The consolidated group must include an election statement as part of its first income tax return filed after the due date under this paragraph (g)(5) for such statement. A statement must be attached to this return indicating that the individual who signed the election was authorized to do so on behalf of the consolidated group. Agency cannot make this election under the authority of section 6402(k) or otherwise.

(B) *Consistency limitation on affirmative elections.* A consolidated group may make an affirmative election under this paragraph (g)(5) with respect to a subsidiary Institution placed in Agency receivership only if the group made, or is deemed to have made, the election under this paragraph (g) with respect to every subsidiary Institution of the group placed in Agency receivership within five years preceding the date the subject Institution was placed in Agency receivership.

(ii) *Effect on Institutions placed in receivership simultaneously or subsequently.* An election under this paragraph (g), other than under paragraph (g)(6)(ii) of this section, applies to the Institution with respect to which the election is made or deemed made (the original Institution) and each subsidiary Institution of the group placed in Agency receivership or

deconsolidated in contemplation of Agency Control or the receipt of FFA simultaneously with the original Institution or within five years thereafter.

(6) *Deemed Election—(i)*

Deconsolidations in contemplation. If one or more members of a consolidated group deconsolidate (within the meaning of § 1.1502-19(c)(1)(ii)(B)) a subsidiary Institution in contemplation of Agency Control or the receipt of FFA, the consolidated group is deemed to make the election described in this paragraph (g) with respect to the Institution on the date the deconsolidation occurs. A subsidiary Institution is conclusively presumed to have been deconsolidated in contemplation of Agency Control or the receipt of FFA if either event occurs within six months after the deconsolidation.

(ii) *Transfers to a Bridge Bank from multiple groups.* On the day an Institution's transfer of deposit liabilities to a Bridge Bank results in the Bridge Bank holding deposit liabilities from both a subsidiary Institution and an Institution not included in the subsidiary Institution's consolidated group, each consolidated group of which a transferring Institution or the Bridge Bank is a subsidiary is deemed to make the election described in this paragraph (g) with respect to its subsidiary Institution. If deposit liabilities of another Institution that is a subsidiary member of any consolidated group subsequently are transferred to the Bridge Bank, the consolidated group of which the Institution is a subsidiary is deemed to make the election described in this paragraph (g) with respect to that Institution at the time of the subsequent transfer.

(h) *Examples.* The following examples illustrate the provisions of this section:

Facts. Corporation X, the common parent of a consolidated group, owns all the stock (with a basis of \$4 million) of Institution M, an insolvent Institution with no Consolidated Subsidiaries. At the close of business on April 30, 2016, M has \$4 million of deposit liabilities, \$1 million of other liabilities, and assets with an adjusted basis of \$4 million and a fair market value of \$3 million.

Example 1. Effect of receivership on consolidation. On May 1, 2016, Agency places M in receivership and begins liquidating M. X does not make an election under paragraph (g) of this section. M remains a member of the X consolidated group after May 1, 2016 under paragraph (f)(1) of this section.

Example 2. Effect of Bridge Bank on consolidation—(i) Additional facts. On May 1, 2016, Agency places M in receivership and causes M to transfer all of its assets and deposit liabilities to Bridge Bank MB.

(ii) *Consequences without an election to disaffiliate.* M recognizes no gain or loss from the transfer and MB succeeds to M's basis in the transferred assets, M's items described in section 381(c) (subject to the conditions and limitations specified in section 381(c)), and TIN under paragraph (d)(1) of this section. (If M had a deferred FFA account, MB would also succeed to that account under paragraph (d)(1) of this section.) MB continues M's taxable year and succeeds to M's status as a member of the X consolidated group after May 1, 2016 under paragraphs (d)(1) and (f) of this section. MB and M are treated as a single entity for income tax purposes under paragraph (e) of this section.

(iii) *Consequences with an election to disaffiliate.* If, on July 1, 2016, X makes an election under paragraph (g) of this section with respect to M, the following consequences are treated as occurring immediately before M was placed in Agency receivership. M must include \$1 million (\$5 million of liabilities – \$4 million of adjusted basis) in income as of May 1, 2016 under paragraph (g)(2) and (3) of this section. M is then treated as a new corporation that is not a member of the X consolidated group and that has assets (including a \$1 million account receivable for future FFA) with a basis of \$5 million and \$5 million of liabilities received from disaffiliated corporation M in a section 351 transaction. New corporation M retains the TIN of disaffiliated corporation M under paragraph (g)(4) of this section. Immediately after the disaffiliation, new corporation M is treated as transferring its assets and deposit liabilities to Bridge Bank MB. New corporation M recognizes no gain or loss from the transfer and MB succeeds to M's TIN and taxable year under paragraph (d)(1) of this section. Bridge Bank MB is treated as a single entity that includes M and has \$5 million of liabilities, an account receivable for future FFA with a basis of \$1 million, and other assets with a basis of \$4 million under paragraph (d)(1) of this section.

■ **Par. 6.** Section 1.597-5 is revised to read as follows:

§ 1.597-5 Taxable Transfers.

(a) *Taxable Transfers—(1) Defined.*

The term *Taxable Transfer* means—

(i) A transaction in which an entity transfers to a transferee other than a Bridge Bank—

(A) Any deposit liability (whether or not the Institution also transfers assets), if FFA is provided in connection with the transaction; or

(B) Any asset for which Agency or a Controlled Entity has any financial obligation (for example, pursuant to a Loss Guarantee or Agency Obligation); or

(ii) A deemed transfer of assets described in paragraph (b) of this section.

(2) *Scope.* This section provides rules governing Taxable Transfers. Rules applicable to both actual and deemed asset acquisitions are provided in

paragraphs (c) and (d) of this section. Special rules applicable only to deemed asset acquisitions are provided in paragraph (e) of this section.

(b) *Deemed asset acquisitions upon stock purchase*—(1) *In general.* In a deemed transfer of assets under this paragraph (b), an Institution (including a Bridge Bank or a Residual Entity) or a Consolidated Subsidiary of the Institution (the Old Entity) is treated as selling all of its assets in a single transaction and is treated as a new corporation (the New Entity) that purchases all of the Old Entity's assets at the close of the day immediately preceding the occurrence of an event described in paragraph (b)(2) of this section. However, such an event results in a deemed transfer of assets under this paragraph (b) only if it occurs—

(i) In connection with a transaction in which FFA is provided;

(ii) While the Institution is a Bridge Bank;

(iii) While the Institution has a positive balance in a deferred FFA account (see § 1.597-2(c)(4)(v) regarding the optional accelerated recapture of deferred FFA); or

(iv) With respect to a Consolidated Subsidiary, while the Institution of which it is a Consolidated Subsidiary is under Agency Control.

(2) *Events.* A deemed transfer of assets under this paragraph (b) results if the Institution or Consolidated Subsidiary—

(i) Becomes a non-member (within the meaning of § 1.1502-32(d)(4)) of its consolidated group, other than pursuant to an election under § 1.597-4(g);

(ii) Becomes a member of an affiliated group of which it was not previously a member, other than pursuant to an election under § 1.597-4(g); or

(iii) Issues stock such that the stock that was outstanding before the imposition of Agency Control or the occurrence of any transaction in connection with the provision of FFA represents 50 percent or less of the vote or value of its outstanding stock (disregarding stock described in section 1504(a)(4) and stock owned by Agency or a Controlled Entity).

(3) *Bridge Banks and Residual Entities.* If a Bridge Bank is treated as selling all of its assets to a New Entity under this paragraph (b), each associated Residual Entity is treated as simultaneously selling its assets to a New Entity in a Taxable Transfer described in this paragraph (b).

(c) *Treatment of transferor*—(1) *FFA in connection with a Taxable Transfer.* A transferor in a Taxable Transfer is treated as having directly received immediately before a Taxable Transfer any Net Worth Assistance that Agency

provides to the New Entity or Acquiring in connection with the transfer. (See § 1.597-2(a) and (c) for rules regarding the inclusion of FFA in income and § 1.597-2(a)(1) for related rules regarding FFA provided to shareholders.) The Net Worth Assistance is treated as an asset of the transferor that is sold to the New Entity or Acquiring in the Taxable Transfer.

(2) *Amount realized in a Taxable Transfer.* In a Taxable Transfer described in paragraph (a)(1)(i) of this section, the amount realized is determined under section 1001(b) by reference to the consideration paid for the assets. In a Taxable Transfer described in paragraph (a)(1)(ii) of this section, the amount realized is the sum of the grossed-up basis of the stock acquired in connection with the Taxable Transfer (excluding stock acquired from the Old or New Entity), plus the amount of liabilities assumed or taken subject to in the deemed transfer, plus other relevant items. The grossed-up basis of the acquired stock equals the acquirers' basis in the acquired stock divided by the percentage of the Old Entity's stock (by value) attributable to the acquired stock.

(3) *Allocation of amount realized*—(i) *In general.* The amount realized under paragraph (c)(2) of this section is allocated among the assets transferred in the Taxable Transfer in the same manner as amounts are allocated among assets under § 1.338-6(b), (c)(1) and (2).

(ii) *Modifications to general rule.* This paragraph (c)(3)(ii) modifies certain of the allocation rules of paragraph (c)(3)(i) of this section. Agency Obligations and Covered Assets in the hands of the New Entity or Acquiring are treated as Class II assets. Stock of a Consolidated Subsidiary is treated as a Class II asset to the extent the fair market value of the Consolidated Subsidiary's Class I and Class II assets (see § 1.597-1(b)) exceeds the amount of its liabilities. The fair market value of an Agency Obligation is deemed to equal its adjusted issue price immediately before the Taxable Transfer.

(d) *Treatment of a New Entity and Acquiring*—(1) *Purchase price.* The purchase price for assets acquired in a Taxable Transfer described in paragraph (a)(1)(i) of this section is the cost of the assets acquired. See § 1.1060-1(c)(1). All assets transferred in related transactions pursuant to an option included in an agreement between the transferor and Acquiring in the Taxable Transfer are included in the group of assets among which the consideration paid is allocated for purposes of determining the New Entity's or Acquiring's basis in each of the assets. The purchase price

for assets acquired in a Taxable Transfer described in paragraph (a)(1)(ii) of this section is the sum of the grossed-up basis of the stock acquired in connection with the Taxable Transfer (excluding stock acquired from the Old or New Entity), plus the amount of liabilities assumed or taken subject to in the deemed transfer, plus other relevant items. The grossed-up basis of the acquired stock equals the acquirers' basis in the acquired stock divided by the percentage of the Old Entity's stock (by value) attributable to the acquired stock. FFA provided in connection with a Taxable Transfer is not included in the New Entity's or Acquiring's purchase price for the acquired assets. Any Net Worth Assistance so provided is treated as an asset of the transferor sold to the New Entity or Acquiring in the Taxable Transfer.

(2) *Allocation of basis*—(i) *In general.* Except as otherwise provided in this paragraph (d)(2), the purchase price determined under paragraph (d)(1) of this section is allocated among the assets transferred in the Taxable Transfer in the same manner as amounts are allocated among assets under § 1.338-6(b), (c)(1) and (2).

(ii) *Modifications to general rule.* The allocation rules contained in paragraph (c)(3)(ii) of this section apply to the allocation of basis among assets acquired in a Taxable Transfer. No basis is allocable to Agency's agreement to provide Loss Guarantees, yield maintenance payments, cost to carry or cost of funds reimbursement payments, or expense reimbursement or indemnity payments. A New Entity's basis in assets it receives from its shareholders is determined under general principles of income taxation and is not governed by this paragraph (d).

(iii) *Allowance and recapture of additional basis in certain cases.* The basis of Class I and Class II assets equals their fair market value. See § 1.597-1(b). If the fair market value of the Class I and Class II assets exceeds the purchase price for the acquired assets, the excess is included ratably as ordinary income by the New Entity or Acquiring over a period of six taxable years beginning in the year of the Taxable Transfer. The New Entity or Acquiring must include as ordinary income the entire amount remaining to be recaptured under the preceding sentence in the taxable year in which an event occurs that would accelerate inclusion of an adjustment under section 481.

(iv) *Certain post-transfer adjustments*—(A) *Agency Obligations.* If an adjustment to the principal amount of an Agency Obligation or cash payment to reflect a more accurate

determination of the condition of the Institution at the time of the Taxable Transfer is made before the earlier of the date the New Entity or Acquiring files its first post-transfer income tax return or the due date of that return (including extensions), the New Entity or Acquiring must adjust its basis in its acquired assets to reflect the adjustment. In making adjustments to the New Entity's or Acquiring's basis in its acquired assets, paragraph (c)(3)(ii) of this section is applied by treating an adjustment to the principal amount of an Agency Obligation pursuant to the first sentence of this paragraph (d)(2)(iv)(A) as occurring immediately before the Taxable Transfer. (See § 1.597-3(c)(3) for rules regarding other adjustments to the principal amount of an Agency Obligation.)

(B) *Covered Assets.* If, immediately after a Taxable Transfer, an asset is not subject to a Loss Guarantee but the New Entity or Acquiring has the right to designate specific assets that will be subject to the Loss Guarantee, the New Entity or Acquiring must treat any asset so designated as having been subject to the Loss Guarantee at the time of the Taxable Transfer. The New Entity or Acquiring must adjust its basis in the Covered Assets and in its other acquired assets to reflect the designation in the manner provided by paragraph (d)(2) of this section. The New Entity or Acquiring must make appropriate adjustments in subsequent taxable years if the designation is made after the New Entity or Acquiring files its first post-transfer income tax return or the due date of that return (including extensions) has passed.

(e) *Special rules applicable to Taxable Transfers that are deemed asset acquisitions—(1) Taxpayer Identification Numbers.* Except as provided in paragraph (e)(3) of this section, the New Entity succeeds to the TIN of the Old Entity in a deemed sale under paragraph (b) of this section.

(2) *Consolidated Subsidiaries—(i) In general.* A Consolidated Subsidiary that is treated as selling its assets in a Taxable Transfer under paragraph (b) of this section is treated as engaging immediately thereafter in a complete liquidation to which section 332 applies. The consolidated group of which the Consolidated Subsidiary is a member does not take into account gain or loss on the sale, exchange, or cancellation of stock of the Consolidated Subsidiary in connection with the Taxable Transfer.

(ii) *Certain minority shareholders.* Shareholders of the Consolidated Subsidiary that are not members of the consolidated group that includes the

Institution do not recognize gain or loss with respect to shares of Consolidated Subsidiary stock retained by the shareholder. The shareholder's basis for that stock is not affected by the Taxable Transfer.

(3) *Bridge Banks and Residual Entities—(i) In general.* A Bridge Bank or Residual Entity's sale of assets to a New Entity under paragraph (b) of this section is treated as made by a single entity under § 1.597-4(e). The New Entity deemed to acquire the assets of a Residual Entity under paragraph (b) of this section is not treated as a single entity with the Bridge Bank (or with the New Entity acquiring the Bridge Bank's assets) and must obtain a new TIN.

(ii) *Treatment of consolidated groups.* At the time of a Taxable Transfer described in paragraph (a)(1)(ii) of this section, treatment of a Bridge Bank as a subsidiary member of a consolidated group under § 1.597-4(f)(1) ceases. However, the New Entity that is deemed to acquire the assets of a Residual Entity is a member of the selling consolidated group after the deemed sale. The group's basis or excess loss account in the stock of the New Entity that is deemed to acquire the assets of the Residual Entity is the group's basis or excess loss account in the stock of the Bridge Bank immediately before the deemed sale, as adjusted for the results of the sale.

(4) *Certain returns.* If an Old Entity without Continuing Equity is not a subsidiary of a consolidated group at the time of the Taxable Transfer, the controlling Agency must file all income tax returns for the Old Entity for periods ending on or prior to the date of the deemed sale described in paragraph (b) of this section that are not filed as of that date.

(5) *Basis limited to fair market value.* If all of the stock of the corporation is not acquired on the date of the Taxable Transfer, the Commissioner may make appropriate adjustments under paragraphs (c) and (d) of this section to the extent using a grossed-up basis of the stock of a corporation results in an aggregate amount realized for, or basis in, the assets other than the aggregate fair market value of the assets.

(f) *Examples.* The following examples illustrate the provisions of this section. For purposes of these examples, an Institution's loans are treated as if they were a single asset. However, in applying these regulations, the fair market value of each loan (including, for purposes of a Covered Asset, the Third-Party Price and the Expected Value) must be determined separately.

Example 1. Branch sale resulting in Taxable Transfer. (i) Institution M is a

calendar-year taxpayer in Agency receivership. M is not a member of a consolidated group. On January 1, 2016, M has \$200 million of liabilities (including deposit liabilities) and assets with an adjusted basis of \$100 million. M has no income or loss for 2016 and, except as described below, M receives no FFA. On September 30, 2016, Agency causes M to transfer six branches (with assets having an adjusted basis of \$1 million) together with \$120 million of deposit liabilities to N. In connection with the transfer, Agency provides \$121 million in cash to N.

(ii) The transaction is a Taxable Transfer in which M receives \$121 million of Net Worth Assistance under paragraph (a)(1) of this section. (M is treated as directly receiving the \$121 million of Net Worth Assistance immediately before the Taxable Transfer under paragraph (c)(1) of this section.) M transfers branches having a basis of \$1 million and is treated as transferring \$121 million in cash (the Net Worth Assistance) to N in exchange for N's assumption of \$120 million of liabilities. Thus, M realizes a loss of \$2 million on the transfer. The amount of the FFA M must include in its income in 2016 is limited by paragraph (c) of § 1.597-2 to \$102 million, which is the sum of the \$100 million excess of M's liabilities (\$200 million) over the total adjusted basis of its assets (\$100 million) at the beginning of 2016 and the \$2 million excess for the taxable year (which results from the Taxable Transfer) of M's deductions (other than carryovers) over its gross income other than FFA. M must establish a deferred FFA account for the remaining \$19 million of FFA under paragraph (c)(4) of § 1.597-2.

(iii) N, as Acquiring, must allocate its \$120 million purchase price for the assets acquired from M among those assets. Cash is a Class I asset. The branch assets are in Classes III and IV. N's adjusted basis in the cash is its amount, that is, \$121 million under paragraph (d)(2) of this section. Because this amount exceeds N's purchase price for all of the acquired assets by \$1 million, N allocates no basis to the other acquired assets and, under paragraph (d)(2) of this section, must recapture the \$1 million excess at an annual rate of \$166,667 in the six consecutive taxable years beginning with 2016 (subject to acceleration for certain events).

Example 2. Stock issuance by Bridge Bank causing Taxable Transfer. (i) On April 1, 2016, Institution P is placed in receivership and caused to transfer assets and liabilities to Bridge Bank PB. On August 31, 2016, the assets of PB consist of \$20 million in cash, loans outstanding with an adjusted basis of \$50 million and a Third-Party Price of \$40 million, and other non-financial assets (primarily branch assets and equipment) with an adjusted basis of \$5 million. PB has deposit liabilities of \$95 million and other liabilities of \$5 million. P, the Residual Entity, holds real estate with an adjusted basis of \$10 million and claims in litigation having a zero basis. P retains no deposit liabilities and has no other liabilities (except its liability to Agency for having caused its deposit liabilities to be satisfied).

(ii) On September 1, 2016, Agency causes PB to issue 100 percent of its common stock

for \$2 million cash to X. On the same day, Agency issues a \$25 million note to PB. The note bears a fixed rate of interest in excess of the applicable Federal rate in effect for September 1, 2016. Agency provides Loss Guarantees guaranteeing PB a value of \$50 million for PB's loans outstanding.

(iii) The stock issuance is a Taxable Transfer in which PB is treated as selling all of its assets to a new corporation, New PB, under paragraph (b)(1) of this section. PB is treated as directly receiving \$25 million of Net Worth Assistance (the issue price of the Agency Obligation) immediately before the Taxable Transfer under paragraph (c)(2) of § 1.597-3 and paragraph (c)(1) of this section. The amount of FFA PB must include in income is determined under paragraphs (a) and (c) of § 1.597-2. PB in turn is deemed to transfer the note (with a basis of \$25 million) to New PB in the Taxable Transfer, together with \$20 million of cash, all its loans outstanding (with a basis of \$50 million) and its other non-financial assets (with a basis of \$5 million). The amount realized by PB from the sale is \$100 million (the amount of PB's liabilities deemed to be assumed by New PB). This amount realized equals PB's basis in its assets; thus, PB realizes no gain or loss on the transfer to New PB.

(iv) Residual Entity P also is treated as selling all its assets (consisting of real estate and claims in litigation) for \$0 (the amount of consideration received by P) to a new corporation (New P) in a Taxable Transfer under paragraph (b)(3) of this section. (P's only liability is to Agency and a liability to Agency is not treated as a debt under paragraph (b) of § 1.597-3.) P's basis in its assets is \$10 million; thus, P realizes a \$10 million loss on the transfer to New P. The combined return filed by PB and P for 2016 will reflect a total loss on the Taxable Transfer of \$10 million (\$0 for PB and \$10 million for P) under paragraph (e)(3) of this section. That return also will reflect FFA income from the Net Worth Assistance, determined under paragraphs (a) and (c) of § 1.597-2.

(v) New PB is treated as having acquired the assets it acquired from PB for \$100 million, the amount of liabilities assumed. In allocating basis among these assets, New PB treats the Agency note and the loans outstanding (which are Covered Assets) as Class II assets. For the purpose of allocating basis, the fair market value of the Agency note is deemed to equal its adjusted issue price immediately before the transfer (\$25 million), and the fair market value of the loans is their Expected Value, \$50 million (the sum of the \$40 million Third-Party Price and the \$10 million that Agency would pay if PB sold the loans for \$40 million) under paragraph (b) of § 1.597-1. Alternatively, if the Third-Party Price for the loans were \$60 million, then the fair market value of the loans would be \$60 million, and there would be no payment from Agency.

(vi) New P is treated as having acquired its assets for no consideration. Thus, its basis in its assets immediately after the transfer is zero. New PB and New P are not treated as a single entity under paragraph (e)(3) of this section.

Example 3. Taxable Transfer of previously disaffiliated Institution. (i) Corporation X, the

common parent of a consolidated group, owns all the stock of Institution M, an insolvent Institution with no Consolidated Subsidiaries. On April 30, 2016, M has \$4 million of deposit liabilities, \$1 million of other liabilities, and assets with an adjusted basis of \$4 million. On May 1, 2016, Agency places M in receivership. X elects under paragraph (g) of § 1.597-4 to disaffiliate M. Accordingly, as of May 1, 2016, new corporation M is not a member of the X consolidated group. On May 1, 2016, Agency causes M to transfer all of its assets and liabilities to Bridge Bank MB. Under paragraphs (e) and (g)(4) of § 1.597-4, MB and M are thereafter treated as a single entity which has \$5 million of liabilities, an account receivable for future FFA with a basis of \$1 million, and other assets with a basis of \$4 million.

(ii) During May 2016, MB earns \$25,000 of interest income and accrues \$20,000 of interest expense on depositor accounts and there is no net change in deposits other than the additional \$20,000 of interest expense accrued on depositor accounts. MB pays \$5,000 of wage expenses and has no other items of income or expense.

(iii) On June 1, 2016, Agency causes MB to issue 100 percent of its stock to Corporation Y. In connection with the stock issuance, Agency provides an Agency Obligation for \$2 million and no other FFA.

(iv) The stock issuance results in a Taxable Transfer under paragraph (b) of this section. MB is treated as receiving the Agency Obligation immediately prior to the Taxable Transfer under paragraph (c)(1) of this section. MB has \$1 million of basis in its account receivable for FFA. This receivable is treated as satisfied, offsetting \$1 million of the \$2 million of FFA provided by Agency in connection with the Taxable Transfer. The status of the remaining \$1 million of FFA as includible income is determined as of the end of the taxable year under paragraph (c) of § 1.597-2. However, under paragraph (b) of § 1.597-2, MB obtains a \$2 million basis in the Agency Obligation received as FFA.

(v) Under paragraph (c)(2) of this section, in the Taxable Transfer, Old Entity MB is treated as selling, to New Entity MB, all of Old Entity MB's assets, having a basis of \$6,020,000 (the original \$4 million of asset basis as of April 30, 2016, plus \$20,000 net cash from May 2016 activities, plus the \$2 million Agency Obligation received as FFA), for \$5,020,000, the amount of Old Entity MB's liabilities assumed by New Entity MB pursuant to the Taxable Transfer. Therefore, Old Entity MB recognizes, in the aggregate, a loss of \$1 million from the Taxable Transfer.

(vi) Because this \$1 million loss causes Old Entity MB's deductions to exceed its gross income (determined without regard to FFA) by \$1 million, Old Entity MB must include in its income the \$1 million of FFA not offset by the FFA receivable under paragraph (c) of § 1.597-2. (As of May 1, 2016, Old Entity MB's liabilities (\$5 million) did not exceed MB's \$5 million adjusted basis of its assets. For the taxable year, MB's deductions of \$1,025,000 (\$1 million loss from the Taxable Transfer, \$20,000 interest expense and \$5,000 of wage expense) exceeded its gross

income (disregarding FFA) of \$25,000 (interest income) by \$1 million. Thus, under paragraph (c) of § 1.597-2, MB includes in income the entire \$1 million of FFA not offset by the FFA receivable.)

(vii) Therefore, Old Entity MB's taxable income for the taxable year ending on the date of the Taxable Transfer is \$0.

(viii) Residual Entity M is also deemed to engage in a deemed sale of its assets to New Entity M under paragraph (b)(3) of this section, but there are no tax consequences as M has no assets or liabilities at the time of the deemed sale.

(ix) Under paragraph (d)(1) of this section, New Entity MB is treated as purchasing Old Entity MB's assets for \$5,020,000, the amount of New Entity MB's liabilities. Of this, \$2 million is allocated to the \$2 million Agency Obligation, and \$3,020,000 is allocated to the other assets New Entity MB is treated as purchasing in the Taxable Transfer.

Example 4. Loss Guarantee. On January 1, 2016, Institution N acquires assets and assumes liabilities of another Institution in a Taxable Transfer. In exchange for assuming \$1,100,000 of the transferring Institution's liabilities, N acquires Net Worth Assistance of \$200,000, loans with an unpaid principal balance of \$1 million, and two foreclosed properties each having a book value of \$100,000 in the hands of the transferring Institution. In connection with the Taxable Transfer, Agency guarantees N a price of \$800,000 on the disposition or charge-off of the loans and a price of \$80,000 on the disposition or charge-off of each of the foreclosed properties. This arrangement constitutes a Loss Guarantee. The Third-Party Price is \$500,000 for the loans and \$50,000 for each of the foreclosed properties. For basis allocation purposes, the loans and foreclosed properties are Class II assets because they are Covered Assets, and N must allocate basis to such assets equal to their fair market value under paragraphs (c)(3)(ii), (d)(2)(ii), and (d)(2)(iii) of this section. The fair market value of the loans is their Expected Value, \$800,000 (the sum of the \$500,000 Third-Party Price and the \$300,000 that Agency would pay if N sold the loans for \$500,000). The fair market value of each foreclosed property is its Expected Value, \$80,000 (the sum of the \$50,000 Third-Party Price and the \$30,000 that Agency would pay if N sold the foreclosed property for \$50,000) under paragraph (b) of § 1.597-1.

Accordingly, N's basis in the loans and in each of the foreclosed properties is \$800,000 and \$80,000, respectively. Because N's aggregate basis in the cash, loans, and foreclosed properties (\$1,160,000) exceeds N's purchase price (\$1,100,000) by \$60,000, N must include \$60,000 in income ratably over six years under paragraph (d)(2)(iii) of this section.

Example 5. Loss Share Agreement. (i) The facts are the same as in *Example 4* except that, in connection with the Taxable Transfer, Agency agrees to reimburse Institution N in an amount equal to zero percent of any loss realized (based on the \$1 million unpaid principal balance of the loans and the \$100,000 book value of each of the foreclosed properties) on the disposition or charge-off of the Covered Assets up to

\$200,000; 50 percent of any loss realized between \$200,000 and \$700,000; and 95 percent of any additional loss realized. This arrangement constitutes a Loss Guarantee that is a Loss Share Agreement. Thus, the Covered Assets are Class II assets, and N allocates basis to such assets equal to their fair market value under paragraphs (c)(3)(ii), (d)(2)(ii), and (d)(2)(iii) of this section. Because the Third-Party Price for all of the Covered Assets is \$600,000 (\$500,000 for the loans and \$50,000 for each of the foreclosed properties), the Average Reimbursement Rate is 33.33% $((\$200,000 \times 0\%) + (\$400,000 \times 50\%) + (\$0 \times 95\%)) / \$600,000$. The Expected Value of the loans is \$666,667 (\$500,000 Third-Party Price + \$166,667 (the amount of the loss if the loans were disposed of for the Third-Party Price \times 33.33%)), and the Expected Value of each foreclosed property is \$66,667 (\$50,000 Third-Party Price + \$16,667 (the amount of the loss if the foreclosed property were sold for the Third-Party Price \times 33.33%)) under paragraph (b) of § 1.597-1. For purposes of allocating basis, the fair market value of the loans is \$666,667 (their Expected Value), and the fair market value of each foreclosed property is \$66,667 (its Expected Value) under paragraph (b) of § 1.597-1.

(ii) At the end of 2016, the Third-Party Price for the loans drops to \$400,000, and the Third-Party Price for each of the foreclosed properties remains at \$50,000. The fair market value of the loans at the end of Year 2 is their Expected Value, \$600,000 (\$400,000 Third-Party Price + \$200,000 (the amount of the loss if the loans were disposed of for the Third-Party Price \times 33.33% (the Average Reimbursement Rate does not change))). Thus, if the loans otherwise may be charged off, marked to a market value, depreciated, or amortized, then the loans may be marked down to \$600,000. The fair market value of each of the foreclosed properties remains at \$66,667 (\$50,000 Third-Party Price + \$16,667 (the amount of the loss if the foreclosed property were sold for the Third-Party Price \times 33.33%)). Therefore, the foreclosed properties may not be charged off or depreciated in 2016.

■ **Par. 7.** Section 1.597-6 is revised to read as follows:

§ 1.597-6 Limitation on collection of income tax.

(a) *Limitation on collection where tax is borne by Agency.* If an Institution without Continuing Equity (or any of its Consolidated Subsidiaries) is liable for income tax that is attributable to the inclusion in income of FFA or gain from a Taxable Transfer, the tax will not be collected if it would be borne by Agency. The final determination of whether the tax would be borne by Agency is within the sole discretion of the Commissioner. In determining whether tax would be borne by Agency, the Commissioner will disregard indemnity, tax-sharing, or similar obligations of Agency, an Institution, or its Consolidated Subsidiaries. Collection of the several income tax liability under

§ 1.1502-6 from members of an Institution's consolidated group other than the Institution or its Consolidated Subsidiaries is not affected by this section. Income tax will continue to be subject to collection except as specifically limited in this section. This section does not apply to taxes other than income taxes.

(b) *Amount of tax attributable to FFA or gain on a Taxable Transfer.* For purposes of paragraph (a) of this section, the amount of income tax in a taxable year attributable to the inclusion of FFA or gain from a Taxable Transfer in the income of an Institution (or a Consolidated Subsidiary) is the excess of the actual income tax liability of the Institution (or the consolidated group in which the Institution is a member) over the income tax liability of the Institution (or the consolidated group in which the Institution is a member) determined without regard to FFA or gain or loss on the Taxable Transfer.

(c) *Reporting of uncollected tax.* A taxpayer must specify on a statement included with its Form 1120 (U.S. Corporate Income Tax Return) the amount of income tax for the taxable year that is potentially not subject to collection under this section. If an Institution is a subsidiary member of a consolidated group, the amount specified as not subject to collection is zero.

(d) *Assessments of tax to offset refunds.* Income tax that is not collected under this section will be assessed and, thus, used to offset any claim for refund made by or on behalf of the Institution, the Consolidated Subsidiary or any other corporation with several liability for the tax.

(e) *Collection of taxes from Acquiring or a New Entity—(1) Acquiring.* No income tax liability (including the several liability for taxes under § 1.1502-6) of a transferor in a Taxable Transfer will be collected from Acquiring.

(2) *New Entity.* Income tax liability (including the several liability for taxes under § 1.1502-6) of a transferor in a Taxable Transfer will be collected from a New Entity only if stock that was outstanding in the Old Entity remains outstanding as stock in the New Entity or is reacquired or exchanged for consideration.

(f) *Effect on section 7507.* This section supersedes the application of section 7507, and the regulations thereunder, for the assessment and collection of income tax attributable to FFA.

■ **Par. 8.** Section 1.597-7 is revised to read as follows:

§ 1.597-7 Effective date.

(a) *FIRREA effective date.* Section 597, as amended by section 1401 of the Financial Institutions Reform, Recovery, and Enforcement Act of 1989 (Pub. L. 101-73, 103 Stat 183 (1989)) ("FIRREA") is generally effective for any FFA received or accrued by an Institution on or after May 10, 1989, and for any transaction in connection with which such FFA is provided, unless the FFA is provided in connection with an acquisition occurring prior to May 10, 1989. See § 1.597-8 for rules regarding FFA received or accrued on or after May 10, 1989, that relates to an acquisition that occurred before May 10, 1989.

(b) *Effective date of regulations.* Sections 1.597-1 through 1.597-6 will be effective on or after the date of publication of the Treasury decision adopting these proposed rules as final regulations in the **Federal Register**, except with respect to FFA provided pursuant to a written agreement that is binding before the date of publication of the Treasury decision adopting these proposed rules as final regulations in the **Federal Register**, and that continues to be binding at all times after such date, in which case §§ 1.597-1 through 1.597-6 as contained in 26 CFR part 1, revised April 1, 2014, will continue to apply unless the taxpayer elects to apply the final regulations on a retroactive basis pursuant to paragraph (c) of this section.

(c) *Elective application to prior years and transactions—(1) In general.* Except as limited in this paragraph (c), an election is available to apply §§ 1.597-1 through 1.597-6 to taxable years prior to the effective date of these regulations. A consolidated group may elect to apply §§ 1.597-1 through 1.597-6 for all members of the group in all taxable years to which section 597, as amended by FIRREA, applies. The common parent makes the election for the group. An entity that is not a member of a consolidated group may elect to apply §§ 1.597-1 through 1.597-6 to all taxable years to which section 597, as amended by FIRREA, applies for which it is not a member of a consolidated group. The election is irrevocable.

(2) *Election unavailable if statute of limitations closed.* The election cannot be made if the period for assessment and collection of tax has expired under the rules of section 6501 for any taxable year in which §§ 1.597-1 through 1.597-6 would affect the determination of the electing entity's or group's income, deductions, gain, loss, basis, or other items.

(3) *Manner of making election.* An Institution or consolidated group makes the election provided by this paragraph

(c) by including a written statement as a part of the taxpayer's or consolidated group's first annual income tax return filed on or after the date of publication of the Treasury decision adopting these proposed rules as final regulations in the **Federal Register**. The statement must contain the following legend at the top of the page: "THIS IS AN ELECTION UNDER § 1.597-7(c)," and must contain the name, address, and employer identification number of the taxpayer or common parent making the election. The statement must include a declaration that "TAXPAYER AGREES TO EXTEND THE STATUTE OF LIMITATIONS ON ASSESSMENT FOR THREE YEARS FROM THE DATE OF THE FILING OF THIS ELECTION UNDER § 1.597-7(c), IF THE LIMITATIONS PERIOD WOULD EXPIRE EARLIER WITHOUT SUCH EXTENSION, FOR ANY ITEMS AFFECTED IN ANY TAXABLE YEAR BY THE FILING OF THIS ELECTION," and a declaration that either "AMENDED RETURNS WILL BE FILED FOR ALL TAXABLE YEARS AFFECTED BY THE FILING OF THIS ELECTION WITHIN 180 DAYS OF MAKING THIS STATEMENT, UNLESS SUCH REQUIREMENT IS WAIVED IN WRITING BY THE INTERNAL REVENUE SERVICE" or "ALL RETURNS PREVIOUSLY FILED ARE CONSISTENT WITH THE PROVISIONS OF §§ 1.597-1 THROUGH 1.597-6." An election with respect to a consolidated group must be made by the common parent of the group, not Agency, and applies to all members of the group.

John Dalrymple,

Deputy Commissioner for Services and Enforcement.

[FR Doc. 2015-12230 Filed 5-19-15; 8:45 am]

BILLING CODE 4830-01-P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1956

[Docket No. OSHA-2015-0003]

Maine State Plan for State and Local Government Employers; Notice of Submission; Proposal To Grant Initial State Plan Approval; Request for Public Comment and Opportunity To Request Public Hearing

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

ACTION: Proposed rule; request for written comments; notice of opportunity to request informal public hearing.

SUMMARY: This document gives notice of the submission by the Maine Department of Labor of a developmental State Plan for occupational safety and health, applicable only to public sector employment (employees of the State and its political subdivisions), for determination of initial approval under Section 18 of the Occupational Safety and Health Act of 1970 (the "Act"). OSHA is seeking written public comment on whether or not initial State Plan approval should be granted and offers an opportunity to interested persons to request an informal public hearing on the question of initial State Plan approval. Approval of the Maine State and Local Government Only State Plan will be contingent upon a determination that the Plan meets, or will meet within three years, OSHA's Plan approval criteria and the availability of funding as contained in the Department of Labor's Fiscal Year 2015 budget.

DATES: Comments and requests for a hearing must be submitted by June 19, 2015.

ADDRESSES: *Written comments:* Submit comments, identified by docket number OSHA-2015-0003, by any of the following methods:

Electronically: Submit comments and attachments electronically at <http://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the instructions on-line for making electronic submissions; or

Fax: If your submission, including attachments, does not exceed 10 pages, you may fax them to the OSHA Docket Office at (202) 693-1648; or

U.S. mail, hand delivery, express mail, messenger or courier service: Submit your comments and attachments to the OSHA Docket Office, Docket Number OSHA-2015-0003, 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 and courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m.-4:45 p.m., EDT.

Instructions for submitting comments: All submissions must include the docket number (Docket No. OSHA-2015-0003) for this rulemaking. Because of security-related procedures, submission by regular mail may result in significant delay. Please contact the OSHA Docket Office for information

about security procedures for making submissions by hand delivery, express mail and messenger or courier service. All comments, including any personal information you provide, are placed in the public docket without change and will be made available online at <http://www.regulations.gov>. Therefore, OSHA cautions you about submitting personal information such as social security numbers and birthdates.

Docket: To read or download submissions in response to this **Federal Register** notice, go to docket number OSHA-2015-0003, at <http://www.regulations.gov>. All 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 page. All submissions, including copyrighted material, are available for inspection at the OSHA Docket Office. Electronic copies of this **Federal Register** document as well as copies of the proposed Maine State and Local Government Only State Plan narrative are available at <http://www.regulations.gov>. This document, as well as news releases and other relevant information, is available at OSHA's Web page at <http://www.osha.gov>. are available at OSHA's Web page at <http://www.osha.gov>. A copy of the documents referenced in this notice may also be obtained from the OSHA Docket Office, at the address above.

FOR FURTHER INFORMATION CONTACT:

For press inquiries: Contact Francis Meilinger, Office of Communications, Room N-3647, OSHA, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210; Telephone (202) 693-1999; email meilinger.francis2@dol.gov.

For general and technical information: Contact Douglas J. Kalinowski, Director, OSHA Directorate of Cooperative and State Programs, Room N-3700, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210, telephone (202) 693-2200; email: kalinowski.doug@dol.gov.

SUPPLEMENTARY INFORMATION:

A. Background

Section 18 of the Occupational Safety and Health Act of 1970 (the "Act"), 29 U.S.C. 667, provides that a State which desires to assume responsibility for the development and enforcement of standards relating to any occupational safety and health issue with respect to which a Federal standard has been promulgated may submit a State Plan to the Assistant Secretary of Labor for

Occupational Safety and Health (“Assistant Secretary”) documenting the proposed program in detail. Regulations promulgated pursuant to the Act at 29 CFR part 1956 provide that a State may submit a State Plan for the development and enforcement of occupational safety and health standards applicable only to employers of the State and its political subdivisions (“public employers”). Under these regulations the Assistant Secretary will approve a State Plan for public employers if the Plan provides for the development and enforcement of standards relating to hazards in employment covered by the Plan which are or will be at least as effective in providing safe and healthful employment and places of employment as standards promulgated and enforced under Section 6 of the Act, giving due consideration to differences between public and private sector employment. In making this determination the Assistant Secretary will consider, among other things, the criteria and indices of effectiveness set forth in 29 CFR part 1956, subpart B. State and local government workers are excluded from Federal OSHA coverage under the Act.

B. Maine State Plan History

Since 1971, the Maine Department of Labor, Bureau of Labor Standards (Bureau), has adopted standards and performed inspections in the public sector (State, county, and municipal employers) as outlined under the provisions of the State’s existing enabling legislation: Maine Revised Statutes, Title 26: Labor and Industry. Maine began working on a State and Local Government Only State Plan in 2012 and submitted a draft Plan to OSHA in February of 2013. OSHA’s review findings were detailed in various memoranda and other documents. OSHA determined that the Maine statutes, as structured, and the proposed State Plan necessitated changes in order to meet the State and Local Government Only State Plan approval criteria in 29 CFR 1956. Maine formally submitted a revised Plan applicable only to public employers for Federal approval on May 2, 2013. Over the next several months, OSHA worked with Maine in identifying areas of the proposed Plan which needed to be addressed or required clarification. In response to Federal review of the proposed State Plan, supplemental assurances, and revisions, corrections and additions to the Plan were submitted on September 4, 2013 and November 7, 2014. Further modifications were submitted by the State on December 19, 2014. Amendments to Maine Revised Statutes,

Title 26 were proposed and enacted by the Maine Legislature and signed into law by the Governor in 2014. The amended legislation provides the basis for establishing a comprehensive occupational safety and health program applicable to the public employers in the State. The revised Plan has been found to be conceptually approvable as a developmental State Plan.

The Act provides for funding of up to 50% of the State Plan costs, but longstanding language in OSHA’s appropriation legislation further provides that OSHA must fund “* * * no less than 50% of the costs . . . required to be incurred” by an approved State Plan. Such Federal funds to support the State Plan must be available prior to State Plan approval. The Fiscal Year 2015 Omnibus Appropriations Act includes \$400,000 in additional OSHA State Plan grant funds to allow for Department of Labor approval of a Maine State Plan. After an opportunity for public comment and a hearing, should one be requested, the Assistant Secretary will approve the Maine State and Local Government Only State Plan if it is determined that the Plan meets the criteria set forth in the Act and applicable regulations at 29 CFR part 1956, subpart B. The approval of a State Plan for state and local government employers in Maine is not a significant regulatory action as defined in Executive Order 12866.

C. Description of the Maine State Plan

The Plan designates the Maine Department of Labor as the State agency responsible for administering the Plan throughout the State. Under the Plan’s legislation, Title 26 of the Maine Revised Statutes, the Maine Department of Labor has full authority to adopt standards and regulations (through the Board of Occupational Safety and Health) and enforce and administer all laws and rules protecting the safety and health of employees of the State and its political subdivisions. Maine will adopt State standards identical to Federal occupational safety and health standards (with minor exceptions) as promulgated through March 30, 2015. The Plan also provides that future OSHA standards and revisions will be adopted by the State within six months of Federal promulgation (30 days for any emergency temporary standard) in accordance with the requirements at 29 CFR 1953.5. Title 26, Chapter 6, Section 571 of the Maine Revised Statutes includes provisions for the granting of permanent and temporary variances from State standards to public employers in terms substantially similar to the variance provisions contained in

the Act. Variances may not be granted unless it is established that adequate protection is afforded employees under the terms of the variance. Title 26, Chapter 6, Section 566 and Chapter 3, Section 44 of the Maine Revised Statutes provides for inspections of covered workplaces. Title 26, Chapter 3, Subsection 50 provides for inspections in response to employee complaints. If a determination is made that an employee complaint does not warrant an inspection, the complainant will be notified in writing of such determination. Additionally, Section 44–A of Chapter 3 provides the opportunity for employer and employee representatives to accompany an inspector during an inspection for the purpose of aiding in the inspection. The Plan in Title 26, Chapter 3, Sections 42–B and 45, provides for notification to employees of their protections and obligations under the Plan by such means as a State poster, required posting of notices of violation, etc. Title 26, Chapter 6, subsection 570 provides for protection of employees against discharge or discrimination resulting from exercise of their rights under the State Acts in terms essentially identical to Section 11(c) of the Federal Act. The Plan also includes provisions for right of entry for inspection, prohibition of advance notice of inspection, and employers’ obligations to maintain records and provide reports as required.

Section 46 of Title 26 contains authority for a system of first instance monetary penalties, and the State’s intent is to issue monetary penalties for serious violations. The State has discretionary authority for civil penalties of up to \$1,000 per day the violation continues for repeat and willful violations. Serious and other-than-serious violations may be assessed a penalty of up to \$1,000 per violation and failure-to-correct violations may be assessed a penalty of up to \$1,000 per day. In addition, criminal penalties can be issued to public employers who willfully violate any standard, rule or order. The Plan provides a scheme of enforcement for compelling compliance under which public employers are issued citations for any violation of standards. These citations must describe the nature of the violation, including reference to the standard, and fix a reasonable time for abatement. The Maine Plan includes the Board of Occupational Safety and Health (Board), which adopts standards, and also is an independent review authority for review of contested cases. The Director of the Bureau will remain responsible for the enforcement process, including the

issuance of citations and penalties, and their defense, if contested. Public employers or their representatives who receive a citation or a proposed penalty may within 15 working days contest the citation, proposed penalty and/or abatement period and request a hearing before the Board. Any public employee or representative aggrieved by a citation or proposed penalty may within 15 working days request a hearing before the Board. Employers may also request informal review of penalties with the Bureau if the employer agrees to abate the cited hazard. The Board's decision is subject to appeal to the courts.

The State currently has a staff of two safety compliance officers and zero health compliance officers. The Bureau delivers OSHA's On-Site Consultation program to private sector employers throughout the State. Maine currently has a staff of three safety and two health consultants, who perform duties equivalent to OSHA's On-Site Consultation program, for state and local government employers. Currently, for these employers, if the state receives a health complaint, a consultant will accompany and assist the enforcement officer. The Plan provides assurances that within six months no staff will have dual roles, and the State will have a fully trained, adequate staff of two safety compliance officers and one health compliance officer for enforcement inspections, and three safety consultants and one health consultant to perform consultation services in the public sector. As new staff members are hired they will perform either enforcement or consultation functions. 29 CFR 1956.10(g) requires that State Plans for public employers provide a sufficient number of adequately trained and qualified personnel necessary for the enforcement of standards. The compliance staffing requirements (or benchmarks) for State Plans covering both the private and public sectors are established based on the "fully effective" test established in *AFL-CIO v. Marshall*, 570 F.2d 1030 (D.C. Cir. 1978). This staffing test, and the complicated formula used to derive benchmarks for complete private/public sector Plans, is not intended, nor is it appropriate, for application to the staffing needs of public employer only Plans. However, the State has given satisfactory assurance in its Plan that it will meet the staffing requirements of 29 CFR 1956.10. The State has also given satisfactory assurances of adequate State matching funds (50%) to support the Plan and is requesting initial Federal funding of \$400,000 for a total initial

program effort of \$800,000. Although the State statute sets forth the general authority and scope for implementing the Maine State and Local Government Only State Plan, the Plan is developmental under the terms of 29 CFR 1956.2(b), in that specific rules, regulations, and implementing procedures must still be adopted or revised to carry out the Plan and make it structurally "at least as effective" as Federal OSHA and fully operational. The Plan sets forth a timetable for the accomplishment of these and other developmental goals within three years of Plan approval. This timetable addresses such general areas as the minor revision of existing legislation and development of procedures for the on-site public sector consultation program. Other developmental aspects include hiring and training of staff, participation in OSHA's Information System (OIS), development of a Field Operations Manual, development of an Annual Performance Plan and a Five-Year Strategic Plan and all other implementing policies, procedures, regulations and instruction necessary for the operation of an effective program.

D. Request for Public Comment and Opportunity To Request Hearing

Public comment on the Maine State and Local Government Only State Plan is hereby requested. Interested persons are invited to submit written data, views, and comments with respect to this proposed initial State Plan approval. These comments must be received on or before June 19, 2015. Written submissions must clearly identify the issues that are addressed and the positions taken with respect to each issue. The State of Maine will be afforded the opportunity to respond to each submission. The Maine Department of Labor must also publish appropriate notice within the State of Maine within five days of publication of this notice, announcing OSHA's proposal to approve a Maine State and Local Government Only State Plan, contingent on the availability of appropriated funds, and giving notice of the opportunity for public comment. Pursuant to 29 CFR 1902.13(f), interested persons may request an informal hearing concerning the proposed initial State Plan approval. Such requests also must be received on or before June 19, 2015 and may be submitted electronically, by facsimile, or by regular mail, hand delivery, express mail, messenger or courier service, as indicated under **ADDRESSES** above. Such requests must present particularized written objections to the

proposed initial State Plan approval. Within 30 days of the close of the comment period, the Assistant Secretary will review all comments submitted; will review all hearing requests; and will schedule an informal hearing if a hearing is required to resolve substantial issues. The Assistant Secretary will, within a reasonable time after the close of the comment period or after the certification of the record if a hearing is held, publish a decision in the **Federal Register**. All written and oral submissions, as well as other information gathered by OSHA, will be considered in any action taken. The record of this proceeding, including written comments and requests for hearing, and all materials submitted in response to this notice and at any subsequent hearing, will be available at <http://www.regulations.gov> or the OSHA Docket Office at the address above.

E. Regulatory Flexibility Act

OSHA certifies pursuant to the Regulatory Flexibility Act of 1980 (5 U.S.C. 601 *et seq.*) that the proposed initial approval of the Maine State Plan will not have a significant economic impact on a substantial number of small entities. By its own terms, the Plan will have no effect on private sector employment, but is limited to the State and its political subdivisions. Moreover, Title 26, Labor and Industry, of the Maine Revised Statutes, was enacted in 1971. This legislation established the Board, whose purpose is to formulate rules that shall, at a minimum, conform with federal standards of occupational safety and health, so the state program could eventually be approved as State and Local Government Only State Plan. Since 1971 the Maine program for public employers has been in operation under the Maine Department of Labor with State funding and all state and local government employers in the State have been subject to its terms. Compliance with State OSHA standards is required by State law; Federal approval of a State Plan imposes regulatory requirements only on the agency responsible for administering the State Plan. Accordingly, no new obligations would be placed on public sector employers as a result of Federal approval of the Plan.

F. Federalism

Executive Order 13132, "Federalism," emphasizes consultation between Federal agencies and the States and establishes specific review procedures the Federal government must follow as it carries out policies which affect state or local governments. OSHA has consulted extensively with Maine

throughout the development, submission and consideration of its proposed State Plan. Although OSHA has determined that the requirements and consultation procedures provided in Executive Order 13132 are not applicable to initial approval decisions under the Act, which have no effect outside the particular State receiving the approval, OSHA has reviewed the Maine initial approval decision proposed today, and believes it is consistent with the principles and criteria set forth in the Executive Order.

Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, U.S. Department of Labor, 200 Constitution Ave. NW., Washington, DC, authorized the preparation of this notice. OSHA is issuing this notice under the authority specified by Section 18 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 667), Secretary of Labor's Order No. 1–2012 (77 FR 3912), and 29 CFR parts 1902 and 1956.

Signed in Washington, DC, on May 14, 2015.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2015–12154 Filed 5–19–15; 8:45 am]

BILLING CODE 4510–26–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2013–0819; FRL–9927–47–Region 5]

Approval and Promulgation of Air Quality Implementation Plans; Illinois; NAAQS Update

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve a revision to the Illinois State Implementation Plan. The submitted state rule revisions update Illinois' ambient air quality standards for sulfur dioxide, ozone, nitrogen dioxide, lead, fine particulate matter, particulate matter, and carbon monoxide and bring them up to date (through 2012) with EPA-promulgated National Ambient Air Quality Standards. The SIP revision also adopts EPA-promulgated monitoring methods and test procedures for the revised state air quality standards.

DATES: Comments must be received on or before June 19, 2015.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2013–0819, by one of the following methods:

1. *www.regulations.gov*: Follow the on-line instructions for submitting comments.
2. *Email*: Aburano.Douglas@epa.gov.
3. *Fax*: (312) 408–2279.
4. *Mail*: Douglas Aburano, Chief, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604.
5. *Hand Delivery*: Douglas Aburano, Chief, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18J), U.S. Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604. Such deliveries are only accepted during the Regional Office normal hours of operation, and special arrangements should be made for deliveries of boxed information. The Regional Office official hours of business are Monday through Friday, 8:30 a.m. to 4:30 p.m., excluding Federal holidays.

Please see the direct final rule which is located in the Rules section of this **Federal Register** for detailed instructions on how to submit comments.

FOR FURTHER INFORMATION CONTACT:

Edward Doty, Air Programs Branch (AR–18J), Environmental Protection Agency, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6057, Doty.Edward@epa.gov.

SUPPLEMENTARY INFORMATION: In the Final Rules section of this **Federal Register**, EPA is approving the State's SIP submittal as a direct final rule without prior proposal because the Agency views this as a noncontroversial submittal and anticipates no adverse comments. A detailed rationale for the approval is set forth in the direct final rule. If no adverse comments are received in response to this rule, no further activity is contemplated. If EPA receives adverse comments, the direct final rule will be withdrawn and all public comments received will be addressed in a subsequent final rule based on this proposed rule. EPA will not institute a second comment period. Any parties interested in commenting on this action should do so at this time. Please note that, if EPA receives adverse comment on an amendment, paragraph, or section of this rule and if that provision may be severed from the remainder of the rule, EPA may adopt as final those provisions of the rule that are not the subject of an adverse comment. For additional information,

see the direct final rule which is located in the Rules section of this **Federal Register**.

Dated: May 4, 2015.

Susan Hedman,

Regional Administrator, Region 5.

[FR Doc. 2015–12253 Filed 5–19–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R09–OAR–2014–0812; FRL–9927–89–Region 9]

Partial Approval and Disapproval of Air Quality State Implementation Plans; Nevada; Infrastructure Requirements for Ozone, Nitrogen Dioxide, and Sulfur Dioxide

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing to partially approve and partially disapprove the Nevada State Implementation Plan (SIP) as meeting the requirements of the Clean Air Act (CAA or the Act) for the implementation, maintenance, and enforcement of the 2008 ozone, 2010 nitrogen dioxide (NO₂), and 2010 sulfur dioxide (SO₂) national ambient air quality standards (NAAQS). CAA section 110(a)(1) requires that each state adopt and submit a SIP for the implementation, maintenance, and enforcement of each NAAQS promulgated by the EPA, and that EPA act on such SIPs. We refer to such SIPs as “infrastructure” SIPs because they are intended to address basic structural SIP requirements for new or revised NAAQS including, but not limited to, legal authority, regulatory structure, resources, permit programs, monitoring, and modeling necessary to assure attainment and maintenance of the standards. In addition to our proposed partial approval and partial disapproval of Nevada's infrastructure SIP, we are proposing to reclassify certain regions of the state for SO₂ emergency episode planning and remove obsolete language from the Nevada SIP. We are taking comments on this proposal and plan to follow with a final action.

DATES: Written comments must be received on or before June 19, 2015.

ADDRESSES: EPA has established a docket for this action, identified by Docket ID Number EPA–R09–OAR–2014–0812. The index to the docket for this action is available electronically at <http://www.regulations.gov> and in hard

copy at EPA Region IX, 75 Hawthorne Street, San Francisco, California. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (e.g., copyrighted material), and some may not be publicly available in either location (e.g., CBI). To inspect the hard copy materials, please schedule an appointment during normal business hours with the contact listed directly below.

FOR FURTHER INFORMATION CONTACT: Tom Kelly, Air Planning Office (AIR-2), U.S. Environmental Protection Agency, Region IX, (415) 972-3856, kelly.thomas@epa.gov.

SUPPLEMENTARY INFORMATION:

Throughout this document, the terms “we,” “us,” and “our” refer to EPA.

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I. EPA’s Approach to the Review of Infrastructure SIP Submissions

EPA is acting upon several SIP submittals from Nevada that address the infrastructure requirements of CAA sections 110(a)(1) and 110(a)(2) for the 2008 ozone, 2010 NO₂, and 2010 SO₂ NAAQS. The requirement for states to make a SIP submittal of this type arises out of CAA section 110(a)(1). Pursuant to section 110(a)(1), states must make SIP submittals “within 3 years (or such shorter period as the Administrator may prescribe) after the promulgation of a national primary ambient air quality standard (or any revision thereof),” and these SIP submittals are to provide for the “implementation, maintenance, and enforcement” of such NAAQS. The statute directly imposes on states the duty to make these SIP submittals, and the requirement to make the submittals is not conditioned upon EPA’s taking any action other than promulgating a new or revised NAAQS. Section 110(a)(2) includes a list of specific

elements that “[e]ach such plan” submittal must address.

EPA has historically referred to these SIP submittals made for the purpose of satisfying the requirements of CAA sections 110(a)(1) and 110(a)(2) as “infrastructure SIP” submittals. Although the term “infrastructure SIP” does not appear in the CAA, EPA uses the term to distinguish this particular type of SIP submittal from submittals that are intended to satisfy other SIP requirements under the CAA, such as “nonattainment SIP” or “attainment SIP” submittals to address the nonattainment planning requirements of part D of title I of the CAA, “regional haze SIP” submittals required by EPA rule to address the visibility protection requirements of CAA section 169A, and nonattainment new source review (NSR) permit program submittals to address the permit requirements of CAA, title I, part D.

Section 110(a)(1) addresses the timing and general requirements for infrastructure SIP submittals, and section 110(a)(2) provides more details concerning the required contents of these submittals. The list of required elements provided in section 110(a)(2) contains a wide variety of disparate provisions, some of which pertain to required legal authority, some of which pertain to required substantive program provisions, and some of which pertain to requirements for both authority and substantive program provisions.¹ EPA therefore believes that while the timing requirement in section 110(a)(1) is unambiguous, some of the other statutory provisions are ambiguous. In particular, EPA believes that the list of required elements for infrastructure SIP submittals provided in section 110(a)(2) contains ambiguities concerning what is required for inclusion in an infrastructure SIP submittal.

The following examples of ambiguities illustrate the need for EPA to interpret some section 110(a)(1) and section 110(a)(2) requirements with respect to infrastructure SIP submittals for a given new or revised NAAQS. One example of ambiguity is that section 110(a)(2) requires that “each” SIP submittal must meet the list of requirements therein, while EPA has long noted that this literal reading of the statute is internally inconsistent and

¹ For example: Section 110(a)(2)(E)(i) provides that states must provide assurances that they have adequate legal authority under state and local law to carry out the SIP; section 110(a)(2)(C) provides that states must have a SIP-approved program to address certain sources as required by part C of title I of the CAA; and section 110(a)(2)(G) provides that states must have legal authority to address emergencies as well as contingency plans that are triggered in the event of such emergencies.

would create a conflict with the nonattainment provisions in part D of title I of the Act, which specifically address nonattainment SIP requirements.² Section 110(a)(2)(I) pertains to nonattainment SIP requirements and part D addresses when attainment plan SIP submittals to address nonattainment area requirements are due. For example, section 172(b) requires EPA to establish a schedule for submittal of such plans for certain pollutants when the Administrator promulgates the designation of an area as nonattainment, and section 107(d)(1)(B) allows up to two years, or in some cases three years, for such designations to be promulgated.³ This ambiguity illustrates that rather than apply all the stated requirements of section 110(a)(2) in a strict literal sense, EPA must determine which provisions of section 110(a)(2) are applicable for a particular infrastructure SIP submittal.

Another example of ambiguity within sections 110(a)(1) and 110(a)(2) with respect to infrastructure SIPs pertains to whether states must meet all of the infrastructure SIP requirements in a single SIP submittal, and whether EPA must act upon such SIP submittal in a single action. Although section 110(a)(1) directs states to submit “a plan” to meet these requirements, EPA interprets the CAA to allow states to make multiple SIP submittals separately addressing infrastructure SIP elements for the same NAAQS. If states elect to make such multiple SIP submittals to meet the infrastructure SIP requirements, EPA can elect to act on such submittals either individually or in a larger combined action.⁴ Similarly, EPA

² See, e.g., “Rule To Reduce Interstate Transport of Fine Particulate Matter and Ozone (Clean Air Interstate Rule); Revisions to Acid Rain Program; Revisions to the NO_x SIP Call; Final Rule,” 70 FR 25162, at 25163–25165, May 12, 2005 (explaining relationship between timing requirement of section 110(a)(2)(D) versus section 110(a)(2)(I)).

³ EPA notes that this ambiguity within section 110(a)(2) is heightened by the fact that various subparts of part D set specific dates for submittal of certain types of SIP submittals in designated nonattainment areas for various pollutants. Note, e.g., that section 182(a)(1) provides specific dates for submittal of emissions inventories for the ozone NAAQS. Some of these specific dates are necessarily later than three years after promulgation of the new or revised NAAQS.

⁴ See, e.g., “Approval and Promulgation of Implementation Plans; New Mexico; Revisions to the New Source Review (NSR) State Implementation Plan (SIP); Prevention of Significant Deterioration (PSD) and Nonattainment New Source Review (NNSR) Permitting,” 78 FR 4339, January 22, 2013 (EPA’s final action approving the structural PSD elements of the New Mexico SIP submitted by the State separately to meet the requirements of EPA’s 2008 PM_{2.5} NSR rule), and “Approval and Promulgation of Air Quality Implementation Plans; New Mexico;

interprets the CAA to allow it to take action on the individual parts of one larger, comprehensive infrastructure SIP submittal for a given NAAQS without concurrent action on the entire submittal. For example, EPA has sometimes elected to act at different times on various elements and sub-elements of the same infrastructure SIP submittal.⁵

Ambiguities within sections 110(a)(1) and 110(a)(2) may also arise with respect to infrastructure SIP submittal requirements for different NAAQS. Thus, EPA notes that not every element of section 110(a)(2) would be relevant, or as relevant, or relevant in the same way, for each new or revised NAAQS. The states' attendant infrastructure SIP submittals for each NAAQS therefore could be different. For example, the monitoring requirements that a state might need to meet in its infrastructure SIP submittal for purposes of section 110(a)(2)(B) could be very different for different pollutants, for example because the content and scope of a state's infrastructure SIP submittal to meet this element might be very different for an entirely new NAAQS than for a minor revision to an existing NAAQS.⁶

EPA notes that interpretation of section 110(a)(2) is also necessary when EPA reviews other types of SIP submittals required under the CAA. Therefore, as with infrastructure SIP submittals, EPA also has to identify and interpret the relevant elements of section 110(a)(2) that logically apply to these other types of SIP submittals. For example, section 172(c)(7) requires that attainment plan SIP submittals required by part D have to meet the "applicable requirements" of section 110(a)(2). Thus, for example, attainment plan SIP submittals must meet the requirements of section 110(a)(2)(A) regarding enforceable emission limits and control measures and section 110(a)(2)(E)(i) regarding air agency resources and

authority. By contrast, it is clear that attainment plan SIP submittals required by part D would not need to meet the portion of section 110(a)(2)(C) that pertains to the air quality prevention of significant deterioration (PSD) program required in part C of title I of the CAA, because PSD does not apply to a pollutant for which an area is designated nonattainment and thus subject to part D planning requirements. As this example illustrates, each type of SIP submittal may implicate some elements of section 110(a)(2) but not others.

Given the potential for ambiguity in some of the statutory language of section 110(a)(1) and section 110(a)(2), EPA believes that it is appropriate to interpret the ambiguous portions of section 110(a)(1) and section 110(a)(2) in the context of acting on a particular SIP submittal. In other words, EPA assumes that Congress could not have intended that each and every SIP submittal, regardless of the NAAQS in question or the history of SIP development for the relevant pollutant, would meet each of the requirements, or meet each of them in the same way. Therefore, EPA has adopted an approach under which it reviews infrastructure SIP submittals against the list of elements in section 110(a)(2), but only to the extent each element applies for that particular NAAQS.

Historically, EPA has elected to use guidance documents to make recommendations to states for infrastructure SIPs, in some cases conveying needed interpretations on newly arising issues and in some cases conveying interpretations that have already been developed and applied to individual SIP submittals for particular elements.⁷ EPA most recently issued guidance for infrastructure SIPs on September 13, 2013 (2013 Infrastructure SIP Guidance).⁸ EPA developed this document to provide states with up-to-date guidance for infrastructure SIPs for any new or revised NAAQS. Within this guidance, EPA describes the duty of states to make infrastructure SIP submittals to meet basic structural SIP requirements within three years of

promulgation of a new or revised NAAQS. EPA also made recommendations about many specific subsections of section 110(a)(2) that are relevant in the context of infrastructure SIP submittals.⁹ The guidance also discusses the substantively important issues that are germane to certain subsections of section 110(a)(2). Significantly, EPA interprets sections 110(a)(1) and 110(a)(2) such that infrastructure SIP submittals need to address certain issues and need not address others. Accordingly, EPA reviews each infrastructure SIP submittal for compliance with the applicable statutory provisions of section 110(a)(2), as appropriate.

As an example, section 110(a)(2)(E)(ii) is a required element of section 110(a)(2) for infrastructure SIP submittals. Under this element, a state must meet the substantive requirements of section 128, which pertain to state boards that approve permits or enforcement orders and heads of executive agencies with similar powers. Thus, EPA reviews infrastructure SIP submittals to ensure that the state's SIP appropriately addresses the requirements of section 110(a)(2)(E)(ii) and section 128. The 2013 Infrastructure SIP Guidance explains EPA's interpretation that there may be a variety of ways by which states can appropriately address these substantive statutory requirements, depending on the structure of an individual state's permitting or enforcement program (e.g., whether permits and enforcement orders are approved by a multi-member board or by a head of an executive agency). However they are addressed by the state, the substantive requirements of section 128 are necessarily included in EPA's evaluation of infrastructure SIP submittals because section 110(a)(2)(E)(ii) explicitly requires that the state satisfy the provisions of section 128.

As another example, EPA's review of infrastructure SIP submittals with respect to the PSD program requirements in sections 110(a)(2)(C), (D)(i)(II), and (J) focuses upon the structural PSD program requirements

Infrastructure and Interstate Transport Requirements for the 2006 PM_{2.5} NAAQS," 78 FR 4337, January 22, 2013 (EPA's final action on the infrastructure SIP for the 2006 PM_{2.5} NAAQS).

⁵ On December 14, 2007, the State of Tennessee, through the Tennessee Department of Environment and Conservation, made a SIP revision to EPA demonstrating that the State meets the requirements of sections 110(a)(1) and (2). EPA proposed action for infrastructure SIP elements (C) and (J) on January 23, 2012 (77 FR 3213) and took final action on March 14, 2012 (77 FR 14976). On April 16, 2012 (77 FR 22533) and July 23, 2012 (77 FR 42997), EPA took separate proposed and final actions on all other section 110(a)(2) infrastructure SIP elements of Tennessee's December 14, 2007 submittal.

⁶ For example, implementation of the 1997 PM_{2.5} NAAQS required the deployment of a system of new monitors to measure ambient levels of that new indicator species for the new NAAQS.

⁷ EPA notes, however, that nothing in the CAA requires EPA to provide guidance or to promulgate regulations for infrastructure SIP submittals. The CAA directly applies to states and requires the submittal of infrastructure SIP submittals, regardless of whether or not EPA provides guidance or regulations pertaining to such submittals. EPA elects to issue such guidance in order to assist states, as appropriate.

⁸ "Guidance on Infrastructure State Implementation Plan (SIP) Elements under Clean Air Act Sections 110(a)(1) and 110(a)(2)," Memorandum from Stephen D. Page, September 13, 2013.

⁹ EPA's September 13, 2013, guidance did not make recommendations with respect to infrastructure SIP submittals to address section 110(a)(2)(D)(i)(I). EPA issued the guidance shortly after the U.S. Supreme Court agreed to review the D.C. Circuit decision in *EME Homer City*, 696 F.3d (D.C. Cir. 2012) which had interpreted the requirements of section 110(a)(2)(D)(i)(I). In light of the uncertainty created by ongoing litigation, EPA elected not to provide additional guidance on the requirements of section 110(a)(2)(D)(i)(I) at that time. As the guidance is neither binding nor required by statute, whether EPA elects to provide guidance on a particular section has no impact on a state's CAA obligations.

contained in part C, title I of the Act and EPA's PSD regulations. Structural PSD program requirements include provisions necessary for the PSD program to address all regulated sources and regulated NSR pollutants, including greenhouse gases (GHGs). By contrast, structural PSD program requirements do not include provisions that are not required under EPA's regulations at 40 CFR 51.166 but are merely available as an option for the state, such as the option to provide grandfathering of complete permit applications with respect to the 2012 PM_{2.5} NAAQS. Accordingly, the latter optional provisions are types of provisions EPA considers irrelevant in the context of an infrastructure SIP action.

For other section 110(a)(2) elements, however, EPA's review of a state's infrastructure SIP submittal focuses on assuring that the state's SIP meets basic structural requirements. For example, section 110(a)(2)(C) includes, *inter alia*, the requirement that states have a program to regulate minor new sources. Thus, EPA evaluates whether the state has a SIP-approved minor NSR program and whether the program addresses the pollutants relevant to that NAAQS. In the context of acting on an infrastructure SIP submittal, however, EPA does not think it is necessary to conduct a review of each and every provision of a state's existing minor source program (*i.e.*, already in the existing SIP) for compliance with the requirements of the CAA and EPA's regulations that pertain to such programs.

With respect to certain other issues, EPA does not believe that an action on a state's infrastructure SIP submittal is necessarily the appropriate type of action in which to address possible deficiencies in a state's existing SIP. These issues include: (i) Existing provisions related to excess emissions from sources during periods of startup, shutdown, or malfunction that may be contrary to the CAA and EPA's policies addressing such excess emissions ("SSM"); (ii) existing provisions related to "director's variance" or "director's discretion" that may be contrary to the CAA because they purport to allow revisions to SIP-approved emissions limits while limiting public process or not requiring further approval by EPA; and (iii) existing provisions for PSD programs that may be inconsistent with current requirements of EPA's "Final NSR Improvement Rule," 67 FR 80186, December 31, 2002, as amended by 72 FR 32526, June 13, 2007 ("NSR Reform"). Thus, EPA believes it may approve an infrastructure SIP submittal without scrutinizing the totality of the

existing SIP for such potentially deficient provisions and may approve the submittal even if it is aware of such existing provisions.¹⁰ It is important to note that EPA's approval of a state's infrastructure SIP submittal should not be construed as explicit or implicit re-approval of any existing potentially deficient provisions that relate to the three specific issues just described.

EPA's approach to review of infrastructure SIP submittals is to identify the CAA requirements that are logically applicable to that submittal. EPA believes that this approach to the review of a particular infrastructure SIP submittal is appropriate, because it would not be reasonable to read the general requirements of section 110(a)(1) and the list of elements in 110(a)(2) as requiring review of each and every provision of a state's existing SIP against all requirements in the CAA and EPA regulations merely for purposes of assuring that the state in question has the basic structural elements for a functioning SIP for a new or revised NAAQS. Because SIPs have grown by accretion over the decades as statutory and regulatory requirements under the CAA have evolved, they may include some outmoded provisions and historical artifacts. These provisions, while not fully up to date, nevertheless may not pose a significant problem for the purposes of "implementation, maintenance, and enforcement" of a new or revised NAAQS when EPA evaluates adequacy of the infrastructure SIP submittal. EPA believes that a better approach is for states and EPA to focus attention on those elements of section 110(a)(2) of the CAA most likely to warrant a specific SIP revision due to the promulgation of a new or revised NAAQS or other factors.

For example, EPA's 2013 Infrastructure SIP Guidance gives simpler recommendations with respect to carbon monoxide than other NAAQS pollutants to meet the visibility requirements of section 110(a)(2)(D)(i)(II), because carbon monoxide does not affect visibility. As a result, an infrastructure SIP submittal for any future new or revised NAAQS for carbon monoxide need only state this fact in order to address the visibility prong of section 110(a)(2)(D)(i)(II).

Finally, EPA believes that its approach with respect to infrastructure

¹⁰ By contrast, EPA notes that if a state were to include a new provision in an infrastructure SIP submittal that contained a legal deficiency, such as a new exemption for excess emissions during SSM events, then EPA would need to evaluate that provision for compliance against the rubric of applicable CAA requirements in the context of the action on the infrastructure SIP.

SIP requirements is based on a reasonable reading of sections 110(a)(1) and 110(a)(2) because the CAA provides other avenues and mechanisms to address specific substantive deficiencies in existing SIPs. These other statutory tools allow EPA to take appropriately tailored action, depending upon the nature and severity of the alleged SIP deficiency. Section 110(k)(5) authorizes EPA to issue a "SIP call" whenever the Agency determines that a state's SIP is substantially inadequate to attain or maintain the NAAQS, to mitigate interstate transport, or to otherwise comply with the CAA.¹¹ Section 110(k)(6) authorizes EPA to correct errors in past actions, such as past approvals of SIP submittals.¹² Significantly, EPA's determination that an action on a state's infrastructure SIP submittal is not the appropriate time and place to address all potential existing SIP deficiencies does not preclude EPA's subsequent reliance on provisions in section 110(a)(2) as part of the basis for action to correct those deficiencies at a later time. For example, although it may not be appropriate to require a state to eliminate all existing inappropriate director's discretion provisions in the course of acting on an infrastructure SIP submittal, EPA believes that section 110(a)(2)(A) may be among the statutory bases that EPA relies upon in the course of addressing such deficiency in a subsequent action.¹³

¹¹ For example, EPA issued a SIP call to Utah to address specific existing SIP deficiencies related to the treatment of excess emissions during SSM events. See "Finding of Substantial Inadequacy of Implementation Plan; Call for Utah State Implementation Plan Revisions," 76 FR 21639, April 18, 2011.

¹² EPA has used this authority to correct errors in past actions on SIP submittals related to PSD programs. See "Limitation of Approval of Prevention of Significant Deterioration Provisions Concerning Greenhouse Gas Emitting-Sources in State Implementation Plans; Final Rule," 75 FR 82536, December 30, 2010. EPA has previously used its authority under CAA section 110(k)(6) to remove numerous other SIP provisions that the Agency determined it had approved in error. See, e.g., 61 FR 38664, July 25, 1996 and 62 FR 34641, June 27, 1997 (corrections to American Samoa, Arizona, California, Hawaii, and Nevada SIPs); 69 FR 67062, November 16, 2004 (corrections to California SIP); and 74 FR 57051, November 3, 2009 (corrections to Arizona and Nevada SIPs).

¹³ See, e.g., EPA's disapproval of a SIP submittal from Colorado on the grounds that it would have included a director's discretion provision inconsistent with CAA requirements, including section 110(a)(2)(A). See, e.g., 75 FR 42342 at 42344, July 21, 2010 (proposed disapproval of director's discretion provisions); 76 FR 4540, January 26, 2011 (final disapproval of such provisions).

II. Background

A. Statutory Framework

Section 110(a)(1) of the CAA requires states to make a SIP submission within 3 years after the promulgation of a new or revised primary NAAQS. Section 110(a)(2) includes a list of specific elements that “[e]ach such plan” submission must include. Many of the section 110(a)(2) SIP elements relate to the general information and authorities that constitute the “infrastructure” of a state’s air quality management program and SIP submittals that address these requirements are referred to as “infrastructure SIPs.” These infrastructure SIP elements required by section 110(a)(2) are as follows:

- Section 110(a)(2)(A): Emission limits and other control measures.
- Section 110(a)(2)(B): Ambient air quality monitoring/data system.
- Section 110(a)(2)(C): Program for enforcement of control measures and regulation of new and modified stationary sources.
 - Section 110(a)(2)(D)(i): Interstate pollution transport.
 - Section 110(a)(2)(D)(ii): Interstate and international pollution abatement.
 - Section 110(a)(2)(E): Adequate resources and authority, conflict of interest, and oversight of local and regional government agencies.
 - Section 110(a)(2)(F): Stationary source monitoring and reporting.
 - Section 110(a)(2)(G): Emergency episodes.
 - Section 110(a)(2)(H): SIP revisions.
 - Section 110(a)(2)(J): Consultation with government officials, public notification, PSD, and visibility protection.
 - Section 110(a)(2)(K): Air quality modeling and submittal of modeling data.
 - Section 110(a)(2)(L): Permitting fees.
 - Section 110(a)(2)(M): Consultation/participation by affected local entities.

Two elements identified in section 110(a)(2) are not governed by the three-year submittal deadline of section 110(a)(1) and are therefore not addressed in this action. These two elements are: Section 110(a)(2)(C) to the extent it refers to permit programs required under part D (nonattainment NSR), and section 110(a)(2)(I), pertaining to the nonattainment planning requirements of part D. As a result, this action does not address infrastructure for the nonattainment NSR portion of section 110(a)(2)(C) or the whole of section 110(a)(2)(I).

B. Regulatory Background

Between 1997 and 2012, EPA promulgated a series of new or revised

NAAQS for ozone, NO₂, and SO₂, triggering a requirement for states to submit infrastructure SIPs. The NAAQS addressed by this infrastructure SIP proposal include the following:

- 2008 ozone NAAQS, which revised the 8-hour ozone standards to 0.075 ppm.¹⁴
- 2010 NO₂ NAAQS, which revised the primary 1971 NO₂ annual standard of 53 parts per billion (ppb) by supplementing it with a new 1-hour average NO₂ standard of 100 ppb, and retained the secondary annual standard of 53 ppb.¹⁵
- 2010 SO₂ NAAQS, which established a new 1-hour average SO₂ standard of 75 ppb, retained the secondary 3-hour average SO₂ standard of 500 ppb, and established a mechanism for revoking the primary 1971 annual and 24-hour SO₂ standards.¹⁶

C. Changes to the Application of PSD Permitting Requirements With GHGs

With respect to Elements (C) and (J), EPA interprets the Clean Air Act to require each state to make an infrastructure SIP submission for a new or revised NAAQS that demonstrates that the air agency has a complete PSD permitting program meeting the current requirements for all regulated NSR pollutants. The requirements of Element D(i)(II) may also be satisfied by demonstrating the air agency has a complete PSD permitting program correctly addressing all regulated NSR pollutants. Nevada has shown that it currently has a PSD program in place that covers all regulated NSR pollutants, including greenhouse gases (GHGs), with the exception of the deficiencies in the NDEP and Washoe County portions of the SIP, described elsewhere in this document.

On June 23, 2014, the United States Supreme Court issued a decision addressing the application of PSD permitting requirements to GHG emissions.¹⁷ The Supreme Court said that the EPA may not treat GHGs as an air pollutant for purposes of determining whether a source is a major source required to obtain a PSD permit. The Court also said that the EPA could continue to require that PSD permits, otherwise required based on emissions of pollutants other than GHGs, contain

limitations on GHG emissions based on the application of Best Available Control Technology (BACT). In order to act consistently with its understanding of the Court’s decision pending further judicial action to effectuate the decision, the EPA is not continuing to apply EPA regulations that would require that SIPs include permitting requirements that the Supreme Court found impermissible. Specifically, EPA is not applying the requirement that a state’s SIP-approved PSD program require that sources obtain PSD permits when GHGs are the only pollutant (i) that the source emits or has the potential to emit above the major source thresholds, or (ii) for which there is a significant emissions increase and a significant net emissions increase from a modification (e.g. 40 CFR 51.166(b)(48)(v)). EPA anticipates a need to revise federal PSD rules in light of the Supreme Court opinion. In addition, EPA anticipates that many states will revise their existing SIP-approved PSD programs in light of the Supreme Court’s decision. The timing and content of subsequent EPA actions with respect to the EPA regulations and state PSD program approvals are expected to be informed by additional legal process before the United States Court of Appeals for the District of Columbia Circuit. At this juncture, EPA is not expecting states to have revised their PSD programs for purposes of infrastructure SIP submissions and is only evaluating such submissions to assure that the state’s program correctly addresses GHGs consistent with the Supreme Court’s decision.

At present, EPA has determined the Clark County SIP is sufficient to satisfy Elements C, D(i)(II), and J with respect to GHGs because the PSD permitting program previously approved by EPA into the SIP continues to require that PSD permits (otherwise required based on emissions of pollutants other than GHGs) contain limitations on GHG emissions based on the application of BACT. Although the SIP-approved Clark County PSD permitting program may currently contain provisions that are no longer necessary in light of the Supreme Court decision, this does not render the infrastructure SIP submission inadequate to satisfy Elements C, (D)(i)(II), and J. The SIP contains the necessary PSD requirements at this time, and the application of those requirements is not impeded by the presence of other previously-approved provisions regarding the permitting of sources of GHGs that EPA does not consider necessary at this time in light of the Supreme Court decision. Accordingly, the Supreme Court

¹⁴ 73 FR 16436, March 27, 2008.

¹⁵ 75 FR 6474, February 9, 2010. The annual NO₂ standard of 0.053 ppm is listed in ppb for ease of comparison with the new 1-hour standard.

¹⁶ 75 FR 35520, June 22, 2010. The annual SO₂ standard of 0.5 ppm is listed in ppb for ease of comparison with the new 1-hour standard.

¹⁷ *Utility Air Regulatory Group v. Environmental Protection Agency*, 134 S.Ct. 2427.

decision does not affect EPA's proposed approval of Clark County's infrastructure SIP as to the requirements of Elements C, D(i)(II), and J.

III. State Submittal and EPA Action

The Nevada Department of Environmental Protection (NDEP) has submitted several infrastructure SIP submittals pursuant to EPA's promulgation of specific NAAQS, including:

Ozone

- The Nevada Division of Environmental Protection Portion of the Nevada State Implementation Plan for the 2008 Ozone NAAQS: Demonstration of Adequacy April 10, 2013.

- State Implementation Plan Revision to Meet the Ozone Infrastructure SIP Requirements of the Clean Air Act section 110(a)(2), Clark County, Nevada, February 2013.

- The Washoe County Portion of the Nevada State Implementation Plan for the 2008 Ozone NAAQS: Demonstration of Adequacy, February 28, 2013.

NO₂

- NDEP letter to EPA, dated May 9, 2013 and Washoe County letter, dated April 26, 2013, containing the Approved Minutes of the February 28, 2013 public hearing and the Certificate of Adoption.

- The Nevada Division of Environmental Protection Portion of the Nevada State Implementation Plan for the 2010 Nitrogen Dioxide Primary NAAQS: Demonstration of Adequacy and appendices, January 18, 2013.

- State Implementation Plan Revision to Meet the Nitrogen Dioxide Infrastructure SIP Requirements of the Clean Air Act section 110(a)(2), and attachments Clark County, Nevada December 2012.

- The Washoe County Portion of the Nevada State Implementation Plan to Meet the Nitrogen Dioxide Infrastructure SIP Requirements of Clean Air Act section 110(a)(2) (draft document) and attachments, January 24, 2014.

SO₂

- The Nevada Division of Environmental Protection Portion of the Nevada State Implementation Plan for the 2010 Sulfur Dioxide Primary NAAQS, and appendices, June 3, 2013.

- State Implementation Plan Revision to Meet the Sulfur Dioxide Infrastructure SIP Requirements of the Clean Air Act section 110(a)(2), and attachments Clark County, Nevada, May 2013.

- The Washoe County Portion of the Nevada State Implementation Plan to

Meet the Sulfur Dioxide Infrastructure SIP Requirements of Clean Air Act section 110(a)(2), and attachments, March 28, 2013.

We find that these submittals meet the procedural requirements for public participation under CAA section 110(a)(2) and 40 CFR 51.102. We are proposing to act on all of these submittals since they collectively address the infrastructure SIP requirements for the NAAQS addressed by this proposed rule. We refer to them collectively herein as "Nevada's Infrastructure SIP Submittals."

IV. EPA's Evaluation and Proposed Action

A. Proposed Approvals and Partial Approvals

We have evaluated Nevada's Infrastructure SIP Submittals and the existing provisions of the Nevada SIP for compliance with the infrastructure SIP requirements (or "elements") of CAA section 110(a)(2) and applicable regulations in 40 CFR part 51 ("Requirements for Preparation, Adoption, and Submittal of State Implementation Plans"). The Technical Support Document (TSD), which is available in the docket to this action, includes our evaluation for many elements, as well as our evaluation of various statutory and regulatory provisions. For some elements, it refers to older TSDs for prior Nevada Infrastructure SIPs, which have also been included in the docket.

Based upon this analysis, we propose to approve the 2008 Ozone, 2010 NO₂, and 2010 SO₂ Nevada Infrastructure SIP with respect to the following Clean Air Act requirements:

- Section 110(a)(2)(A): Emission limits and other control measures.
- Section 110(a)(2)(B): Ambient air quality monitoring/data system.
- Section 110(a)(2)(C) (in part): Program for enforcement of control measures and regulation of new stationary sources (full approval for Clark County).
 - Section 110(a)(2)(D) (in part, see below): Interstate Pollution Transport.
 - Section 110(a)(2)(D)(i)(II) (in part)—significant contribution to nonattainment, or prongs 1 and 2 (full approval of NDEP, Clark County and Washoe County for the NO₂ NAAQS).
 - Section 110(a)(2)(D)(i)(II) (in part)—interference with maintenance, or prong 3 (full approval for Clark County).
 - Section 110(a)(2)(D)(i)(II) (full approval)—visibility transport, or prong 4.
 - Section 110(a)(2)(D)(ii) (in part)—interstate pollution abatement and

international air pollution (full approval for Clark County).

- Section 110(a)(2)(E): Adequate resources and authority, conflict of interest, and oversight of local governments and regional agencies.
- Section 110(a)(2)(F): Stationary source monitoring and reporting.
- Section 110(a)(2)(G): Emergency episodes.
- Section 110(a)(2)(H): SIP revisions.
- Section 110(a)(2)(J) (in part): Consultation with government officials, public notification, and prevention of significant deterioration (PSD) and visibility protection (full approval for Clark County).
 - Section 110(a)(2)(K): Air quality modeling and submission of modeling data.
 - Section 110(a)(2)(L): Permitting fees.
 - Section 110(a)(2)(M): Consultation/participation by affected local entities.

EPA is taking no action on Interstate Transport—significant contribution to nonattainment for NDEP, Clark County and Washoe County on the Ozone and SO₂ NAAQS (section 110(a)(2)(D)(i)(II)).

B. Proposed Partial Disapprovals

EPA proposes to disapprove Nevada's Infrastructure SIP Submittals with respect to the following infrastructure SIP requirements:

- Section 110(a)(2)(C) (in part): Program for enforcement of control measures and regulation of new and modified stationary sources (for all NAAQS addressed by this proposed rule and covered by the NDEP and Washoe County PSD permitting programs).
 - Section 110(a)(2)(D)(i)(II) (in part, see below): Interstate pollution transport.
 - Section 110(a)(2)(D)(i)(II) (in part)—interference with maintenance, or prong 3 (disapproved for all NAAQS addressed by this proposed rule and covered by the NDEP and Washoe County PSD permitting programs).
 - Section 110(a)(2)(D)(ii) (in part)—interstate pollution abatement and international air pollution (disapproved for all NAAQS addressed by this proposed rule and covered by the NDEP and Washoe County PSD permitting programs).
 - Section 110(a)(2)(J) (in part): Consultation with government officials, public notification, PSD, and visibility protection (for all NAAQS addressed by this proposed rule and covered by the NDEP and Washoe County PSD permitting programs).
- As explained more fully in our TSD, we are proposing to disapprove the NDEP and Washoe County portions of Nevada's Infrastructure Submittals with

respect to the PSD-related requirements of sections 110(a)(2)(C), 110(a)(2)(D)(i)(II), 110(a)(2)(D)(ii), and the PSD requirements of section 110(a)(2)(J). The Nevada SIP does not fully satisfy the statutory and regulatory requirements for PSD permit programs under part C, title I of the Act, because NDEP and Washoe County currently implement the Federal PSD program in 40 CFR 52.21 for all regulated NSR pollutants, pursuant to delegation agreements with EPA. See 40 CFR 52.1485.¹⁸ Accordingly, although the Nevada SIP remains deficient with respect to PSD requirements in both the NDEP and Washoe County portions of the SIP, these deficiencies are adequately addressed in both areas by the federal PSD program and do not create new FIP obligations.

In EPA's evaluation of Nevada's Infrastructure SIP Submittal for Lead (Pb), the requirements under sections 110(a)(2)(C), 110(a)(2)(D)(i)(II) and 110(a)(2)(J) regarding Clark County's PSD permitting program, specifically PSD increments for PM_{2.5}, initiated a requirement for the development of a Federal Implementation Plan (FIP) or sanctions. This deficiency has been addressed by the recent changes to the Clark County PSD permitting program, as discussed in Element C of the TSD.

C. Defining the Nevada Intrastate Air Quality Control Region

In reviewing the Nevada SIP Infrastructure submittal for compliance with CAA section 110(a)(2)(G), as discussed in section D below, we noted that the Nevada Intrastate Air Quality Control Region has not been defined in subpart B of 40 CFR part 81. The emergency episode priority classifications for the Region is provided by 40 CFR 52.1471 for many NAAQS. Additionally, EPA identified the counties of the Nevada Intrastate Region in a 1972 EPA report titled: Federal Air Quality Control Regions.¹⁹ To rectify the apparent **Federal Register** omission, we are proposing to define the Nevada Intrastate Air Quality Control

Region in subpart B of 40 CFR part 81, consistent with *Federal Air Quality Control Regions*, as comprised of the following counties: Elko, Humboldt, Pershing, Lander, Eureka, White Pine, Lincoln, Nye, Esmeralda, Mineral, and Churchill. On its own, this proposed change does not alter the priority classification of the Region for emergency episode purposes.

D. Proposed Approval of Reclassification Requests for Emergency Episode Planning

NDEP's portion of Nevada's SO₂ Infrastructure Submittal requested that EPA reclassify the Nevada Intrastate Air Quality Region with respect to the emergency episode planning requirements of CAA section 110(a)(2)(G) and 40 CFR part 51, subpart H. The priority thresholds for classification of regions are listed in 40 CFR 51.150 while the specific classifications of air quality control regions in Nevada are listed at 40 CFR 52.1471. Consistent with the provisions of 40 CFR 51.153, reclassification of an air quality control region must rely on the most recent three years of air quality data. Regions classified Priority I, IA, or II are required to have SIP-approved emergency episode contingency plans, while those classified Priority III are not required to have plans.²⁰ We interpret 40 CFR 51.153 as establishing the means for states to review air quality data and request a higher or lower classification for any given region and as providing the regulatory basis for EPA to reclassify such regions, as appropriate, under the authorities of CAA sections 110(a)(2)(G) and 301(a)(1).

The Nevada Intrastate Air Quality Control Region is classified as priority IA for SO₂. Priority IA means the region is classified as Priority I "primarily because of emissions from a single point source."²¹ As our TSD further clarifies, the point source appears to have been the copper smelter in McGill, Nevada, within the Steptoe Valley, operated by the Kennecott Minerals Company. The Kennecott smelter was the only major source of SO₂ emissions within the Nevada Interstate Region when the priority classifications were established in 1980.²²

Our attainment finding for Steptoe Valley (SO₂) nonattainment area stated that the Kennecott facility ceased operation in 1983, removed all smelting equipment in 1987, and demolished the facility's stack in 1993.²³ It continued

on to state "ambient air quality monitoring from 1979 to 1983 indicates there were no violations during the last years of the smelter operation." NDEP has not collected SO₂ monitoring data since 1983, nor are they currently required to do so.²⁴ Based on the information above and presented in our TSD, we are proposing to approve Nevada's request to reclassify the Nevada Intrastate Air Quality Region to Priority III for SO₂ emergency episode planning.

We also evaluated the Las Vegas Intrastate Air Quality Control Region (*i.e.* Clark County), which is also currently classified as Priority IA for SO₂. Their ambient air quality data for 2011–2013 does not exceed the Priority II level of 260–455 µg/m³ set at 40 CFR 51.150(d)(1). Therefore, based on the last three years of available data, we are proposing to reclassify the Las Vegas Intrastate Region to Priority III for SO₂.

E. Proposed Removal of Historic SIP Provisions

NDEP also requested that EPA remove paragraphs (a) and (b) of 40 CFR 52.1475, "Control strategy and regulations: Sulfur oxides." This section was added to the Nevada SIP ". . . to promulgate substitute regulations for the control of SO₂ at the Kennecott Copper Corporation Smelter, McGill, Nevada . . ." because we had disapproved Nevada's proposed SO₂ emission controls for the Kennecott smelter.²⁵ 40 CFR 52.1475 no longer applies since the Kennecott smelter is nonexistent and the area was redesignated as attainment. Since the provision serves no purpose beyond providing historic information, we are proposing to remove 40 CFR 52.1475 from the Nevada SIP.

F. Request for Public Comments

EPA is soliciting public comments on the issues discussed in this document or on other relevant matters. We will accept comments from the public on this proposal for the next 30 days. We will consider these comments before taking final action.

V. Statutory and Executive Order Reviews

Executive Order 12866: Regulatory Planning and Review

This action is not a "significant regulatory action" under the terms of

²⁴ SO₂ monitoring is not required for the Nevada Intrastate Air Quality Control Region, because it's population weighted exposure index does not exceed 5000 (million person-tons per year of SO₂), per 40 CFR part 58, appendix D 4.4.2.

²⁵ 40 FR 5508.

¹⁸ EPA fully delegated the implementation of the federal PSD programs to NDEP on October 19, 2004 ("Agreement for Delegation of the Federal Prevention of Significant Deterioration (PSD) Program by the United States Environmental Protection Agency, Region 9 to the Nevada Division of Environmental Protection"), as updated on September 15, 2011 and November 7, 2012, and to Washoe County on March 13, 2008 ("Agreement for Delegation of the Federal Prevention of Significant Deterioration (PSD) Program by the United States Environmental Protection Agency, Region 9 to the Washoe County District Health Department").

¹⁹ Federal Air Quality Control Regions, U.S. EPA, January 1972 <<http://nepis.epa.gov/Exe/ZyPDF.cgi/P10053PA.PDF?Dockey=P10053PA.PDF>> (last visited April 1, 2015).

²⁰ 40 CFR 51.151 and 51.152.

²¹ 40 CFR 51.150(c).

²² 40 FR 5508.

²³ 67 FR 17939.

Executive Order (EO) 12866 (58 FR 51735, October 4, 1993) and is therefore not subject to review under the EO.

Paperwork Reduction Act

This action does not impose an information collection burden under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*, because this proposed partial approval and partial disapproval of SIP revisions under CAA section 110 will not in-and-of itself create any new information collection burdens but simply proposes to approve certain State requirements, and to disapprove certain other State requirements, for inclusion into the SIP. Burden is defined at 5 CFR 1320.3(b).

Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA) generally requires an agency to conduct a regulatory flexibility analysis of any rule subject to notice and comment rulemaking requirements unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Small entities include small businesses, small not-for-profit enterprises, and small governmental jurisdictions. For purposes of assessing the impacts of this rule on small entities, small entity is defined as: (1) A small business as defined by the Small Business Administration's (SBA) regulations at 13 CFR 121.201; (2) a small governmental jurisdiction that is a government of a city, county, town, school district or special district with a population of less than 50,000; and (3) a small organization that is any not-for-profit enterprise which is independently owned and operated and is not dominant in its field.

After considering the economic impacts of this proposed rule, we certify that this proposed action will not have a significant impact on a substantial number of small entities. This proposed rule does not impose any requirements or create impacts on small entities. This proposed partial SIP approval and partial SIP disapproval under CAA section 110 will not in-and-of itself create any new requirements but simply proposes to approve certain State requirements, and to disapprove certain other State requirements, for inclusion into the SIP. Accordingly, it affords no opportunity for EPA to fashion for small entities less burdensome compliance or reporting requirements or timetables or exemptions from all or part of the rule. Therefore, this action will not have a significant economic impact on a substantial number of small entities.

We continue to be interested in the potential impacts of this proposed rule

on small entities and welcome comments on issues related to such impacts.

Unfunded Mandates Reform Act

This action contains no Federal mandates under the provisions of Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), 2 U.S.C. 1531–1538 for State, local, or tribal governments or the private sector. EPA has determined that the proposed partial approval and partial disapproval action does not include a Federal mandate that may result in estimated costs of \$100 million or more to either State, local, or tribal governments in the aggregate, or to the private sector. This action proposes to approve certain pre-existing requirements, and to disapprove certain other pre-existing requirements, under State or local law, and imposes no new requirements. Accordingly, no additional costs to State, local, or tribal governments, or to the private sector, result from this proposed action.

Executive Order 13132: Federalism

Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), requires EPA to develop an accountable process to ensure “meaningful and timely input by State and local officials in the development of regulatory policies that have federalism implications.” “Policies that have federalism implications” is defined in the Executive Order to include regulations that 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 action does not have federalism implications. It will 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, as specified in Executive Order 13132, because it merely proposes to approve certain State requirements, and to disapprove certain other State requirements, for inclusion into the SIP and does not alter the relationship or the distribution of power and responsibilities established in the Clean Air Act. Thus, Executive Order 13132 does not apply to this action.

Executive Order 13175: Coordination With Indian Tribal Governments

This action does not have tribal implications, as specified in Executive Order 13175 (65 FR 67249, November 9,

2000), because the SIP on which EPA is proposing action would not apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law. Thus, Executive Order 13175 does not apply to this proposed action.

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern health or safety risks, such that the analysis required under section 5–501 of the Executive Order has the potential to influence the regulation. This proposed action is not subject to Executive Order 13045 because it is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997). This proposed partial approval and partial disapproval under CAA section 110 will not in-and-of itself create any new regulations but simply proposes to approve certain State requirements, and to disapprove certain other State requirements, for inclusion into the SIP.

Executive Order 13211: Actions 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 it is not a significant regulatory action under Executive Order 12866.

National Technology Transfer and Advancement Act

Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (“NTTAA”), Public Law 104–113, 12(d) (15 U.S.C. 272 note) directs EPA to use voluntary consensus standards in its regulatory activities unless to do so would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (*e.g.*, materials specifications, test methods, sampling procedures, and business practices) that are developed or adopted by voluntary consensus standards bodies. NTTAA directs EPA to provide Congress, through OMB, explanations when the Agency decides not to use available and applicable voluntary consensus standards.

The EPA believes that this proposed action is not subject to requirements of Section 12(d) of NTTAA because application of those requirements would be inconsistent with the Clean Air Act.

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

Executive Order 12898 (59 FR 7629 (Feb. 16, 1994)) establishes federal executive policy on environmental justice. Its main provision directs federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations and low-income populations in the United States.

EPA lacks the discretionary authority to address environmental justice in this proposed rulemaking.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Approval and promulgation of implementation plans, Incorporation by reference, Intergovernmental relations, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, and Sulfur dioxide.

Dated: May 8, 2015.

Alexis Strauss,

Acting Regional Administrator, Region IX.

[FR Doc. 2015-12243 Filed 5-19-15; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA-R06-OAR-2013-0616; FRL-9927-23-Region 6]

Approval and Promulgation of Implementation Plans; New Mexico; Revisions to the New Source Review (NSR) State Implementation Plan (SIP) for Albuquerque-Bernalillo County; Prevention of Significant Deterioration (PSD) Permitting

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve two revisions to the New Mexico State Implementation Plan (SIP) to update the Albuquerque-Bernalillo County Prevention of Significant Deterioration (PSD) SIP permitting program consistent with federal requirements. New Mexico submitted the Albuquerque-Bernalillo County PSD SIP permitting revisions on July 26, 2013, and March 4, 2015, which

included a request for parallel processing of the submitted 2015 revisions. These submittals contain revisions to address the requirements of the EPA's May 2008, July 2010, and October 2012 PM_{2.5} PSD Implementation Rules and to incorporate revisions consistent with the EPA's March 2011 Fugitives Interim Rule, July 2011 Greenhouse Gas (GHG) Biomass Deferral Rule, and July 2012 GHG Tailoring Rule Step 3 and GHG PALs Rule. The EPA is proposing to find that these revisions to the New Mexico SIP meet the Federal Clean Air Act (the Act or CAA) and EPA regulations, and are consistent with EPA policies. We are proposing this action under section 110 and part C of title I of the Act. The EPA is not approving these rules within the exterior boundaries of a reservation or other areas within any Tribal Nation's jurisdiction.

DATES: Written comments should be received on or before June 19, 2015.

ADDRESSES: Submit your comments, identified by Docket No. EPA-R06-OAR-2013-0616, by one of the following methods:

- www.regulations.gov: Follow the online instructions.
- **Email:** Ms. Ashley Mohr at mohr.ashley@epa.gov.
- **Mail or delivery:** Ms. Ashley Mohr, Air Permits Section (6PD-R), Environmental Protection Agency, 1445 Ross Avenue, Suite 1200, Dallas, Texas 75202-2733.

Instructions: Direct your comments to Docket ID No. EPA-R06-OAR-2013-0616. The EPA's policy is that all comments received will be included in the public docket without change and may be made available online at www.regulations.gov, including any personal information provided, unless the comment includes information claimed to be Confidential Business Information (CBI) or other information the disclosure of which is restricted by statute. Do not submit information through www.regulations.gov or email, if you believe that it is CBI or otherwise protected from disclosure. The www.regulations.gov Web site is an "anonymous access" system, which means that the 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 the EPA without going through 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, the EPA recommends that you include your name and other contact information in the body of your comment along with any disk or CD-ROM submitted. If the EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, the EPA may not be able to consider your comment. Electronic files should avoid the use of special characters and any form of encryption and should be free of any defects or viruses.

Docket: The index to the docket for this action is available electronically at www.regulations.gov and in hard copy at EPA Region 6, 1445 Ross Avenue, Suite 700, Dallas, Texas. While all documents in the docket are listed in the index, some information may be publicly available only at the hard copy location (e.g., copyrighted material), and some may not be publicly available at either location (e.g., CBI).

FOR FURTHER INFORMATION CONTACT: Ms. Ashley Mohr, (214) 665-7289, mohr.ashley@epa.gov. To inspect the hard copy materials, please schedule an appointment with Ms. Ashley Mohr or Mr. Bill Deese at (214) 665-7253.

SUPPLEMENTARY INFORMATION:

Throughout this document wherever "we," "us," or "our" is used, we mean the EPA.

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I. Background

The Act at section 110(a)(2)(C) requires states to develop and submit to the EPA for approval into the State Implementation Plan (SIP), preconstruction review and permitting programs applicable to certain new and modified stationary sources of air pollutants for attainment and nonattainment areas that cover both major and minor new sources and modifications, collectively referred to as the New Source Review (NSR) SIP. The Clean Air Act (CAA) NSR SIP program is composed of three separate programs: Prevention of Significant Deterioration (PSD), Nonattainment New Source Review (NNSR), and Minor NSR. PSD is established in part C of title I of the CAA and applies in areas that meet the National Ambient Air Quality Standards (NAAQS)—"attainment areas"—as well as areas where there is insufficient information to determine if the area meets the NAAQS—"unclassifiable

areas.” The NNSR SIP program is established in part D of title I of the CAA and applies in areas that are not in attainment of the NAAQS—“nonattainment areas.” The Minor NSR SIP program addresses construction or modification activities that do not emit, or have the potential to emit, beyond certain major source thresholds, and thus do not qualify as “major” and applies regardless of the designation of the area in which a source is located. The EPA regulations governing the criteria that states must satisfy for EPA approval of the NSR programs as part of the SIP are contained in 40 CFR 51.160—51.166.

A. New Mexico's SIP Submittals

Since the EPA's last SIP approval on September 19, 2012, of PSD SIP requirements for Albuquerque-Bernalillo County,¹ the State of New Mexico has submitted two revisions to the Albuquerque-Bernalillo County PSD program: (1) A SIP revision submittal dated July 26, 2013, which affects sixteen sections under 20.11.61 NMAC; and (2) a request for parallel processing of a SIP revision dated March 4, 2015, which affects two sections under 20.11.61 NMAC.

i. Summary of the January 26, 2013, SIP Submittal

The July 26, 2013, SIP submittal contains revisions to adopt and implement: (1) the EPA's 2008 NSR PM_{2.5} Rule, (2) the EPA's 2010 PM_{2.5} PSD Increment—Significant Impact Levels (SILs)—Significant Monitoring Concentration (SMC) Rule, (3) the EPA's 2012 PM_{2.5} NSR Implementation Rule, (4) the EPA's 2011 Fugitives Interim Rule, (5) the EPA's 2011 Biomass Deferral Rule, and (6) the EPA's 2012 GHG Tailoring Rule Step 3 and GHG PALs Rule. The July 2013 submittal from New Mexico also contains other non-substantive revisions to the Albuquerque-Bernalillo County PSD program that are not directly associated with the incorporation of the EPA Rules. As part of this proposed rulemaking, the EPA is addressing these non-substantive revisions and the substantive revisions to the New Mexico SIP that were submitted to adopt and implement the six aforementioned rulemakings by the EPA.

ii. Summary of the March 4, 2015, SIP Submittal

On March 4, 2015, New Mexico submitted a request for the parallel processing of additional SIP revisions to the Albuquerque-Bernalillo County PSD

program. This means that the EPA is proposing approval of the submitted revisions at the same time that the public comment and rulemaking process is taking place at the state and local level. These proposed revisions to part 61 are being made in response to comments the EPA provided on the July 26, 2013, SIP submittal. Specifically, the March 2015 parallel processing request contains proposed revisions to Section 7—Definitions and Section 11—Applicability. New Mexico's parallel processing request was made in accordance with paragraph 2.3.1 of appendix V to 40 CFR part 51. As part of this proposed rulemaking, the EPA is addressing the proposed revisions to the New Mexico SIP contained in the March 4, 2015, parallel processing request. As required by paragraph 2.3.2 of appendix V to 40 CFR part 51, the EPA will not take final action on the proposed revisions contained in the March 4, 2015, submittal until the final SIP revision submittal containing these revisions to the Albuquerque-Bernalillo County PSD program as a final adoption is received from New Mexico. Therefore, the EPA is proposing to approve the SIP revision request after the completion of the state public process and final submittal. More information regarding the anticipated timeline of the state's rulemaking process is contained in the TSD accompanying this proposed action.

B. Relevant EPA Rulemakings

i. Summary of the EPA's 2008 NSR PM_{2.5} Rule

On May 8, 2008, the EPA finalized the NSR PM_{2.5} Rule to implement the PM_{2.5} NAAQS. See 73 FR 28321. As a result of the EPA's final NSR PM_{2.5} Rule, states were required to submit applicable SIP revisions to the EPA no later than May 16, 2011, to address this Rule's PSD and NNSR SIP requirements. With respect to PSD permitting, the SIP revision submittals are required to meet the following PSD SIP requirements to implement the PM_{2.5} NAAQS: (1) Require PSD permits to address directly emitted PM_{2.5} and precursor pollutants; (2) establish significant emission rates for direct PM_{2.5} and precursor pollutants (including SO₂ and NO_x); and (3) account for gases that condense to form particles (condensables) in PM_{2.5} and PM₁₀ emission limits in PSD permits.

Prior to the adoption of the revisions included in the July 26, 2013, SIP submittal, the Albuquerque-Bernalillo County Air Board adopted revisions to 20.11.61 NMAC to incorporate all but one of the amendments consistent with the EPA's 2008 NSR PM_{2.5} Rule. These

revisions were approved by the EPA on September 19, 2012. See 77 FR 58032. New Mexico's July 26, 2013, SIP revision submittal incorporates the final remaining amendment to 20.11.61 NMAC to be consistent with the revisions to the federal rules at 40 CFR 51.166(i)(5) contained in the EPA's 2008 rulemaking. Specifically, the July 2013 SIP submittal amends 20.11.61 NMAC to include an additional exemption that gives the department discretion to exempt a stationary source from air monitoring requirements for a particular pollutant. The EPA finds that New Mexico's July 26, 2013, SIP revision submittal is consistent with the 2008 NSR PM_{2.5} Rule for PSD and meets the requirements of section 110 and part C of the CAA.

ii. Summary of the EPA's 2010 PM_{2.5} PSD Increment—SILs—SMC Rule

On October 20, 2010, the EPA finalized the PM_{2.5} PSD Increment—SILs—SMC Rule to provide additional regulatory requirements under the PSD SIP program regarding the implementation of the PM_{2.5} NAAQS for NSR. See 75 FR 64864. As a result, the PM_{2.5} PSD Increment—SILs—SMC Rule required states to submit SIP revisions to adopt the required PSD increments by July 20, 2012. Specifically, the SIP rule requires a state's submitted PSD SIP revision to adopt and submit for the EPA approval the PM_{2.5} increments pursuant to section 166(a) of the CAA to prevent significant deterioration of air quality in areas meeting the NAAQS. States could also discretionarily choose to adopt and submit for EPA approval SILs used as a screening tool (by a major source subject to PSD) to evaluate the impact a proposed major source or modification may have on the NAAQS or PSD increment and a SMC, (also a screening tool) used by a major source subject to PSD to determine the subsequent level of data gathering required for a PSD permit application for emissions of PM_{2.5}. More detail on the PM_{2.5} PSD Increment—SILs—SMC Rule can be found in the EPA's October 20, 2010, final rule. See 75 FR 64864.

(a) What are PSD increments?

Under section 165(a)(3) of the CAA, a PSD permit applicant must demonstrate that emissions from the proposed construction and operation of a facility “will not cause, or contribute to, air pollution in excess of any maximum allowable increase or allowable concentration for any pollutant.” In other words, when a source applies for a PSD SIP permit to emit a regulated pollutant in an attainment or unclassifiable area, the permitting

¹ See 77 FR 58032.

authority implementing the PSD SIP must determine if emissions of the regulated pollutant from the source will cause significant deterioration in air quality. Significant deterioration occurs when the amount of the new pollution exceeds the applicable PSD increment, which is the “maximum allowable increase” of an air pollutant allowed to occur above the applicable baseline concentration² for that pollutant. PSD increments prevent air quality in attainment and unclassifiable areas from deteriorating to the level set by the NAAQS. Therefore, an increment is the mechanism used to estimate “significant deterioration” of air quality for a pollutant in an area.

For PSD baseline purposes, a baseline area for a particular pollutant emitted from a source includes the attainment or unclassifiable/attainment area in which the source is located as well as any other attainment or unclassifiable/attainment area in which the source’s emissions of that pollutant are projected (by air quality modeling) to result in an ambient pollutant increase of at least 1 µg/m³ (annual average). See 40 CFR 51.166(b)(15)(i) and (ii). Under the EPA’s existing regulations, the establishment of a baseline area for any PSD increment results from the submission of the first complete PSD permit application and is based on the location of the proposed source and its emissions impact on the area. Once the baseline area is established, subsequent PSD sources locating in that area need to consider that a portion of the available increment may have already been consumed by previous emissions increases. In general, the submittal date of the first complete PSD permit application in a particular area is the operative “baseline date.”³ On or before the date of the first complete PSD application, emissions generally are considered to be part of the baseline concentration, except for certain emissions from major stationary sources. Most emissions increases that occur after the baseline date will be counted toward the amount of increment consumed. Similarly, emissions decreases after the baseline date restore or expand the amount of increment that is available. See 75 FR

64864. As described in the PM_{2.5} PSD Increment—SILs—SMC Rule, pursuant to the authority under section 166(a) of the CAA the EPA promulgated numerical increments for PM_{2.5} as a new pollutant⁴ for which the NAAQS were established after August 7, 1977,⁵ and derived 24-hour and annual PM_{2.5} increments for the three area classifications (Class I, II and III) using the “contingent safe harbor” approach. See 75 FR 64864 at 64869 and table at 40 CFR 51.166(c)(1).

In addition to PSD increments for the PM_{2.5} NAAQS, the PM_{2.5} PSD Increment—SILs—SMC Rule amended the definition at 40 CFR 51.166 and 52.21 for “major source baseline date” and “minor source baseline date” to establish the PM_{2.5} NAAQS specific dates (including trigger dates) associated with the implementation of PM_{2.5} PSD increments. See 75 FR 64864. In accordance with section 166(b) of the CAA, the EPA required the states to submit revised implementation plans adopting the PM_{2.5} PSD increments to the EPA for approval within 21 months from promulgation of the final rule (by July 20, 2012). Each state was responsible for determining how increment consumption and the setting of the minor source baseline date for PM_{2.5} would occur under its own PSD program. Regardless of when a state begins to require PM_{2.5} increment analysis and how it chooses to set the PM_{2.5} minor source baseline date, the emissions from sources subject to PSD for PM_{2.5} for which construction commenced after October 20, 2010, (major source baseline date) consume the PM_{2.5} increment and therefore should be included in the increment analyses occurring after the minor source baseline date is established for an area under the state’s revised PSD SIP program.

(b) What are PSD SILs and SMC?

The EPA’s PM_{2.5} PSD Increment—SILs—SMC Rule also established SILs and SMC for the PM_{2.5} NAAQS to address air quality modeling and monitoring provisions for fine particle pollution in areas protected by the PSD

program. The SILs and SMC are numerical values that represent thresholds of insignificant, *i.e.*, de minimis, modeled source impacts or monitored (ambient) concentrations, respectively. The de minimis principle is grounded in a decision described by the court case *Alabama Power Co. v. Costle*, 636 F.2d 323, 360 (D.C. Cir. 1980). In this case reviewing the EPA’s 1978 PSD regulations, the court recognized that “there is likely a basis for an implication of de minimis authority to provide exemption when the burdens of regulation yield a gain of trivial or no value.” 636 F.2d at 360. The EPA established such values for PM_{2.5} in the PM_{2.5} PSD Increment—SILs—SMC rule to be used as screening tools by a major source subject to PSD to determine the subsequent level of analysis and data gathering required for a PSD permit application for emissions of PM_{2.5}. See 75 FR 64864. As part of the response to comments in the PM_{2.5} PSD Increment—SILs—SMC Rule final rulemaking, the EPA explained that the agency considers that the SILs and SMC used as de minimis thresholds for the various pollutants are useful tools that enable permitting authorities and PSD applicants to screen out “insignificant” activities; however, the fact remains that these values are not required by the Act as part of an approvable SIP program.

(c) SILs-SMC Litigation

The PM_{2.5} SILs and SMC were subject to litigation before the U.S. Court of Appeals. (*Sierra Club v. EPA*, Case No. 10–1413, D.C. Circuit). In response to the litigation, the EPA filed a brief on April 6, 2012, which contained a request that the Court vacate and remand to the EPA portions of two PSD PM_{2.5} rules (40 CFR 51.166 and 40 CFR 52.21) addressing the PM_{2.5} SILs so that the EPA could voluntarily correct errors in those provisions. On January 22, 2013, the Court granted the EPA’s request for vacature and remand of the PM_{2.5} SILs provisions and also vacated parts of 40 CFR 51.166 and 40 CFR 52.21 that established the PM_{2.5} SMC, finding that the EPA was precluded from using the PM_{2.5} SMC to exempt permit applicants from the statutory requirement to compile preconstruction monitoring data. As a result of the Court’s decision, States should avoid including language in SIP revision submittals that are the same as or have similar effects as the vacated PM_{2.5} SILs and SMC language in 40 CFR 51.166 and 52.21. As stated previously, neither the PM_{2.5} SILs nor the PM_{2.5} SMC are required elements of the PSD SIP for PM_{2.5}.

² Section 169(4) of the CAA provides that the baseline concentration of a pollutant for a particular baseline area is generally the same air quality at the time of the first application for a PSD permit in the area.

³ Baseline dates are pollutant specific. That is, a complete PSD application establishes the baseline date only for those regulated NSR pollutants that are projected to be emitted in significant amounts (as defined in the regulations) by the applicant’s new source or modification. Thus, an area may have different baseline dates for different pollutants.

⁴ The EPA generally characterized the PM_{2.5} NAAQS as a NAAQS for a new indicator of PM. The EPA did not replace the PM₁₀ NAAQS with the NAAQS for PM_{2.5} when the PM_{2.5} NAAQS were promulgated in 1997. The EPA rather retained the annual and 24-hour NAAQS for PM₁₀ as if PM_{2.5} was a new pollutant even though the EPA had already developed air quality criteria for PM generally. See 75 FR 64864 (October 20, 2010).

⁵ The EPA interprets 166(a) to authorize the EPA to promulgate pollutant-specific PSD regulations meeting the requirements of section 166(c) and 166(d) for any pollutant for which the EPA promulgates a NAAQS after 1977.

New Mexico's July 26, 2013, SIP revision submittal includes revisions to 20.11.61 NMAC that incorporate the amendments to the PSD regulations consistent with the changes in the 2010 PM_{2.5} PSD Increment—SILs—SMC Rule. Consistent with the January 2013 vacature and remand by the U.S. Court of Appeals for the D.C. Circuit (the D.C. Circuit), the SIP revision submittal also correctly excludes those amendments from the EPA's 2010 Rule that established the PM_{2.5} SILs and SMC. Therefore, the EPA finds that these revisions in the July 2013 submittal are consistent with the 2010 rulemaking and subsequent Court decision and meet the requirements of section 110 and part C of the CAA.

iii. Summary of the EPA's 2012 PM_{2.5} NSR Implementation Rule

On October 12, 2012, the EPA finalized amendments to its rules for the CAA NSR permitting program regarding the definition of "regulated NSR pollutant." This rulemaking clarified when condensable particulate matter should be measured. The final rule continued to require that condensable particulate matter be included as part of the emissions measurements for regulation of PM_{2.5}/PM₁₀. As a result of the EPA's final 2012 NSR PM_{2.5} Rule, the inadvertent requirement that measurements of condensable particulate matter emissions be included as part of the measurement and regulation of "particulate matter emissions" was removed.

New Mexico's July 26, 2013, SIP revision submittal includes a revision to the definition of "regulated NSR pollutant." Specifically, the SIP revision revises this definition found at 20.11.61.7(WW) NMAC to include the clarifying language related to the condensable particulate matter portion accounted for in PM_{2.5} and PM₁₀ emissions. The EPA notes that as part of the July 2013 SIP revision submittal, New Mexico did not remove the requirement for condensable particulate matter emissions to be included in particulate matter emissions. Therefore, the definition of "regulated NSR pollutant" at 20.11.61.7(WW) NMAC is more stringent than the federal definition. See 40 CFR 51.166(b)(49). The EPA finds that the revisions to the definition of "regulated NSR pollutant" in the July 26, 2013, submittal meet the federal requirements in that the definition is more stringent than the federal definition.

iv. Summary of the EPA's 2011 Fugitives Interim Rule

On March 8, 2011, the EPA issued an interim rule to stay a December 2008 rule known as the Fugitives Emissions Rule. The 2008 Rule established new provisions for how fugitive emissions should be treated for NSR permitting. The EPA's 2011 interim rule replaced the stay issued by the EPA on March 31, 2010, which inadvertently covered portions of the NSR permitting requirements that should not have been stayed. The 2011 rulemaking stayed the 2008 Fugitive Emissions Rule as originally intended and reverted the regulatory text back to the language that existed prior to those amendments, which the EPA is reconsidering in response to a 2009 Natural Resources Defense Council petition for reconsideration of the 2008 Fugitive Emissions Rule.

New Mexico's July 26, 2013, SIP revision submittal includes revisions to 20.11.61 NMAC that incorporate the amendments to the PSD regulations consistent with the changes in the 2011 Fugitives Interim Rule. The EPA finds that these revisions in the July 2013 submittal are consistent with the 2011 rulemaking and meet the requirements of section 110 and part C of the CAA.

v. Summary of the EPA's 2011 Biomass Deferral Rule

On July 20, 2011, the EPA promulgated the Biomass Deferral Rule, which deferred, for a period of three years, the application of the PSD and title V permitting requirements to CO₂ emissions from bioenergy and other biogenic stationary sources. See 76 FR 43490. On July 12, 2013, the U.S. Court of Appeals for the D.C. Circuit issued its decision to vacate the Biomass Deferral Rule. See *Center for Biological Diversity v. EPA* (D.C. Cir. No. 11–1101).

New Mexico's July 26, 2013, SIP revision submittal includes revisions to 20.11.61 NMAC that incorporate the 2011 Biomass Deferral Rule into the Albuquerque-Bernalillo County PSD program. However, as discussed in this proposed rulemaking, New Mexico's March 4, 2015, SIP Submittal contains revisions to update the PSD program to remove the biomass deferral, which was vacated in 2013. The EPA finds that the combined revisions from the July 2013 and March 2015 submittals are consistent with current PSD regulations with respect to the vacated Biogas Referral Rule and meet the requirements of section 110 and part C of the CAA.

vi. Summary of the the EPA's 2012 Tailoring Rule and GHG PALs Rule

On June 3, 2010, the EPA issued a final rule, known as the Tailoring Rule, which phased in permitting requirements for GHG emissions from stationary sources under the CAA PSD and title V permitting programs (75 FR 31514). For Step 1 of the Tailoring Rule, which began on January 2, 2011, PSD or title V requirements applied to sources of GHG emissions only if the sources were subject to PSD or title V "anyway" due to their emissions of non-GHG pollutants. These sources are referred to as "anyway sources." Step 2 of the Tailoring Rule, which began on July 1, 2011, applied the PSD and title V permitting requirements under the CAA to sources that were classified as major, and, thus, required to obtain a permit, based solely on their potential GHG emissions and to modifications of otherwise major sources that required a PSD permit because they increased only GHG above applicable levels in the EPA regulations.

On July 12, 2012, the EPA promulgated the final "Prevention of Significant Deterioration and Title V Greenhouse Gas Tailoring Rule Step 3 and GHG Plantwide Applicability Limits" (GHG Tailoring Rule Step 3 and GHG PALs).⁶ 77 FR 41051. In the Tailoring Rule Step 3 portion of this rule, the EPA decided against further phase in of the PSD and title V requirements to apply to sources emitting lower levels of greenhouse gas emissions. Thus, the thresholds for determining PSD applicability based on emission of greenhouse gases remained the same as established in Step 2 of the Tailoring Rule. The Step 3 portions of the EPA's July 12, 2012, final rule are not relevant to today's proposed action on the New Mexico SIP revision.

The GHG PALs portion of the July 12, 2012, final rule promulgated revisions to the EPA regulations under 40 CFR part 52 for establishing PALs for GHG emissions. For a full discussion of the EPA's rationale for the GHG PALs provisions, see the notice of final rulemaking at 77 FR 41051. A PAL

⁶ For a complete history of the EPA's rulemakings related to GHG emissions please review the following final actions:

"Endangerment and Cause or Contribute Findings for Greenhouse Gases Under Section 202(a) of the Clean Air Act." 74 FR 66496 (December 15, 2009).

"Interpretation of Regulations that Determine Pollutants Covered by Clean Air Act Permitting Programs." 75 FR 17004 (April 2, 2010).

"Light-Duty Vehicle Greenhouse Gas Emission Standards and Corporate Average Fuel Economy Standards; Final Rule." 75 FR 25324 (May 7, 2010).

"Prevention of Significant Deterioration and Title V Greenhouse Gas Tailoring Rule; Final Rule." 75 FR 31514 (June 3, 2010).

establishes a site-specific plantwide emission level for a pollutant that allows the source to make changes at the facility without triggering the requirements of the PSD program, provided that emissions do not exceed the PAL level. Under the EPA's interpretation of the federal PAL provisions, such PALs are already available under PSD for non-GHG pollutants and for GHGs on a mass basis, and the EPA revised the PAL regulations to allow for GHG PALs to be established on a carbon dioxide equivalent (CO₂e) basis as well. See 77 FR 41052. The EPA finalized these revisions in an effort to streamline federal and SIP PSD permitting programs by allowing sources and permitting authorities to address GHGs using a PAL in a manner similar to the use of PALs for non-GHG pollutants. See 77 FR 41051, 41052.

II. The EPA's Evaluation

New Mexico's July 26, 2013, and March 4, 2015, SIP revision submittals include amendments to the Albuquerque-Bernalillo County PSD program found in 20.11.61 NMAC to incorporate changes to federal PSD provisions resulting from the following EPA rulemakings: 2008 NSR PM_{2.5} Rule, 2010 PM_{2.5} PSD Increment—SILs—SMC Rule, 2012 PM_{2.5} PSD Implementation Rule, 2011 Fugitives Interim Rule, 2011 Biomass Deferral Rule, and 2012 GHG Tailoring Rule Step 3 and GHG PALs Rule. The July 26, 2013, SIP revisions also contains additional non-substantive revisions to 20.11.61 NMAC including formatting revisions, inclusion of acronyms, and rewording of provisions to make this Part consistent with other provisions of the NMAC.

On June 23, 2014, the United States Supreme Court, in *Utility Air Regulatory Group v. Environmental Protection Agency*,⁷ issued a decision addressing the application of PSD permitting requirements to GHG emissions. The Supreme Court said that the EPA may not treat GHGs as an air pollutant for purposes of determining whether a source is a major source (or modification thereof) required to obtain a PSD permit. The Court also said that the EPA could continue to require that PSD permits, otherwise required based on emissions of pollutants other than GHGs, contain limitations on GHG emissions based on the application of Best Available Control Technology (BACT). The Supreme Court decision effectively upheld PSD permitting requirements for GHG emissions under Step 1 of the Tailoring Rule for "anyway

sources" and invalidated PSD permitting requirements for Step 2 sources.

In accordance with the Supreme Court decision, on April 10, 2015, the D.C. Circuit issued an amended judgment vacating the regulations that implemented Step 2 of the Tailoring Rule, but not the regulations that implement Step 1 of the Tailoring Rule. A copy of the judgment is included in the docket to this rulemaking.⁸ The amended judgment preserves, without the need for additional rulemaking by the EPA, the application of the Best Available Control Technology (BACT) requirement to GHG emissions from sources that are required to obtain a PSD permit based on emissions of pollutants other than GHGs ("anyway" sources). The D.C. Circuit's judgment vacated the regulations at issue in the litigation, including 40 CFR 51.166(b)(48)(v), "to the extent they require a stationary source to obtain a PSD permit if greenhouse gases are the only pollutant (i) that the source emits or has the potential to emit above the applicable major source thresholds, or (ii) for which there is a significant emissions increase from a modification."

The EPA may need to take additional steps to revise federal PSD rules in light of the Supreme Court decision and recent D.C. Circuit judgment. In addition, the EPA anticipates that many states will revise their existing SIP-approved PSD programs. The EPA is not expecting states to have revised their existing PSD program regulations at this juncture. However, the EPA is evaluating PSD program submissions to assure that the state's program correctly addresses GHGs consistent with both decisions.

New Mexico's existing approved SIP for the Albuquerque-Bernalillo County PSD program contains the greenhouse gas permitting requirements required under 40 CFR 51.166, as amended in the Tailoring Rule. As a result, the Albuquerque-Bernalillo County's SIP-approved PSD permitting program continues to require that PSD permits (otherwise required based on emissions of pollutants other than GHGs) contain limitations on GHG emissions based on the application of BACT when sources emit or increase greenhouse gases in the amount of 75,000 tons per year (tpy), measured as carbon dioxide equivalent. Although the SIP-approved Albuquerque-Bernalillo County PSD permitting program may also currently

contain provisions that are no longer necessary in light of the D.C. Circuit's judgment or the Supreme Court decision, this does not prevent the EPA from approving the submission addressed in this rule. New Mexico's July 26, 2013, and March 4, 2015, SIP submissions do not add any greenhouse gas permitting requirements that are inconsistent either decision.

Likewise, this revision does add to the New Mexico SIP for the Albuquerque-Bernalillo County PSD program elements of the EPA's July 12, 2012, rule implementing Step 3 of the phase in of PSD permitting requirements for greenhouse gases described in the Tailoring Rule, which became effective on August 13, 2012. Specifically, the incorporation of the Step 3 rule provisions will allow GHG-emitting sources to obtain PALs for their GHG emissions on a CO₂e basis. The GHG PAL provisions, as currently written, include some provisions that may no longer be appropriate in light of both the D.C. Circuit's judgment and the Supreme Court decision. Since the Supreme Court has determined that sources and modifications may not be defined as "major" solely on the basis of the level of greenhouse gases emitted or increased, PALs for greenhouse gases may no longer have value in some situations where a source might have triggered PSD based on greenhouse gas emissions alone. However, PALs for GHGs may still have a role to play in determining whether a modification that triggers PSD for a pollutant other than greenhouse gases should also be subject to BACT for greenhouse gases. These provisions, like the other GHG provisions discussed previously, may be revised at some future time. However, these provisions do not add new requirements for sources or modifications that only emit or increase greenhouse gases above the major source threshold or the 75,000 tpy greenhouse gas level in section 52.21(b)(49)(iv). Rather, the PALs provisions provide increased flexibility to sources that wish to address their GHG emissions in a PAL. Since this flexibility may still be valuable to sources in at least one context described above, we believe that it is appropriate to approve these provisions into the New Mexico SIP at this juncture.

As discussed in this rulemaking and the accompanying TSD, the EPA finds that the revisions to the Albuquerque-Bernalillo County PSD program contained in the July 26, 2013, and March 4, 2015, SIP revision submittals are consistent with the aforementioned the EPA rulemakings and meet the associated federal requirements. The

⁸Original case is *Coalition for Responsible Regulation v. EPA*, D.C. Cir., No. 09-1322, 06/26/20, judgment entered for No. 09-1322 on 04/10/2015.

⁷134 S.Ct. 2427 (2014).

EPA therefore proposes to find the proposed SIP revisions to be fully approvable.

III. Proposed Action

The EPA is proposing to approve revisions to the Albuquerque-Bernalillo County PSD program that were submitted by New Mexico as a SIP revision on July 26, 2013, and March 4, 2015. We are proposing approval of the portions of the July 26, 2013, and March 4, 2015, submittals that revised the following sections under 20.11.61:

- 20.11.61.2 NMAC—Scope,
- 20.11.61.5 NMAC—Effective Date,
- 20.11.61.6 NMAC—Objective,
- 20.11.61.7 NMAC—Definitions,
- 20.11.61.10 NMAC—Documents,
- 20.11.61.11 NMAC—Applicability,
- 20.11.61.12 NMAC—Obligations of Owners or Operators of Sources,
- 20.11.61.14 NMAC—Control Technology Review and Innovative Control Technology,
- 20.11.61.15 NMAC—Ambient Impact Requirements,
- 20.11.61.18 NMAC—Air Quality Analysis and Monitoring Requirements,
- 20.11.61.20 NMAC—Actuals Plantwide Applicability Limits (PALs),
- 20.11.61.23 NMAC—Exclusions from Increment Consumption,
- 20.11.61.24 NMAC—Sources Impacting Federal Class I Areas-Additional Requirements,
- 20.11.61.27 NMAC—Table 2-Significant Emission Rates,
- 20.11.61.29 NMAC—Table 4-Allowable PSD Increments, and
- 20.11.61.30 NMAC—Table 5-Maximum Allowable Increases for Class I Variances.

The EPA has determined that these revisions to the New Mexico SIP's Albuquerque-Bernalillo County PSD program are approvable because the submitted rules are adopted and submitted in accordance with the CAA and are consistent with the EPA regulations regarding PSD permitting. The EPA is proposing this action under section 110 and part C of the Act.

The EPA is severing from our proposed approval action the revisions to 20.11.60 NMAC submitted on July 26, 2013, which are revisions to the Albuquerque-Bernalillo County NNSR Program and will be addressed in a separate action.

IV. Incorporation by Reference

In this rule, the EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, the EPA is proposing to incorporate by reference the New Mexico regulations discussed

in section III. of this preamble. The EPA has made, and will continue to make, these documents generally available electronically through www.regulations.gov and/or in hard copy at the appropriate EPA office (see the **ADDRESSES** section of this preamble for more information).

V. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, the EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- Does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- Is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- Does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);
- Does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- Is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- Is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- Is not subject to requirements of section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- Does not provide the EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule is not proposed to apply on any Indian reservation land or in any other area where the EPA or an Indian tribe has demonstrated that tribe has jurisdiction. In those areas of Indian country, the proposed rule does not have tribal implications and will not impose substantial direct costs on tribal governments or preempt tribal law as specified by Executive Order 13175 (65 FR 67249, November 9, 2000).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

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

Dated: April 24, 2015.

Ron Curry,

Regional Administrator, Region 6.

[FR Doc. 2015-11780 Filed 5-19-15; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 52 and 81

[EPA-R03-OAR-2015-0029; FRL-9928-00-Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Redesignation Request and Associated Maintenance Plan for the Pittsburgh-Beaver Valley Nonattainment Area for the 1997 Annual and 2006 24-Hour Fine Particulate Matter Standard

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve the Commonwealth of Pennsylvania's December 22, 2014 request to redesignate to attainment the Pittsburgh-Beaver Valley nonattainment area (Pittsburgh Area or Area) for the 1997 annual and 2006 24-hour fine particulate matter (PM_{2.5}) National Ambient Air Quality Standards (NAAQS or standards). EPA is also proposing to determine that the Area continues to attain the 1997 annual and 2006 24-hour PM_{2.5} NAAQS. In addition, EPA is proposing to approve as a revision to the Pennsylvania State Implementation Plan (SIP) the associated maintenance plan that was submitted with the redesignation

request, to show maintenance of the 1997 annual and 2006 24-hour PM_{2.5} NAAQS through 2025 for the Area. EPA is also proposing to approve as revisions to the Pennsylvania SIP the 2007 emissions inventories for the 1997 annual PM_{2.5} NAAQS and the 2011 emissions inventories for the 2006 24-hour PM_{2.5} NAAQS that were included in the maintenance plan. The maintenance plan also included the 2017 and 2025 PM_{2.5} and nitrogen oxides (NO_x) motor vehicle emissions budgets (MVEBs) for the Area for both NAAQS which EPA is proposing to approve for conformity purposes. This rulemaking action to propose approval of the 1997 annual and 2006 24-hour PM_{2.5} NAAQS redesignation request and associated maintenance plan for the Area is based on EPA's determination that Pennsylvania has met the criteria for redesignation to attainment specified in the Clean Air Act (CAA) for both NAAQS.

DATES: Written comments must be received on or before June 19, 2015.

ADDRESSES: Submit your comments, identified by Docket ID Number EPA-R03-OAR-2015-0029 by one of the following methods:

A. *www.regulations.gov*. Follow the on-line instructions for submitting comments.

B. *Email: fernandez.cristina@epa.gov*.

C. *Mail: EPA-R03-OAR-2015-0029*, Cristina Fernandez, Associate Director, Office of Air Quality Planning, Mailcode 3AP30, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103.

D. *Hand Delivery:* At the previously-listed EPA Region III address. Such deliveries are only accepted during the Docket's normal hours of operation, and special arrangements should be made for deliveries of boxed information.

Instructions: Direct your comments to Docket ID No. EPA-R03-OAR-2015-0029. EPA's policy is that all comments received will be included in the public docket without change, and may be made available online at *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 *www.regulations.gov* or email. The *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 *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 disk or CD-ROM you submit. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may 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.

Docket: All documents in the electronic docket are listed in the *www.regulations.gov* index. Although listed in the index, some information is not publicly available, *i.e.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available either electronically in *www.regulations.gov* or in hard copy during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania. Copies of the State submittal are available at the Pennsylvania Department of Environmental Protection, Bureau of Air Quality Control, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105.

FOR FURTHER INFORMATION CONTACT: Rose Quinto, (215) 814-2182 or by email at *quinto.rose@epa.gov*.

SUPPLEMENTARY INFORMATION:

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I. Background

The first air quality standards for PM_{2.5} were established on July 18, 1997 (62 FR 38652). EPA promulgated an annual standard at a level of 15 micrograms per cubic meter (µg/m³), based on a three-year average of annual mean PM_{2.5} concentrations (the 1997 annual PM_{2.5} NAAQS). In the same rulemaking action, EPA promulgated a 24-hour standard of 65 µg/m³, based on a three-year average of the 98th percentile of 24-hour concentrations.

On January 5, 2005 (70 FR 944), EPA published air quality area designations for the 1997 PM_{2.5} NAAQS. In that rulemaking action, EPA designated the Pittsburgh-Beaver Valley Area as nonattainment for the 1997 annual PM_{2.5} NAAQS. *Id.* at 1000. The Pittsburgh-Beaver Valley Area is comprised of Beaver, Butler, Washington, Westmoreland Counties and portions of Allegheny, Armstrong, Green and Lawrence Counties. *See* 40 CFR 81.339.

On October 17, 2006 (71 FR 61144), EPA retained the annual average standard at 15 µg/m³, but revised the 24-hour standard to 35 µg/m³, based again on the three-year average of the 98th percentile of 24-hour concentrations (the 2006 24-hour PM_{2.5} NAAQS). On November 13, 2009 (74 FR 58688), EPA published designations for the 2006 24-hour PM_{2.5} NAAQS, which became effective on December 14, 2009. In that rulemaking action, EPA designated the Pittsburgh-Beaver Valley Area as nonattainment for the 2006 24-hour PM_{2.5} NAAQS. *See* 40 CFR 81.339.

On October 12, 2012 (77 FR 62147) and May 2, 2014 (79 FR 25014), EPA made determinations that the Pittsburgh Area had attained the 1997 annual and 2006 24-hour PM_{2.5} NAAQS, respectively. Pursuant to 40 CFR 51.1004(c) and based on these determinations, the requirements for the Area to submit an attainment demonstration and associated reasonably available control measures (RACM), a reasonable further progress (RFP) plan, contingency measures, and other planning SIPs related to the attainment of either the 1997 annual or 2006 24-hour PM_{2.5} NAAQS were, and continue to be, suspended until such time as: the Area is redesignated to attainment for each standard, at which time the requirements no longer apply; or EPA determines that the Area has again violated any of the standards, at which time such plans are required to be submitted. On October 12, 2012 (77 FR 62147), EPA also determined in accordance with section 179(c) of the CAA, that the Pittsburgh Area attained

the 1997 annual PM_{2.5} NAAQS by its applicable attainment date of April 5, 2010.

On December 22, 2014, the Commonwealth of Pennsylvania, through the Pennsylvania Department of Environmental Protection (PADEP), formally submitted a request to redesignate the Pittsburgh-Beaver Valley Area from nonattainment to attainment for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS. Concurrently, PADEP submitted a combined maintenance plan for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS for the Area as a SIP revision to ensure continued attainment throughout the Area over the next 10 years. The maintenance plan includes the 2017 and 2025 PM_{2.5} and NO_x MVEBs for the Area for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS. The maintenance plan also includes the 2007 comprehensive emissions inventories for the 1997 annual PM_{2.5} NAAQS and the 2011 comprehensive emissions inventories for the 2006 24-hour PM_{2.5} NAAQS for PM_{2.5}, NO_x, sulfur dioxide (SO₂), volatile organic compounds (VOCs), and ammonia (NH₃).

In this proposed rulemaking action, EPA addresses the effects of several decisions of the United States Court of Appeals for the District of Columbia (D.C. Circuit Court) and a decision of the United States Supreme Court: (1) The D.C. Circuit Court's August 21, 2012 decision to vacate and remand to EPA the Cross-State Air Pollution Control Rule (CSAPR); (2) the Supreme Court's April 29, 2014 reversal of the vacature of CSAPR, and remand to the D.C. Circuit Court; (3) the D.C. Circuit Court's October 23, 2014 decision to lift the stay of CSAPR; and (4) the D.C. Circuit Court's January 4, 2013 decision to remand to EPA two final rules implementing the 1997 annual PM_{2.5} NAAQS.

II. EPA's Requirements

A. Criteria for Redesignation to Attainment

The CAA provides the requirements for redesignating a nonattainment area to attainment. Specifically, section 107(d)(3)(E) of the CAA allows for redesignation providing that: (1) EPA determines that the area has attained the applicable NAAQS; (2) EPA has fully approved the applicable implementation plan for the area under section 110(k); (3) EPA determines that the improvement in air quality is due to permanent and enforceable reductions in emissions resulting from implementation of the applicable SIP and applicable Federal air pollutant

control regulations and other permanent and enforceable reductions; (4) EPA has fully approved a maintenance plan for the area as meeting the requirements of section 175A of the CAA; and (5) the state containing such area has met all requirements applicable to the area under section 110 and part D of the CAA. Each of these requirements are discussed in Section V. of this proposed rulemaking action.

EPA provided guidance on redesignations in the "SIPs; General Preamble for the Implementation of Title I of the CAA Amendments of 1990," (57 FR 13498, April 16, 1992) (the General Preamble) and has provided further guidance on processing redesignation requests in the following documents: (1) "Procedures for Processing Requests to Redesignate Areas to Attainment," Memorandum from John Calcagni, Director, Air Quality Management Division, September 4, 1992 (hereafter referred to as the 1992 Calcagni Memorandum); (2) "SIP Actions Submitted in Response to CAA Deadlines," Memorandum from John Calcagni, Director, Air Quality Management Division, October 28, 1992; and (3) "Part D New Source Review (Part D NSR) Requirements for Areas Requesting Redesignation to Attainment," Memorandum from Mary D. Nichols, Assistant Administrator for Air and Radiation, October 14, 1994.

B. Requirements of a Maintenance Plan

Section 175A of the CAA sets forth the elements of a maintenance plan for areas seeking redesignation from nonattainment to attainment. Under section 175A, the plan must demonstrate continued attainment of the applicable NAAQS for at least 10 years after approval of a redesignation of an area to attainment. Eight years after the redesignation, the state must submit a revised maintenance plan demonstrating that attainment will continue to be maintained for the 10 years following the initial 10-year period. To address the possibility of future NAAQS violations, the maintenance plan must contain such contingency measures, with a schedule for implementation, as EPA deems necessary to assure prompt correction of any future PM_{2.5} violations.

The 1992 Calcagni Memorandum provides additional guidance on the content of a maintenance plan. The Memorandum states that a maintenance plan should address the following provisions: (1) An attainment emissions inventory; (2) a maintenance demonstration showing maintenance for 10 years; (3) a commitment to maintain an ambient air quality monitoring

network in accordance with 40 CFR part 58; (4) verification of continued attainment; and (5) a contingency plan to prevent or correct future violations of the NAAQS.

Under the CAA, states are required to submit, at various times, control strategy SIP revisions for nonattainment areas and maintenance plans for areas seeking redesignation to attainment for a given NAAQS. These emission control strategy SIP revisions (e.g., RFP and attainment demonstration SIP revisions) and maintenance plans also create MVEBs based on onroad mobile source emissions for the relevant criteria pollutants and/or their precursors, where appropriate, to address pollution from onroad transportation sources. The MVEBs are the portions of the total allowable emissions that are allocated to onroad vehicle use that, together with emissions from all other sources in the area, will provide attainment, RFP, or maintenance, as applicable. The budget serves as a ceiling on emissions from an area's planned transportation system. Under 40 CFR part 93, a MVEB for an area seeking a redesignation to attainment is established for the last year of the maintenance plan.

The maintenance plan for the Pittsburgh Area, comprised of Beaver, Butler, Washington, Westmoreland Counties and portions of Allegheny, Armstrong, Green and Lawrence Counties in Pennsylvania, includes the 2017 and 2025 PM_{2.5} and NO_x MVEBs for transportation conformity purposes. The transportation conformity determination for the Area is further discussed in Section V.C. of this proposed rulemaking action and in a technical support document (TSD), "Adequacy Findings for the Motor Vehicle Emissions Budgets (MVEBs) in the 1997 Annual Fine Particulate Matter (PM_{2.5}) National Ambient Air Quality Standard (NAAQS) and the 2006 24-Hour PM_{2.5} NAAQS Maintenance Plan for the Pittsburgh-Beaver Valley, Pennsylvania (PA) Nonattainment Area" (Adequacy Findings TSD), dated April 23, 2015, available on line at www.regulations.gov, Docket ID No. EPA-R03-OAR-2015-0029.

III. Summary of Proposed Actions

EPA is proposing to take several rulemaking actions related to the redesignation of the Pittsburgh Area to attainment for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS. EPA is proposing to find that the Pittsburgh Area meets the requirements for redesignation of the 1997 annual and 2006 24-hour PM_{2.5} NAAQS under section 107(d)(3)(E) of the CAA. EPA is thus proposing to approve

Pennsylvania's request to change the legal designation of the Pittsburgh-Beaver Valley Area from nonattainment to attainment for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS. EPA is also proposing to approve the associated maintenance plan for the Pittsburgh Area as a revision to the Pennsylvania SIP for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS, including the 2017 and 2025 PM_{2.5} and NO_x MVEBs for the Area for transportation conformity purposes. Approval of the maintenance plan is one of the CAA criteria for redesignation of the Area to attainment for both NAAQS. Pennsylvania's combined maintenance plan is designed to ensure continued attainment of the 1997 annual and 2006 24-hour PM_{2.5} NAAQS in the Area for at least 10 years after redesignation.

EPA previously determined that the Pittsburgh Area attained both the 1997 annual and 2006 24-hour PM_{2.5} NAAQS (see 77 FR 62147 (October 12, 2012) and 79 FR 25014 (May 2, 2014)), and EPA is proposing to find that the Area continues to attain both NAAQS. In order to meet the requirements of section 172(c)(3) of the CAA, EPA is also proposing to approve the 2007 comprehensive emissions inventories for the 1997 annual PM_{2.5} NAAQS and the 2011 comprehensive emissions inventories for the 2006 24-hour PM_{2.5} NAAQS submitted with Pennsylvania's maintenance plan that includes an inventory of PM_{2.5}, SO₂, NO_x, VOC, and NH₃ for the Area as a revision to the Pennsylvania SIP. EPA's analysis of the proposed actions is provided in Section V. of this proposed rulemaking.

IV. Effects of Recent Court Decisions on Proposed Actions

A. Effect of the Court Decisions Regarding EPA's CSAPR

1. Background

The D.C. Circuit Court and the Supreme Court have issued a number of decisions and orders regarding the status of EPA's regional trading programs for transported air pollution, the Clean Air Interstate Rule (CAIR) and CSAPR, that impact this proposed redesignation action. In 2008, the D.C. Circuit Court initially vacated CAIR, *North Carolina v. EPA*, 531 F.3d 896 (D.C. Cir. 2008), but ultimately remanded the rule to EPA without vacatur to preserve the environmental benefits provided by CAIR, *North Carolina v. EPA*, 550 F.3d 1176, 1178 (D.C. Cir. 2008). On August 8, 2011 (76 FR 48208), acting on the D.C. Circuit Court's remand, EPA promulgated CSAPR, to address interstate transport of emissions and resulting secondary air

pollutants and to replace CAIR.¹ CSAPR requires substantial reductions of SO₂ and NO_x emissions from electric generating units (EGUs) in 28 states in the Eastern United States.

Implementation of CSAPR was scheduled to begin on January 1, 2012, when CSAPR's cap-and-trade programs would have superseded the CAIR cap-and-trade programs. Numerous parties filed petitions for review of CSAPR, and on December 30, 2011, the D.C. Circuit Court issued an order staying CSAPR pending resolution of the petitions and directing EPA to continue to administer CAIR. *EME Homer City Generation, L.P. v. EPA*, No. 11-1302 (D.C. Cir. Dec. 30, 2011), Order at 2.

On August 21, 2012, the D.C. Circuit Court issued its ruling, vacating and remanding CSAPR to EPA and once again ordering continued implementation of CAIR. *EME Homer City Generation, L.P. v. EPA*, 696 F.3d 7, 38 (D.C. Cir. 2012). The D.C. Circuit Court subsequently denied EPA's petition for rehearing en banc. *EME Homer City Generation, L.P. v. EPA*, No. 11-1302, 2013 WL 656247 (D.C. Cir. Jan. 24, 2013), at *1. EPA and other parties then petitioned the Supreme Court for a writ of certiorari, and the Supreme Court granted the petitions on June 24, 2013. *EPA v. EME Homer City Generation, L.P.*, 133 S. Ct. 2857 (2013).

On April 29, 2014, the Supreme Court vacated and reversed the D.C. Circuit Court's decision regarding CSAPR, and remanded that decision to the D.C. Circuit Court to resolve remaining issues in accordance with its ruling. *EPA v. EME Homer City Generation, L.P.*, 134 S. Ct. 1584 (2014). EPA moved to have the stay of CSAPR lifted by the D.C. Circuit Court in light of the Supreme Court decision. *EME Homer City Generation, L.P. v. EPA*, Case No. 11-1302, Document No. 1499505 (D.C. Cir. filed June 26, 2014). In its motion, EPA asked the D.C. Circuit Court to toll CSAPR's compliance deadlines by three years, so that the Phase 1 emissions budgets apply in 2015 and 2016 (instead of 2012 and 2013), and the Phase 2 emissions budgets apply in 2017 and beyond (instead of 2014 and beyond). On October 23, 2014, the D.C. Circuit Court granted EPA's motion and lifted the stay of CSAPR which was imposed on December 30, 2011. *EME Homer City Generation, L.P. v. EPA*, No. 11-1302 (D.C. Cir. Oct. 23, 2014), Order at 3. On December 3, 2014, EPA issued an

¹ CAIR addressed the 1997 annual PM_{2.5} NAAQS and the 1997 8-hour ozone NAAQS. CSAPR addresses contributions from upwind states to downwind nonattainment and maintenance of the 2006 24-hour PM_{2.5} NAAQS as well as the ozone and PM_{2.5} NAAQS addressed by CAIR.

interim final rule to clarify how EPA will implement CSAPR consistent with the D.C. Circuit Court's order granting EPA's motion requesting lifting the stay and tolling the rule's deadlines. See 79 FR 71663 (December 3, 2014) (interim final rulemaking). Consistent with that rule, EPA began implementing CSAPR on January 1, 2015.

2. Proposal on This Issue

Because CAIR was promulgated in 2005 and incentivized sources and states to begin achieving early emission reductions, the air quality data examined by EPA in issuing a final determination of attainment for the Pittsburgh Area in 2012 (October 12, 2012, 77 FR 62147) and the air quality data from the Area since 2005 necessarily reflect reductions in emissions from upwind sources as a result of CAIR, and Pennsylvania included CAIR as one of the measures that helped to bring the Area into attainment. However, modeling conducted by EPA during the CSAPR rulemaking process, which used a baseline emissions scenario that "backed out" the effects of CAIR, see 76 FR 48223, projected that the counties in the Pittsburgh Area would have design values below the 1997 annual and the 2006 24-hour PM_{2.5} NAAQS for 2012 and 2014 without taking into account emission reductions from CAIR or CSAPR. See Appendix B of EPA's "Air Quality Modeling Final Rule Technical Support Document," (Pages B-57, B-58, B-85, B-86 and B-87), which is available in the docket for this proposed rulemaking action. In addition, the 2011-2013 quality-assured, quality-controlled, and certified monitoring data for the Pittsburgh Area confirms that the PM_{2.5} design values for the Area remained well below the 1997 annual and 2006 24-hour PM_{2.5} NAAQS in 2013.

The status of CSAPR is not relevant to this redesignation. CSAPR was promulgated in June 2011, and the rule was stayed by the D.C. Circuit Court just six months later, before the trading programs it created were scheduled to go into effect. As stated previously, EPA began implementing CSAPR on January 1, 2015, subsequent to the emission reductions documented in the Commonwealth's December 22, 2014 request for redesignation. Therefore, the Area's attainment of the 1997 annual or the 2006 24-hour PM_{2.5} NAAQS cannot have been a result of any emission reductions associated with CSAPR. In summary, neither the status of CAIR nor the current status of CSAPR affects any of the criteria for proposed approval of

this redesignation request for the Pittsburgh Area.

B. Effect of the D.C. Circuit Court Decision Regarding PM_{2.5} Implementation Under Subpart 4 of Part D of Title I of the CAA

1. Background

On January 4, 2013, in *NRDC v. EPA*, the D.C. Circuit Court remanded to EPA the “Final Clean Air Fine Particle Implementation Rule” (72 FR 20586, April 25, 2007) and the “Implementation of the New Source Review (NSR) Program for PM_{2.5}” final rule (73 FR 28321, May 16, 2008) (collectively, 1997 PM_{2.5} Implementation Rule). 706 F.3d 428 (D.C. Cir. 2013). The D.C. Circuit Court found that EPA erred in implementing the 1997 annual PM_{2.5} NAAQS pursuant to the general implementation provisions of subpart 1 of part D of Title I of the CAA (subpart 1), rather than the particulate-matter-specific provisions of subpart 4 of part D of Title I (subpart 4).

Prior to the January 4, 2013 decision, the states had worked towards meeting the air quality goals of the 1997 and 2006 PM_{2.5} NAAQS in accordance with EPA regulations and guidance derived from subpart 1 of part D of Title I of the CAA. In response to the D.C. Circuit Court’s remand, EPA took this history into account by setting a new deadline for any remaining submissions that may be required for moderate nonattainment areas as a result of the D.C. Circuit Court’s decision regarding the applicability of subpart 4 of part D of Title I of the CAA.

On June 2, 2014 (79 FR 31566), EPA issued a final rule, “Identification of Nonattainment Classification and Deadlines for Submission of SIP Provisions for the 1997 and 2006 PM_{2.5} NAAQS” (the PM_{2.5} Subpart 4 Classification and Deadline Rule), which identifies the classification under subpart 4 as “moderate” for areas currently designated nonattainment for the 1997 annual and/or 2006 24-hour PM_{2.5} NAAQS. The rule set a deadline for states to submit attainment plans and meet other subpart 4 requirements. The rule specified December 31, 2014 as the deadline for states to submit any additional attainment-related SIP elements that may be needed to meet the applicable requirements of subpart 4 for areas currently designated nonattainment for the 1997 PM_{2.5} and/or 2006 PM_{2.5} NAAQS and to submit SIPs addressing the nonattainment new source review (NSR) requirements in subpart 4.

As explained in detail in the following section, since Pennsylvania

submitted its request to redesignate the Pittsburgh Area on December 22, 2014, any additional attainment-related SIP elements that may be needed for the Area to meet the applicable requirements of subpart 4 were not due at the time Pennsylvania submitted its request to redesignate the Area for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS.

2. Proposal on This Issue

In this proposed rulemaking action, EPA addresses the effect of the D.C. Circuit Court’s January 4, 2013 ruling and the June 2, 2014 PM_{2.5} Subpart 4 Classification and Deadline Rule on the redesignation request for the Area. EPA is proposing to determine that the D.C. Circuit Court’s January 4, 2013 decision does not prevent EPA from redesignating the Area to attainment for the 1997 annual and the 2006 24-hour PM_{2.5} NAAQS. Even in light of the D.C. Circuit Court’s decision, redesignation for this Area is appropriate under the CAA and EPA’s longstanding interpretations of the CAA’s provisions regarding redesignation. EPA first explains its longstanding interpretation that requirements that are imposed, or that become due, after a complete redesignation request is submitted for an area that is attaining the standard, are not applicable for purposes of evaluating a redesignation request. Second, EPA then shows that, even if EPA applies the subpart 4 requirements to the redesignation requests of the Area and disregards the provisions of its 1997 PM_{2.5} Implementation Rule recently remanded by the D.C. Circuit Court, Pennsylvania’s request for redesignation of the Area still qualifies for approval. EPA’s discussion also takes into account the effect of the D.C. Circuit Court’s ruling and the June 2, 2014 PM_{2.5} Subpart 4 Classification and Deadline Rule on the maintenance plans of the Area, which EPA views as approvable even when subpart 4 requirements are considered.

a. Applicable Requirements Under Subpart 4 for Purposes of Evaluating the Redesignation Request of the Area

With respect to the 1997 PM_{2.5} Implementation Rule, the D.C. Circuit Court’s January 4, 2013 ruling rejected EPA’s reasons for implementing the PM_{2.5} NAAQS solely in accordance with the provisions of subpart 1, and remanded that matter to EPA, so that it could address implementation of the 1997 annual PM_{2.5} NAAQS under subpart 4 of part D of the CAA, in addition to subpart 1. For the purposes of evaluating Pennsylvania’s December 22, 2014 redesignation request for the

Area, to the extent that implementation under subpart 4 would impose additional requirements for areas designated nonattainment, EPA believes that those requirements are not “applicable” for the purposes of section 107(d)(3)(E) of the CAA, and thus EPA is not required to consider subpart 4 requirements with respect to the redesignation of the area. Under its longstanding interpretation of the CAA, EPA has interpreted section 107(d)(3)(E) to mean, as a threshold matter, that the part D provisions which are “applicable” and which must be approved in order for EPA to redesignate an area include only those which came due prior to a state’s submittal of a complete redesignation request. *See* 1992 Calcagni Memorandum. *See also* “SIP Requirements for Areas Submitting Requests for Redesignation to Attainment of the Ozone and Carbon Monoxide (CO) NAAQS on or after November 15, 1992,” Memorandum from Michael Shapiro, Acting Assistant Administrator, Air and Radiation, September 17, 1993 (Shapiro memorandum); Final Redesignation of Detroit-Ann Arbor, (60 FR 12459, 12465–66, March 7, 1995); Final Redesignation of St. Louis, Missouri, (68 FR 25418, 25424–27, May 12, 2003); *Sierra Club v. EPA*, 375 F.3d 537, 541 (7th Cir. 2004) (upholding EPA’s redesignation rulemaking applying this interpretation and expressly rejecting Sierra Club’s view that the meaning of “applicable” under the statute is “whatever should have been in the plan at the time of attainment rather than whatever actually was in the plan and already implemented or due at the time of attainment”).² In this case, at the time that Pennsylvania submitted its redesignation request for the Pittsburgh Area for the 1997 annual and the 2006 24-hour PM_{2.5} NAAQS, the requirements under subpart 4 were not due.³

EPA’s view that, for purposes of evaluating the redesignation of the Area, the subpart 4 requirements were not due at the time Pennsylvania submitted the redesignation request is in keeping with the EPA’s interpretation of subpart 2 requirements for subpart 1 ozone areas redesignated subsequent to the D.C.

² Applicable requirements of the CAA that come due subsequent to the area’s submittal of a complete redesignation request remain applicable until a redesignation is approved, but are not required as a prerequisite to redesignation. Section 175A(c) of the CAA.

³ EPA found Pennsylvania’s December 22, 2014 submittal redesignation of the Area complete on January 22, 2015. EPA’s complete determination is available in the docket for this rulemaking.

Circuit Court's decision in *South Coast Air Quality Mgmt. Dist. v. EPA*, 472 F.3d 882 (D.C. Cir. 2006). In *South Coast*, the D.C. Circuit Court found that EPA was not permitted to implement the 1997 8-hour ozone standard solely under subpart 1, and held that EPA was required under the statute to implement the standard under the ozone-specific requirements of subpart 2 as well. Subsequent to the *South Coast* decision, in evaluating and acting upon redesignation requests for the 1997 8-hour ozone standard that were submitted to EPA for areas under subpart 1, EPA applied its longstanding interpretation of the CAA that "applicable requirements," for purposes of evaluating a redesignation, are those that had been due at the time the redesignation request was submitted. See, e.g., Proposed Redesignation of Manitowoc County and Door County Nonattainment Areas (75 FR 22047, 22050, April 27, 2010). In those rulemaking actions, EPA therefore, did not consider subpart 2 requirements to be "applicable" for the purposes of evaluating whether the area should be redesignated under section 107(d)(3)(E) of the CAA.

EPA's interpretation derives from the provisions of section 107(d)(3) of the CAA. Section 107(d)(3)(E)(v) states that, for an area to be redesignated, a state must meet "all requirements 'applicable' to the area under section 110 and part D." Section 107(d)(3)(E)(ii) provides that EPA must have fully approved the "applicable" SIP for the area seeking redesignation. These two sections read together support EPA's interpretation of "applicable" as only those requirements that came due prior to submission of a complete redesignation request.

First, holding states to an ongoing obligation to adopt new CAA requirements that arose after the state submitted its redesignation request, in order to be redesignated, would make it problematic or impossible for EPA to act on redesignation requests in accordance with the 18-month deadline Congress set for EPA action in section 107(d)(3)(D). If "applicable requirements" were interpreted to be a continuing flow of requirements with no reasonable limitation, states, after submitting a redesignation request, would be forced continuously to make additional SIP submissions that in turn would require EPA to undertake further notice-and-comment rulemaking actions to act on those submissions. This would create a regime of unceasing rulemaking that would delay action on the redesignation request beyond the 18-

month timeframe provided by the CAA for this purpose.

Second, a fundamental premise for redesignating a nonattainment area to attainment is that the area has attained the relevant NAAQS due to emission reductions from existing controls. Thus, an area for which a redesignation request has been submitted would have already attained the NAAQS as a result of satisfying statutory requirements that came due prior to the submission of the request. Absent a showing that unadopted and unimplemented requirements are necessary for future maintenance, it is reasonable to view the requirements applicable for purposes of evaluating the redesignation request as including only those SIP requirements that have already come due. These are the requirements that led to attainment of the NAAQS. To require, for redesignation approval, that a state also satisfy additional SIP requirements coming due after the state submits its complete redesignation request, and while EPA is reviewing it, would compel the state to do more than is necessary to attain the NAAQS, without a showing that the additional requirements are necessary for maintenance.

In the context of this redesignation, the timing and nature of the D.C. Circuit Court's January 4, 2013 decision in *NRDC v. EPA*, and EPA's June 2, 2014 PM_{2.5} Subpart 4 Classification and Deadline Rule compound the consequences of imposing requirements that come due after the redesignation request is submitted. Pennsylvania submitted its redesignation request for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS on December 22, 2014 for the Pittsburgh Area, which is prior to the deadline by which the area is required to meet the attainment plan and other requirements pursuant to subpart 4.

To require Pennsylvania's fully-complete and pending redesignation request for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS to comply now with requirements of subpart 4 that the D.C. Circuit Court announced only in January 2013 and for which the December 31, 2014 deadline to comply occurred subsequent to EPA's receipt of Pennsylvania's December 22, 2014 redesignation request would be to give retroactive effect to such requirements and provide Pennsylvania a unique and earlier deadline for compliance solely on the basis of submitting its redesignation request for the Area. The D.C. Circuit Court recognized the inequity of this type of retroactive impact in *Sierra Club v. Whitman*, 285

F.3d 63 (D.C. Cir. 2002),⁴ where it upheld the D.C. Circuit Court's ruling refusing to make retroactive EPA's determination that the areas did not meet their attainment deadlines. In that case, petitioners urged the D.C. Circuit Court to make EPA's nonattainment determination effective as of the date that the statute required, rather than the later date on which EPA actually made the determination. The D.C. Circuit Court rejected this view, stating that applying it "would likely impose large costs on States, which would face fines and suits for not implementing air pollution prevention plans . . . even though they were not on notice at the time." *Id.* at 68. Similarly, it would be unreasonable to penalize Pennsylvania by rejecting its December 22, 2014 redesignation request for an area that EPA previously determined was attaining the 1997 annual and 2006 24-hour PM_{2.5} NAAQS and that met all applicable requirements known to be in effect at the time of the request. For EPA now to reject the redesignation request solely because Pennsylvania did not expressly address subpart 4 requirements which came due after receipt of such request, (and for which it had little to no notice), would inflict the same unfairness condemned by the D.C. Circuit Court in *Sierra Club v. Whitman*.

b. Subpart 4 Requirements and Pennsylvania's Redesignation Request

Even if EPA were to take the view that the D.C. Circuit Court's January 4, 2013 decision, or the June 2, 2014 PM_{2.5} Subpart 4 Classification and Deadline Rule, requires that, in the context of pending redesignation requests for the 1997 annual and the 2006 24-hour PM_{2.5} NAAQS, which were submitted prior to December 31, 2014, subpart 4 requirements must be considered as being due and in effect, EPA proposes to determine that the Area still qualifies for redesignation to attainment for the 1997 annual and the 2006 24-hour PM_{2.5} NAAQS. As explained subsequently, EPA believes that the redesignation request for the Area, though not expressed in terms of subpart 4 requirements, substantively meets the requirements of that subpart for purposes of redesignating the Area to

⁴ *Sierra Club v. Whitman* was discussed and distinguished in a recent D.C. Circuit Court decision that addressed retroactivity in a quite different context, where, unlike the situation here, EPA sought to give its regulations retroactive effect. *National Petrochemical and Refiners Ass'n v. EPA*, 630 F.3d 145, 163 (D.C. Cir. 2010), *rehearing denied* 643 F.3d 958 (D.C. Cir. 2011), *cert denied* 132 S. Ct. 571 (2011).

attainment for the 1997 annual and the 2006 24-hour PM_{2.5} NAAQS.

With respect to evaluating the relevant substantive requirements of subpart 4 for purposes of redesignating the Area, EPA notes that subpart 4 incorporates components of subpart 1 of part D, which contains general air quality planning requirements for areas designated as nonattainment. See section 172(c). Subpart 4 itself contains specific planning and scheduling requirements for coarse particulate matter (PM₁₀)⁵ nonattainment areas, and under the D.C. Circuit Court's January 4, 2013 decision in *NRDC v. EPA*, these same statutory requirements also apply for PM_{2.5} nonattainment areas. EPA has longstanding general guidance that interprets the 1990 amendments to the CAA, making recommendations to states for meeting the statutory requirements for SIPs for nonattainment areas. See the General Preamble. In the General Preamble, EPA discussed the relationship of subpart 1 and subpart 4 SIP requirements, and pointed out that subpart 1 requirements were to an extent "subsumed by, or integrally related to, the more specific PM₁₀ requirements" (57 FR 13538, April 16, 1992). The subpart 1 requirements include, among other things, provisions for attainment demonstrations, RACM, RFP, emissions inventories, and contingency measures.

For the purposes of this redesignation request, in order to identify any additional requirements which would apply under subpart 4, consistent with EPA's June 2, 2014 PM_{2.5} Subpart 4 Classification and Deadline Rule, EPA is considering the areas to be "moderate" PM_{2.5} nonattainment areas. As EPA explained in its June 2, 2014 rule, section 188 of the CAA provides that all areas designated nonattainment areas under subpart 4 are initially to be classified by operation of law as "moderate" nonattainment areas, and remain moderate nonattainment areas unless and until EPA reclassifies the area as a "serious" nonattainment area. Accordingly, EPA believes that it is appropriate to limit the evaluation of the potential impact of subpart 4 requirements to those that would be applicable to moderate nonattainment areas. Sections 189(a) and (c) of subpart 4 apply to moderate nonattainment areas and include the following: (1) An approved permit program for construction of new and modified major stationary sources (section 189(a)(1)(A)); (2) an attainment demonstration (section 189(a)(1)(B)); (3) provisions for RACM

(section 189(a)(1)(C)); and (4) quantitative milestones demonstrating RFP toward attainment by the applicable attainment date (section 189(c)).

The permit requirements of subpart 4, as contained in section 189(a)(1)(A), refer to and apply the subpart 1 permit provisions requirements of sections 172 and 173 to PM₁₀, without adding to them. Consequently, EPA believes that section 189(a)(1)(A) does not itself impose for redesignation purposes any additional requirements for moderate areas beyond those contained in subpart 1.⁶ In any event, in the context of redesignation, EPA has long relied on the interpretation that a fully approved nonattainment NSR program is not considered an applicable requirement for redesignation, provided the area can maintain the standard with a prevention of significant deterioration (PSD) program after redesignation. A detailed rationale for this view is described in a memorandum from Mary Nichols, Assistant Administrator for Air and Radiation, dated October 14, 1994, entitled, "Part D NSR Requirements for Areas Requesting Redesignation to Attainment." See also rulemakings for Detroit, Michigan (60 FR 12467–12468, March 7, 1995); Cleveland-Akron-Lorain, Ohio (61 FR 20458, 20469–20470, May 7, 1996); Louisville, Kentucky (66 FR 53665, October 23, 2001); and Grand Rapids, Michigan (61 FR 31834–31837, June 21, 1996). With respect to the specific attainment planning requirements under subpart 4,⁷ when EPA evaluates a redesignation request under either subpart 1 or 4, any area that is attaining the PM_{2.5} NAAQS is viewed as having satisfied the attainment planning requirements for these subparts. For redesignations, EPA has for many years interpreted attainment-linked requirements as not applicable for areas attaining the standard. In the General Preamble, EPA stated that: "The requirements for RFP will not apply in evaluating a request for redesignation to attainment since, at a minimum, the air quality data for the area must show that the area has already attained. Showing that the State will make RFP towards attainment will, therefore, have no meaning at that point."

The General Preamble also explained that: "[t]he section 172(c)(9) requirements are directed at ensuring

⁶ The potential effect of section 189(e) on section 189(a)(1)(A) for purposes of evaluating this redesignation is discussed in this rulemaking action.

⁷ EPA refers here to attainment demonstration, RFP, RACM, milestone requirements, and contingency measures.

RFP and attainment by the applicable date. These requirements no longer apply when an area has attained the standard and is eligible for redesignation. Furthermore, section 175A for maintenance plans . . . provides specific requirements for contingency measures that effectively supersede the requirements of section 172(c)(9) for these areas." *Id.* EPA similarly stated in its 1992 Calcagni Memorandum that, "The requirements for reasonable further progress and other measures needed for attainment will not apply for redesignations because they only have meaning for areas not attaining the standard."

It is evident that even if we were to consider the D.C. Circuit Court's January 4, 2013 decision in *NRDC v. EPA*, or the June 2, 2014 PM_{2.5} Subpart 4 Classification and Deadline Rule, to mean that attainment-related requirements specific to subpart 4 were either due prior to Pennsylvania's December 22, 2014 redesignation request and must now be imposed retroactively,⁸ those requirements do not apply to areas that are attaining the 1997 annual and the 2006 24-hour PM_{2.5} NAAQS for the purpose of evaluating pending requests to redesignate the areas to attainment. EPA has consistently enunciated this interpretation of applicable requirements under section 107(d)(3)(E) since the General Preamble was published more than twenty years ago. Courts have recognized the scope of EPA's authority to interpret "applicable requirements" in the redesignation context. See *Sierra Club v. EPA*, 375 F.3d 537 (7th Cir. 2004).

Moreover, even outside the context of redesignations, EPA has viewed the obligations to submit attainment-related SIP planning requirements of subpart 4 as inapplicable for areas that EPA determines are attaining the 1997 annual and 2006 24-hour PM_{2.5} NAAQS. EPA's prior "Clean Data Policy" rulemakings for the PM₁₀ NAAQS, also governed by the requirements of subpart 4, explain EPA's reasoning. They describe the effects of a determination of attainment on the attainment-related SIP planning requirements of subpart 4. See "Determination of Attainment for Coso Junction Nonattainment Area," (75 FR 27944, May 19, 2010). See also *Coso Junction Proposed PM₁₀ Redesignation*, (75 FR 36023, 36027, June 24, 2010); *Proposed and Final Determinations of Attainment for San Joaquin*

⁸ As explained earlier, EPA does not believe that the D.C. Circuit Court's January 4, 2013 decision should be interpreted so as to impose these requirements on the states retroactively. *Sierra Club v. Whitman*, *supra*.

⁵ PM₁₀ refers to particulates nominally 10 micrometers in diameter or smaller.

Nonattainment Area (71 FR 40952, 40954–55, July 19, 2006; and 71 FR 63641, 63643–47, October 30, 2006). In short, EPA in this context has also long concluded that to require states to meet superfluous SIP planning requirements is not necessary and not required by the CAA, so long as those areas continue to attain the relevant NAAQS.

As stated previously in this proposed rulemaking action, on October 12, 2012 (77 FR 62147) and May 2, 2014 (79 FR 25014), EPA made determinations that the Pittsburgh Area had attained the 1997 annual and 2006 24-hour PM_{2.5} NAAQS, respectively. Pursuant to 40 CFR 51.1004(c) and based on these determinations, the requirements for the Area to submit an attainment demonstration and associated RACM, RFP plan, contingency measures, and other planning SIPs related to the attainment of either the 1997 annual or 2006 24-hour PM_{2.5} NAAQS were, and continue to be, suspended until such time as: the Area is redesignated to attainment for each standard, at which time the requirements no longer apply; or EPA determines that the Area has again violated any of the standards, at which time such plans are required to be submitted. Under its longstanding interpretation, EPA is proposing to determine here that the Area meets the attainment-related plan requirements of subparts 1 and 4 for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS. Thus, EPA is proposing to conclude that the requirements to submit an attainment demonstration under 189(a)(1)(B), a RACM determination under section 172(c)(1) and section 189(a)(1)(c), a RFP demonstration under 189(c)(1), and contingency measure requirements under section 172(c)(9) are satisfied for purposes of evaluating this redesignation request.

c. Subpart 4 and Control of PM_{2.5} Precursors

The D.C. Circuit Court in *NRDC v. EPA* remanded to EPA the two rules at issue in the case with instructions to EPA to re-promulgate them consistent with the requirements of subpart 4. EPA in this section addresses the D.C. Circuit Court's opinion with respect to PM_{2.5} precursors. While past implementation of subpart 4 for PM₁₀ has allowed for control of PM₁₀ precursors, such as NO_x from major stationary, mobile, and area sources in order to attain the standard as expeditiously as practicable, section 189(e) of the CAA specifically provides that control requirements for major stationary sources of direct PM₁₀ shall also apply to PM₁₀ precursors from those sources, except where EPA determines that major stationary sources

of such precursors “do not contribute significantly to PM₁₀ levels which exceed the standard in the area.”

EPA's 1997 PM_{2.5} Implementation Rule, remanded by the D.C. Circuit Court, contained rebuttable presumptions concerning certain PM_{2.5} precursors applicable to attainment plans and control measures related to those plans. Specifically, in 40 CFR 51.1002, EPA provided, among other things, that a state was “not required to address VOC [and NH₃] as . . . PM_{2.5} attainment plan precursor[s] and to evaluate sources of VOC [and NH₃] emissions in the State for control measures.” EPA intended these to be rebuttable presumptions. EPA established these presumptions at the time because of uncertainties regarding the emission inventories for these pollutants and the effectiveness of specific control measures in various regions of the country in reducing PM_{2.5} concentrations. EPA also left open the possibility for such regulation of VOC and NH₃ in specific areas where that was necessary.

The D.C. Circuit Court in its January 4, 2013 decision made reference to both section 189(e) and 40 CFR 51.1002, and stated that, “In light of our disposition, we need not address the petitioners' challenge to the presumptions in [40 CFR 51.1002] that VOCs and NH₃ are not PM_{2.5} precursors, as subpart 4 expressly governs precursor presumptions.” *NRDC v. EPA*, at 27, n.10.

Elsewhere in the D.C. Circuit Court's opinion, however, the D.C. Circuit Court observed: “NH₃ is a precursor to fine particulate matter, making it a precursor to both PM_{2.5} and PM₁₀. For a PM₁₀ nonattainment area governed by subpart 4, a precursor is presumptively regulated. See 42 U.S.C. 7513a(e) [section 189(e)].” *Id.* at 21, n.7.

For a number of reasons, the redesignation of the Pittsburgh Area for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS is consistent with the D.C. Circuit Court's decision on this aspect of subpart 4. While the D.C. Circuit Court, citing section 189(e), stated that “for a PM₁₀ area governed by subpart 4, a precursor is ‘presumptively’ regulated,” the D.C. Circuit Court expressly declined to decide the specific challenge to EPA's 1997 PM_{2.5} Implementation Rule provisions regarding NH₃ and VOC as precursors. The D.C. Circuit Court had no occasion to reach whether and how it was substantively necessary to regulate any specific precursor in a particular PM_{2.5} nonattainment area, and did not address what might be necessary for purposes of acting upon a redesignation request.

However, even if EPA takes the view that the requirements of subpart 4 were deemed applicable at the time the state submitted the redesignation request, and disregards the 1997 PM_{2.5} Implementation Rule's rebuttable presumptions regarding NH₃ and VOC as PM_{2.5} precursors, the regulatory consequence would be to consider the need for regulation of all precursors from any sources in the Area to demonstrate attainment and to apply the section 189(e) provisions to major stationary sources of precursors. In the case of the Pittsburgh Area, EPA believes that doing so is consistent with proposing redesignation of the Area for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS. The Area has attained the 1997 annual and 2006 24-hour PM_{2.5} NAAQS without any specific additional controls of NH₃ and VOC emissions from any sources in the Area.

Precursors in subpart 4 are specifically regulated under the provisions of section 189(e), which requires, with important exceptions, control requirements for major stationary sources of PM₁₀ precursors.⁹ Under subpart 1 and EPA's prior implementation rule, all major stationary sources of PM_{2.5} precursors were subject to regulation, with the exception of NH₃ and VOC. Thus, EPA must address here whether additional controls of NH₃ and VOC from major stationary sources are required under section 189(e) of subpart 4 in order to redesignate the Area for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS. As explained subsequently, EPA does not believe that any additional controls of NH₃ and VOC are required in the context of this redesignation.

In the General Preamble, EPA discusses its approach to implementing section 189(e). See 57 FR 13538–13542. With regard to precursor regulation under section 189(e), the General Preamble explicitly stated that control of VOC under other CAA requirements may suffice to relieve a state from the need to adopt precursor controls under section 189(e). See 57 FR 13542. EPA in this rulemaking action, proposes to determine that the Pennsylvania SIP revision has met the provisions of section 189(e) with respect to NH₃ and VOC as precursors. These proposed determinations are based on EPA's findings that: (1) The Pittsburgh Area contains no major stationary sources of

⁹ Under either subpart 1 or subpart 4, for purposes of demonstrating attainment as expeditiously as practicable, a state is required to evaluate all economically and technologically feasible control measures for direct PM emissions and precursor emissions, and adopt those measures that are deemed reasonably available.

NH₃; and (2) existing major stationary sources of VOC are adequately controlled under other provisions of the CAA regulating the ozone NAAQS.¹⁰ In the alternative, EPA proposes to determine that, under the express exception provisions of section 189(e), and in the context of the redesignation of the Area, which is attaining the 1997 annual and 2006 24-hour PM_{2.5} NAAQS, at present NH₃ and VOC precursors from major stationary sources do not contribute significantly to levels exceeding the 1997 annual and 2006 24-hour PM_{2.5} NAAQS in the Area. *See* 57 FR 13539–42.

EPA notes that its 1997 PM_{2.5} Implementation Rule provisions in 40 CFR 51.1002 were not directed at evaluation of PM_{2.5} precursors in the context of redesignation, but at SIP plans and control measures required to bring a nonattainment area into attainment of the 1997 annual PM_{2.5} NAAQS. By contrast, redesignation to attainment primarily requires the nonattainment area to have already attained due to permanent and enforceable emission reductions, and to demonstrate that controls in place can continue to maintain the standard. Thus, even if we regard the D.C. Circuit Court's January 4, 2013 decision as calling for "presumptive regulation" of NH₃ and VOC for PM_{2.5} under the attainment planning provisions of subpart 4, those provisions in and of themselves do not require additional controls of these precursors for an area that already qualifies for redesignation. Nor does EPA believe that requiring Pennsylvania to address precursors differently than it has already would result in a substantively different outcome.

Although, as EPA has emphasized, its consideration here of precursor requirements under subpart 4 is in the context of a redesignation to attainment, EPA's existing interpretation of subpart 4 requirements with respect to precursors in attainment plans for PM₁₀ contemplates that states may develop attainment plans that regulate only those precursors that are necessary for purposes of attainment in the area in question, *i.e.*, states may determine that only certain precursors need be regulated for attainment and control purposes.¹¹ Courts have upheld this

approach to the requirements of subpart 4 for PM₁₀.¹² EPA believes that application of this approach to PM_{2.5} precursors under subpart 4 is reasonable. Because the Area has already attained the 1997 annual and 2006 24-hour PM_{2.5} NAAQS with its current approach to regulation of PM_{2.5} precursors, EPA believes that it is reasonable to conclude in the context of this redesignation that there is no need to revisit an attainment control strategy with respect to the treatment of precursors. Even if the D.C. Circuit Court's decision is construed to impose an obligation, in evaluating this redesignation request, to consider additional precursors under subpart 4, it would not affect EPA's approval here of Pennsylvania's request for redesignation of the Pittsburgh Area for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS. In the context of a redesignation, Pennsylvania has shown that the Area has attained both standards. Moreover, Pennsylvania has shown, and EPA proposes to determine, that attainment of the 1997 annual and 2006 24-hour PM_{2.5} NAAQS in this Area is due to permanent and enforceable emission reductions on all precursors necessary to provide for continued attainment of the standards. *See* Section V.A.3 of this rulemaking action. It follows logically that no further control of additional precursors is necessary. Accordingly, EPA does not view the January 4, 2013 decision of the D.C. Circuit Court as precluding redesignation of the Area to attainment for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS at this time.

In summary, even if, prior to submitting its December 22, 2014 redesignation request, or subsequent to such submission and prior to December 31, 2014, Pennsylvania was required to address precursors for the Area under subpart 4 rather than under subpart 1, as interpreted in EPA's remanded 1997 PM_{2.5} Implementation Rule, EPA would still conclude that the Area had met all applicable requirements for purposes of redesignation in accordance with section 107(d)(3)(E)(ii) and (v) of the CAA.

V. EPA's Analysis of Pennsylvania's Submittal

EPA is proposing several rulemaking actions for the Pittsburgh Area: (1) To redesignate the Pittsburgh Area to attainment for the 1997 annual and 2006

24-hour PM_{2.5} NAAQS; (2) to approve into the Pennsylvania SIP the associated maintenance plan for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS; and (3) to approve the 2007 comprehensive emissions inventory for the 1997 annual PM_{2.5} NAAQS and the 2011 comprehensive emissions inventories for the 2006 24-hour PM_{2.5} NAAQS to satisfy section 172(c)(3) requirement, which is one of the CAA criteria for redesignation. EPA's proposed approval of the redesignation request and maintenance plan for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS are based upon EPA's determination that the Area continues to attain both standards, which EPA is proposing in this rulemaking action, and that all other redesignation criteria have been met for the Area. In addition, EPA is proposing to approve the 2017 and 2025 PM_{2.5} and NO_x MVEBs included in the maintenance plan for the Pittsburgh Area for transportation conformity purposes. The following is a description of how Pennsylvania's December 22, 2014 submittal satisfies the requirements of the CAA including specifically section 107(d)(3)(E) for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS.

A. Redesignation Request

1. Attainment

On October 12, 2012 (77 FR 62147), EPA determined that the Pittsburgh Area attained the 1997 annual PM_{2.5} NAAQS by its applicable attainment date of April 5, 2010, based upon quality-assured and certified ambient air quality monitoring data for 2007–2009. In a separate rulemaking action dated May 2, 2014 (79 FR 25014), EPA determined that the Pittsburgh Area attained the 2006 24-hour PM_{2.5} NAAQS, based on quality-assured and certified ambient air quality monitoring data for 2010–2012 and 2011–2013. The basis and effect of these determinations of attainment for both the 1997 annual and 2006 24-hour PM_{2.5} NAAQS were discussed in the notices of the proposed (77 FR 34297 (June 11, 2012) and 78 FR 49403 (August 14, 2013), respectively) and final (77 FR 62147 and 79 FR 25014, respectively) rulemakings which determined the Area attained the 1997 annual and 2006 24-hour PM_{2.5} NAAQS, respectively.

EPA has reviewed the ambient air quality PM_{2.5} monitoring data in the Pittsburgh Area consistent with the requirements contained in 40 CFR part 50, and recorded in EPA's Air Quality System (AQS), including quality-assured, quality-controlled, and state-certified data for the monitoring periods

¹⁰ The Area has reduced VOC emissions through the implementation of various control programs including VOC Reasonably Available Control Technology (RACT) regulations and various onroad and nonroad motor vehicle control programs.

¹¹ *See, e.g.,* "Approval and Promulgation of Implementation Plans for California—San Joaquin Valley PM₁₀ Nonattainment Area; Serious Area Plan for Nonattainment of the 24-Hour and Annual PM₁₀

Standards," (69 FR 30006, May 26, 2004) (approving a PM₁₀ attainment plan that impose controls on direct PM₁₀ and NO_x emissions and did not impose controls on SO₂, VOC, or NH₃ emissions).

¹² *See, e.g., Assoc. of Irrigated Residents v. EPA et al.*, 423 F.3d 989 (9th Cir. 2005).

2008–2010, 2009–2011, 2010–2012, and 2011–2013. This data, provided in Tables 1 and 2, shows that the Area continues to attain the 1997 annual and 2006 24-hour PM_{2.5} NAAQS.

TABLE 1—DESIGN VALUES FOR THE PITTSBURGH AREA FOR THE 1997 ANNUAL PM_{2.5} NAAQS (μG/M³) FOR 2008–2010, 2009–2011, 2010–2012, AND 2011–2013

Monitor ID #	2008–2010	2009–2011	2010–2012	2011–2013
Avalon, 420030002	* 16.3	* 14.7	13.4	11.4
South Fayette, 420030067	11.1	11	10.5	9.6
North Braddock, 420031301	13.3	12.7	12.5	* 11.7
Washington, 421250200	11.8	11.3	11.1	10.3
Charleroi, 421250005	12.9	12.6	11.9	11
Florence, 421255001	10.8	9	7.2	7.2
Harrison 2, 420031008	13	12.4	* 11.7	10.6
Beaver Falls, 420070014	13.1	12.4	12	11.6
Greensburg, 42129008	13.4	13.7	12.6	11.1
Lawrenceville, 420030008	12.2	11.6	11.1	10.3
North Park, 420030093	10.1	9.7	9.4	8.8

* This data is shown in EPA's AQS as incomplete. Additional statistical analysis was done to ensure the Pittsburgh-Beaver Valley Area meets the completeness requirement of the Clean Data Determination.

TABLE 2—DESIGN VALUES FOR THE PITTSBURGH AREA FOR THE 2006 24-HOUR PM_{2.5} NAAQS (μG/M³) FOR 2008–2010, 2009–2011, 2010–2012, AND 2011–2013

Monitor ID #	2008–2010	2009–2011	2010–2012	2011–2013
Avalon, 420030002	* 38	* 34	29	25
South Fayette, 420030067	26	27	26	24
North Braddock, 420031301	35	34	33	29
Washington, 421250200	26	27	25	23
Charleroi, 421250005	28	28	26	25
Florence, 421255001	25	20	17	16
Harrison 2, 420031008	* 31	* 30	28	25
Beaver Falls, 420070014	30	29	27	26
Greensburg, 42129008	32	* 33	* 29	* 26
Lawrenceville, 420030008	28	27	26	23
North Park, 420030093	* 25	25	23	19

* This data is shown in EPA's AQS as incomplete. Additional statistical analysis was done to ensure the Pittsburgh-Beaver Valley Area meets the completeness requirement of the Clean Data Determination.

EPA's review of the monitoring data from 2008 through 2013 supports EPA's previous determinations that the Area has attained the 1997 annual and 2006 24-hour PM_{2.5} NAAQS, and that the Area continues to attain both standards. In addition, as discussed subsequently, with respect to the maintenance plan, Pennsylvania commits to maintain an ambient air quality monitoring network in accordance with 40 CFR part 58. Thus, based upon an analysis of currently available data, EPA is proposing to determine that the Pittsburgh Area continues to attain the 1997 annual and 2006 24-hour PM_{2.5} NAAQS.

2. The Area Has Met All Applicable Requirements Under Section 110 and Subpart 1 of the CAA and Has a Fully Approved SIP Under Section 110(k)

In accordance with section 107(d)(3)(E)(v), the SIP revision for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS for the Pittsburgh Area must be fully approved under section 110(k) and all the requirements applicable to the

Area under section 110 of the CAA (general SIP requirements) and part D of Title I of the CAA (SIP requirements for nonattainment areas) must be met.

a. Section 110 General SIP Requirements

Section 110(a)(2) of Title I of the CAA delineates the general requirements for a SIP, which include enforceable emissions limitations and other control measures, means, or techniques, provisions for the establishment and operation of appropriate devices necessary to collect data on ambient air quality, and programs to enforce the limitations. The general SIP elements and requirements set forth in section 110(a)(2) include, but are not limited to, the following: (1) Submittal of a SIP that has been adopted by the state after reasonable public notice and hearing; (2) provisions for establishment and operation of appropriate procedures needed to monitor ambient air quality; (3) implementation of a minor source permit program and provisions for the implementation of part C requirements

(PSD); (4) Provisions for the implementation of part D requirements for NSR permit programs; (5) provisions for air pollution modeling; and (6) provisions for public and local agency participation in planning and emission control rule development.

Section 110(a)(2)(D) of the CAA requires that SIPs contain certain measures to prevent sources in a state from significantly contributing to air quality problems in another state. To implement this provision for various NAAQS, EPA has required certain states to establish programs to address transport of air pollutants in accordance with EPA's Finding of Significant Contribution and Rulemaking for Certain States in the Ozone Transport Assessment Group Region for Purposes of Reducing Regional Transport of Ozone (63 FR 57356, October 27, 1998), also known as the NO_x SIP Call; amendments to the NO_x SIP Call (64 FR 26298, May 14, 1999 and 65 FR 11222, March 2, 2000), CAIR (70 FR 25162, May 12, 2005) and CSAPR. However,

section 110(a)(2)(D) requirements for a state are not linked with a particular nonattainment area's designation and classification in that state. EPA believes that the requirements linked with a particular nonattainment area's designation and classification are the relevant measures to evaluate in reviewing a redesignation request. The transport SIP submittal requirements, where applicable, continue to apply to a state regardless of the designation of any one particular area in the state. Thus, EPA does not believe that these requirements are applicable requirements for purposes of redesignation.

In addition, EPA believes that the other section 110(a)(2) elements not connected with nonattainment plan submissions and not linked with an area's attainment status are not applicable requirements for purposes of redesignation. The Area will still be subject to these requirements after it is redesignated. EPA concludes that the section 110(a)(2) and part D requirements which are linked with a particular area's designation and classification are the relevant measures to evaluate in reviewing a redesignation request, and that section 110(a)(2) elements not linked to the area's nonattainment status are not applicable for purposes of redesignation. This approach is consistent with EPA's existing policy on applicability of conformity (*i.e.*, for redesignations) and oxygenated fuels requirement. *See* Reading, Pennsylvania, proposed and final rulemakings (61 FR 53174, October 10, 1996), (62 FR 24826, May 7, 1997); Cleveland-Akron-Lorain, Ohio final rulemaking (61 FR 20458, May 7, 1996); and Tampa, Florida, final rulemaking (60 FR 62748, December 7, 1995). For additional discussion on this issue, *see* the Cincinnati, Ohio redesignation (65 FR at 37890, June 19, 2000) and the Pittsburgh-Beaver Valley, Pennsylvania redesignation (66 FR at 53099, October 19, 2001).

EPA has reviewed the Pennsylvania SIP and has concluded that it meets the general SIP requirements under section 110(a)(2) of the CAA to the extent they are applicable for purposes of redesignation. EPA has previously approved provisions of Pennsylvania's SIP addressing section 110(a)(2) requirements, including provisions addressing PM_{2.5}. *See* 77 FR 58955 (September 25, 2012) (approving infrastructure SIP submittals for 1997 and 2006 PM_{2.5} NAAQS). These requirements are, however, statewide requirements that are not linked to the PM_{2.5} nonattainment status of the Area. Therefore, EPA believes that these SIP

elements are not applicable requirements for purposes of review of the Commonwealth's PM_{2.5} redesignation request.

b. Subpart 1 Requirements

Subpart 1 sets forth the basic nonattainment plan requirements applicable to PM_{2.5} nonattainment areas. Under section 172, states with nonattainment areas must submit plans providing for timely attainment and must meet a variety of other requirements.

EPA's longstanding interpretation of the nonattainment planning requirements of section 172 is that once an area is attaining the NAAQS, those requirements are not "applicable" for purposes of section 107(d)(3)(E)(ii) and therefore need not be approved into the SIP before EPA can redesignate the area. In the 1992 General Preamble for Implementation of Title I, EPA set forth its interpretation of applicable requirements for purposes of evaluating redesignation requests when an area is attaining a standard. *See* 57 FR 13498, 13564 (April 16, 1992). EPA noted that the requirements for RFP and other measures designed to provide for attainment do not apply in evaluating redesignation requests because those nonattainment planning requirements "have no meaning" for an area that has already attained the standard. *Id.* This interpretation was also set forth in the 1992 Calcagni Memorandum. EPA's understanding of section 172 also forms the basis of its Clean Data Policy, which was articulated with regard to PM_{2.5} in 40 CFR 51.1004(c), and suspends a state's obligation to submit most of the attainment planning requirements that would otherwise apply, including an attainment demonstration and planning SIPs to provide for RFP, RACM, and contingency measures under section 172(c)(9).¹³ Courts have upheld EPA's interpretation of section 172(c)(1)'s "reasonably available" control measures and control technology as meaning only those controls that advance attainment, which precludes the need to require additional measures where an area is already attaining. *NRDC v. EPA*, 571 F.3d 1245, 1252 (D.C. Cir. 2009); *Sierra Club v. EPA*, 294 F.3d 155, 162 (D.C. Cir. 2002); *Sierra Club v. EPA*, 314 F.3d 735, 744 (5th Cir. 2002).

Therefore, because attainment has been reached for the 1997 annual and

2006 24-hour PM_{2.5} NAAQS in the Pittsburgh Area (*see* October 12, 2012 (77 FR 62147) and May 2, 2014 (79 FR 25014)), no additional measures are needed to provide for attainment, and section 172(c)(1) requirements for an attainment demonstration and RACM are no longer considered to be applicable for purposes of redesignation as long as the Area continues to attain each standard until redesignation. Section 172(c)(2)'s requirement that nonattainment plans contain provisions promoting reasonable further progress toward attainment is also not relevant for purposes of redesignation because EPA has determined that the Pittsburgh Area has monitored attainment of the 1997 annual and 2006 24-hour PM_{2.5} NAAQS. In addition, because the Pittsburgh Area has attained the 1997 annual and 2006 24-hour PM_{2.5} NAAQS and is no longer subject to a RFP requirement, the requirement to submit the section 172(c)(9) contingency measures is not applicable for purposes of redesignation. Section 172(c)(6) requires the SIP to contain control measures necessary to provide for attainment of the NAAQS. Because attainment has been reached, no additional measures are needed to provide for attainment.

The requirement under section 172(c)(3) of the CAA was not suspended by EPA's clean data determination for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS and is the only remaining requirement under section 172 to be considered for purposes of redesignation of the Area.

Section 172(c)(3) of the CAA requires submission and approval of a comprehensive, accurate, and current inventory of actual emissions. For purposes of the PM_{2.5} NAAQS, this emissions inventory should address not only direct emissions of PM_{2.5}, but also emissions of all precursors with the potential to participate in PM_{2.5} formation, *i.e.*, SO₂, NO_x, VOC and NH₃.

To satisfy the 172(c)(3) requirement for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS, Pennsylvania's December 22, 2014 redesignation request and maintenance plan contains 2007 and 2011 comprehensive emissions inventories. PADEP submitted the 2007 and 2011 emissions inventories to fulfill its obligation to submit a comprehensive inventory under section 172(c)(3) of the CAA, because that inventory has gone through extensive quality assurance. The 2007 and 2011 emissions inventories were the most current accurate and comprehensive emissions inventories of PM_{2.5}, NO_x, SO₂, VOC, and NH₃ for the Area when the Area attained the 1997

¹³ This regulation was promulgated as part of the 1997 PM_{2.5} NAAQS implementation rule that was subsequently challenged and remanded in *NRDC v. EPA*, 706 F.3d 428 (D.C. Cir. 2013), as discussed in Section IV.B of this rulemaking. However, the Clean Data Policy portion of the implementation rule was not at issue in that case.

annual and 2006 24-hour PM_{2.5} NAAQS. Thus, as part of this rulemaking action, EPA is proposing to approve Pennsylvania's 2007 comprehensive emissions inventory for the 1997 annual PM_{2.5} NAAQS and the 2011 comprehensive emissions inventories for the 2006 24-hour PM_{2.5} NAAQS, as satisfying the requirement of section 172(c)(3) of the CAA. Final approval of the 2007 and 2011 comprehensive emissions inventories will satisfy the

emissions inventory requirement under section 172(c)(3) of the CAA. The 2007 and 2011 comprehensive emissions inventories address the general source categories of point sources, area sources, on-road mobile sources, and non-road mobile sources. A summary of the 2007 and 2011 comprehensive emissions inventories are shown in Tables 3 and 4. For more information on EPA's analysis of the 2007 and 2011 emissions inventories, see the TSDs prepared by

the EPA Region III Office of Air Monitoring and Analysis dated April 22, 2015, "Technical Support Document (TSD) for the Redesignation Request and Maintenance Plan for the Pittsburgh-Beaver Valley 1997 and 2006 PM_{2.5} Nonattainment Area" (Inventory TSDs), available in the docket for this rulemaking action at www.regulations.gov. See Docket ID No. EPA-R03-OAR-2015-0029.

TABLE 3—2007 EMISSIONS FOR THE PITTSBURGH-BEAVER VALLEY AREA, IN TONS PER YEAR (TPY)

Sector	PM _{2.5}	NO _x	SO ₂	VOC	NH ₃
Point	8,913	92,750	438,716	3,186	584
Area	6,392	7,946	12,817	28,991	2,474
Onroad	1,692	49,052	378	20,194	858
Nonroad	1,151	21,175	694	10,834	16
Total	18,148	170,923	452,605	63,205	3,932

TABLE 4—2011 EMISSIONS FOR THE PITTSBURGH-BEAVER VALLEY AREA, IN TPY

Sector	PM _{2.5}	NO _x	SO ₂	VOC	NH ₃
Point	7,287	80,746	122,541	3,333	322
Area	7,455	19,667	3,841	26,012	3,109
Onroad	967	29,184	149	14,813	624
Nonroad	667	7,110	20	7,832	10
Total	16,376	136,707	126,551	51,990	4,065

Section 172(c)(4) of the CAA requires the identification and quantification of allowable emissions for major new and modified stationary sources in an area, and section 172(c)(5) requires source permits for the construction and operation of new and modified major stationary sources anywhere in the nonattainment area. EPA has determined that, since PSD requirements will apply after redesignation, areas being redesignated need not comply with the requirement that a nonattainment NSR program be approved prior to redesignation, provided that the area demonstrates maintenance of the NAAQS without part D NSR. A more detailed rationale for this view is described in a memorandum from Mary Nichols, Assistant Administrator for Air and Radiation, dated October 14, 1994, entitled, "Part D New Source Review Requirements for Areas Requesting Redesignation to Attainment." Nevertheless, Pennsylvania currently has an approved NSR program codified in Pennsylvania's regulations at 25 Pa. Code Chapter 127.201, *et. seq.* See 77 FR 41276, July 13, 2012 (approving NSR program into the SIP). See also 49 FR 33127, August 21, 1984 (approving Pennsylvania's PSD program which

incorporates by reference the Federal PSD program at 40 CFR 52.21). However, Pennsylvania's PSD program for PM_{2.5} will become effective in the Pittsburgh Area upon redesignation to attainment.

Section 172(c)(7) of the CAA requires the SIP to meet the applicable provisions of section 110(a)(2). As noted previously, EPA believes the Pennsylvania SIP meets the requirements of section 110(a)(2) that are applicable for purposes of redesignation.

Section 175A requires a state seeking redesignation to attainment to submit a SIP revision to provide for the maintenance of the NAAQS in the area "for at least 10 years after the redesignation." In conjunction with its request to redesignate the Pittsburgh Area to attainment status, Pennsylvania submitted a SIP revision on December 22, 2014 to provide for maintenance of the 1997 annual and 2006 24-hour PM_{2.5} NAAQS in the Pittsburgh Area for at least 10 years after redesignation, throughout 2025. Pennsylvania is requesting that EPA approve the maintenance plan to meet the requirement of section 175A of the CAA for both NAAQS. Once approved, the maintenance plan for the Area will

ensure that the SIP for Pennsylvania meets the requirements of the CAA regarding maintenance of the 1997 annual and 2006 24-hour PM_{2.5} NAAQS for the Area. EPA's analysis of the maintenance plan is provided in Section V.B. of this proposed rulemaking action.

Section 176(c) of the CAA requires states to establish criteria and procedures to ensure that Federally supported or funded projects conform to the air quality planning goals in the applicable SIP. The requirement to determine conformity applies to transportation plans, programs, and projects that are developed, funded or approved under Title 23 of the United States Code (U.S.C.) and the Federal Transit Act (transportation conformity) as well as to all other Federally supported or funded projects (general conformity). State transportation conformity SIP revisions must be consistent with Federal conformity regulations relating to consultation, enforcement and enforceability which EPA promulgated pursuant to its authority under the CAA. EPA approved Pennsylvania's transportation conformity SIP requirements on April 29, 2009 (74 FR 19541).

EPA interprets the conformity SIP requirements as not applying for

purposes of evaluating a redesignation request under CAA section 107(d) because state conformity rules are still required after redesignation, and Federal conformity rules apply where state rules have not been approved. *See Wall v. EPA*, 265 F. 3d 426 (6th Cir. 2001) (upholding this interpretation) and 60 FR 62748 (December 7, 1995) (discussing Tampa, Florida).

Thus, for purposes of redesignating to attainment the Pittsburgh Area for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS, EPA proposes that upon final approval of the 2007 and 2011 comprehensive emissions inventories as proposed in this rulemaking action, Pennsylvania will meet all the applicable SIP requirements under part D of Title I of the CAA for purposes of redesignating the Area to attainment for both the 1997 annual and 2006 24-hour PM_{2.5} NAAQS.

c. The Area Has a Fully Approved Applicable SIP Under Section 110(k) of the CAA

Upon final approval of the 2007 and 2011 comprehensive emissions inventories as proposed in this rulemaking action, EPA will have fully approved all applicable requirements of Pennsylvania's SIP for the Pittsburgh Area for purposes of redesignation to attainment for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS in accordance with section 110(k) of the CAA.

3. Permanent and Enforceable Reductions in Emissions

For redesignating a nonattainment area to attainment, section 107(d)(3)(E)(iii) requires EPA to determine that the air quality improvement in the area is due to permanent and enforceable reductions in emissions resulting from implementation of the SIP and

applicable Federal air pollution control regulations and other permanent and enforceable reductions. Pennsylvania has calculated the change in emissions between 2005, a year showing nonattainment for the 1997 annual and the 2006 24-hour PM_{2.5} NAAQS in the Pittsburgh Area, and 2007, the year for which the Area monitored attainment for 1997 annual PM_{2.5} NAAQS, and 2011, the year for which the Area monitored attainment for the 2006 24-hour PM_{2.5} NAAQS.

A summary of the emissions reductions in tpy of PM_{2.5}, NO_x, SO₂, VOC, and NH₃ from 2005 to 2007 in the Pittsburgh Area, submitted by PADEP, is provided in Table 5. For more information on EPA's analysis of the 2007 emissions inventories, *see* EPA's Inventory TSDs dated April 22, 2015, available in the docket for this rulemaking action at www.regulations.gov.

TABLE 5—EMISSION REDUCTIONS FROM 2005 TO 2007 IN THE PITTSBURGH-BEAVER VALLEY AREA

	Sector	2005	2007	Net reduction 2005–2007	Percent reduction 2005–2007
PM _{2.5}	Point	27,817	8,913	18,904	67.9
	Area	7,916	6,392	1,524	19.3
	On-road	1,898	1,692	206	10.9
	Non-road	1,539	1,151	388	25.2
	Total	39,170	18,148	21,022	53.7
NO _x	Point	92,808	92,750	58	0.0
	Area	8,622	7,946	676	7.8
	On-road	58,268	49,052	9,216	15.8
	Non-road	31,519	21,175	10,344	32.8
	Total	191,217	170,923	20,294	10.6
SO ₂	Point	470,511	438,716	31,795	6.8
	Area	9,905	12,817	-2,912	-29.4
	On-road	875	378	497	56.8
	Non-road	2,364	694	1,670	70.6
	Total	483,655	452,605	31,050	6.4
VOC	Point	5,553	3,186	2,367	42.6
	Area	36,683	28,991	7,692	20.9
	On-road	22,306	20,194	2,112	9.5
	Non-road	11,499	10,834	665	5.8
	Total	76,041	63,205	12,836	16.9
NH ₃	Point	738	584	154	20.9
	Area	2,948	2,474	474	16.1
	On-road	934	858	76	8.1
	Non-road	14	16	-2	-14.3
	Total	4,634	3,932	702	15.1

A summary of the emissions reductions in tpy of PM_{2.5}, NO_x, SO₂, VOC, and NH₃ from 2005 to 2011 in the Pittsburgh Area, submitted by PADEP, is

provided in Table 6. For more information on EPA's analysis of the 2011 emissions inventories, *see* EPA's Inventory TSDs dated April 22, 2015,

available in the docket for this rulemaking action at www.regulations.gov.

TABLE 6—EMISSION REDUCTIONS FROM 2005 TO 2011 IN THE PITTSBURGH-BEAVER VALLEY AREA

	Sector	2005	2011	Net reduction 2005–2011	Percent reduction 2005–2011
PM _{2.5}	Point	27,817	7,287	20,530	73.8
	Area	7,916	7,455	461	5.8
	On-road	1,898	967	931	49.1
	Non-road	1,539	667	872	56.6
	Total	39,170	16,376	22,794	58.2
NO _x	Point	92,808	80,746	12,062	12.9
	Area	8,622	19,667	– 11,045	– 128.1
	On-road	58,268	29,184	29,084	50.0
	Non-road	31,519	7,110	24,409	77.4
	Total	191,217	136,707	54,510	28.5
SO ₂	Point	470,511	122,541	347,970	73.9
	Area	9,905	3,841	6,064	61.1
	On-road	875	149	762	82.9
	Non-road	2,364	20	2,344	99.1
	Total	483,655	126,551	357,104	73.8
VOC	Point	5,553	3,333	2,200	40.0
	Area	36,683	26,012	10,671	29.1
	On-road	22,306	14,813	7,493	33.6
	Non-road	11,499	7,832	3,667	31.9
	Total	76,041	51,990	24,051	31.6
NH ₃	Point	738	322	416	56.3
	Area	2,948	3,109	– 161	– 5.5
	On-road	934	624	310	33.2
	Non-road	14	10	4	28.6
	Total	4,634	4,065	569	12.3

The reduction in emissions and the corresponding improvement in air quality in the Pittsburgh Area from 2005 to 2007 for the 1997 annual PM_{2.5} NAAQs, and 2005 to 2011 for the 2006 24-hour PM_{2.5} NAAQs, can be attributed to a number of regulatory control measures that have been implemented in the Area and contributing areas in recent years.

a. Federal Measures Implemented

Reductions in PM_{2.5} precursor emissions have occurred statewide and in upwind states as a result of Federal emission control measures, with additional emission reductions expected to occur in the future.

Control of NO_x and SO₂

PM_{2.5} concentrations in the Pittsburgh Area are impacted by the transport of sulfates and nitrates, and the Area's air quality is strongly affected by regulation of SO₂ and NO_x emissions from power plants.

NO_x SIP Call—On October 27, 1998 (63 FR 57356), EPA issued the NO_x SIP Call requiring the District of Columbia and 22 states to reduce emissions of

NO_x, a precursor to ozone pollution.¹⁴ Affected states were required to comply with Phase I of the SIP Call beginning in 2004 and Phase II beginning in 2007. Emission reductions resulting from regulations developed in response to the NO_x SIP Call are permanent and enforceable. By imposing an emissions cap regionally, the NO_x SIP Call reduced NO_x emissions from large EGUs and large non-EGUs such as industrial boilers, internal combustion engines, and cement kilns. In response to the NO_x SIP Call, Pennsylvania adopted its NO_x Budget Trading Program regulations for EGUs and large industrial boilers, with emission reductions starting in May 2003. Pennsylvania's NO_x Budget Trading Program regulation was approved into the Pennsylvania SIP on August 21, 2001 (66 FR 43795). To meet other requirements of the NO_x SIP Call, Pennsylvania adopted NO_x control regulations for cement plants and

¹⁴ Although the NO_x SIP Call was issued in order to address ozone pollution, reductions of NO_x as a result of that program have also impacted PM_{2.5} pollution, for which NO_x is also a precursor emission.

internal combustion engines, with emission reductions starting in May 2005. These regulations were approved into the Pennsylvania SIP on September 29, 2006 (71 FR 57428).

CAIR—As previously noted, CAIR (70 FR 25162, May 12, 2005) created regional cap-and-trade programs to reduce SO₂ and NO_x emissions in 27 eastern states, including Pennsylvania. EPA approved the Commonwealth's CAIR regulation, codified in 25 Pa. Code Chapter 145, Subchapter D, into the Pennsylvania SIP on December 10, 2009 (74 FR 65446). In 2009, the CAIR ozone season NO_x trading program superseded the NO_x Budget Trading Program, although the emission reduction obligations of the NO_x SIP Call were not rescinded. See 40 CFR 51.121(r) and 51.123(aa). EPA promulgated CSAPR to replace CAIR as an emission trading program for EGUs. As discussed previously, pursuant to the D.C. Circuit Court's October 23, 2014 Order, the stay of CSAPR has been lifted and implementation of CSAPR commenced in January 2015. EPA expects that the implementation of CSAPR will preserve the reductions achieved by CAIR and

result in additional SO₂ and NO_x emission reductions throughout the maintenance period.

Tier 2 Emission Standards for Vehicles and Gasoline Sulfur Standards

These emission control requirements result in lower NO_x emissions from new cars and light duty trucks, including sport utility vehicles. The Federal rules were phased in between 2004 and 2009. EPA estimated that, after phasing in the new requirements, the following vehicle NO_x emission reductions will have occurred nationwide: Passenger cars (light duty vehicles) (77 percent); light duty trucks, minivans, and sports utility vehicles (86 percent); and larger sports utility vehicles, vans, and heavier trucks (69 to 95 percent). Some of the emissions reductions resulting from new vehicle standards occurred during the 2008–2010 attainment period; however, additional reductions will continue to occur throughout the maintenance period as new vehicles replace older vehicles. EPA expects fleet wide average emissions to decline by similar percentages as new vehicles replace older vehicles.

Heavy-Duty Diesel Engine Rule

EPA issued the Heavy-Duty Diesel Engine Rule in July 2000. This rule included standards limiting the sulfur content of diesel fuel, which went into effect in 2004. A second phase took effect in 2007 which reduced PM_{2.5} emissions from heavy-duty highway engines and further reduced the highway diesel fuel sulfur content to 15 parts per million (ppm). Standards for gasoline engines were phased in starting in 2008. The total program is estimated to achieve a 90 percent reduction in direct PM_{2.5} emissions and a 95 percent reduction in NO_x emissions for new engines using low sulfur diesel fuel.

Nonroad Diesel Rule

On June 29, 2004 (69 FR 38958), EPA promulgated the Nonroad Diesel Rule for large nonroad diesel engines, such as those used in construction, agriculture, and mining, to be phased in between 2008 and 2014. The rule phased in requirements for reducing the sulfur content of diesel used in nonroad diesel engines. The reduction in sulfur content prevents damage to the more advanced emission control systems needed to meet the engine standards. It will also reduce fine particulate emissions from diesel engines. The combined engine standards and the sulfur in fuel reductions will reduce NO_x and PM emissions from large nonroad engines by over 90 percent, compared to current

nonroad engines using higher sulfur content diesel.

Nonroad Large Spark-Ignition Engine and Recreational Engine Standards

In November 2002, EPA promulgated emission standards for groups of previously unregulated nonroad engines. These engines include large spark-ignition engines such as those used in forklifts and airport ground-service equipment; recreational vehicles using spark-ignition engines such as off-highway motorcycles, all-terrain vehicles, and snowmobiles; and recreational marine diesel engines. Emission standards from large spark-ignition engines were implemented in two tiers, with Tier 1 starting in 2004 and Tier 2 in 2007. Recreational vehicle emission standards are being phased in from 2006 through 2012. Marine Diesel engine standards were phased in from 2006 through 2009. With full implementation of all of the nonroad spark-ignition engine and recreational engine standards, an overall 80 percent reduction in NO_x is expected by 2020. Some of these emission reductions occurred by the 2002–2007 attainment period and additional emission reductions will occur during the maintenance period as the fleet turns over.

Federal Standards for Hazardous Air Pollutants

As required by the CAA, EPA developed Maximum Available Control Technology (MACT) Standards to regulate emissions of hazardous air pollutants from a published list of industrial sources referred to as “source categories.” The MACT standards have been adopted and incorporated by reference in Section 6.6 of Pennsylvania’s Air Pollution Control Act and implementing regulations in 25 Pa. Code § 127.35 and are also included in Federally enforceable permits issued by PADEP for affected sources. The Industrial/Commercial/Institutional (ICI) Boiler MACT standards (69 FR 55217, September 13, 2004 and 76 FR 15554, February 21, 2011) are estimated to reduce emissions of PM, SO₂, and VOCs from major source boilers and process heaters nationwide. Also, the Reciprocating Internal Combustion Engines (RICE) MACT will reduce NO_x and PM emissions from engines located at facilities such as pipeline compressor stations, chemical and manufacturing plants, and power plants.

b. State Measures

Heavy-Duty Diesel Emissions Control Program

In 2002, Pennsylvania adopted the Heavy-Duty Diesel Emissions Control Program for model years starting in May 2004. The program incorporates California standards by reference and required model year 2005 and beyond heavy-duty diesel highway engines to be certified to the California standards, which were more stringent than the Federal standards for model years 2005 and 2006. After model year 2006, Pennsylvania required implementation of the Federal standards that applied to model years 2007 and beyond, discussed in the Federal measures section of this proposed rulemaking action. This program reduced emissions of NO_x statewide.

Vehicle Emission Inspection/Maintenance (I/M) Program

The Pittsburgh Area has had a vehicle emissions inspection program since 1984, and in 2004, Pennsylvania revised the implementation of its Vehicle Emission I/M program in the Pittsburgh Area, and applies to model year 1975 and newer gasoline-powered vehicles that are 9,000 pounds and under. The program, approved into the Pennsylvania SIP on October 6, 2005 (70 FR 58313), consists of annual on-board diagnostics and gas cap test for model year 1996 vehicles and newer, and an annual visual inspection of pollution control devices and gas cap test for model year 1995 vehicles and older. This program reduces emissions of NO_x from affected vehicles.

Regulation of Cement Kilns and Large Stationary Internal Combustion Engines

On December 10, 2009 (74 FR 65446), EPA approved Pennsylvania regulation 25 Pa. Code Chapter 145, Subchapters B and C (relating to emissions of NO_x from stationary internal combustion engines, and emissions of NO_x from cement manufacturing).

Consumer Products Regulation

Pennsylvania regulation 25 Pa. Code Chapter 130, Subchapter B (Consumer Products) established, effective January 1, 2005, VOC emission limits to numerous categories of consumer products, and applies statewide to any person who sells, supplies, offers for sale, or manufactures such consumer products on or after January 5, 2005 for use in Pennsylvania. It was approved into the Pennsylvania SIP on December 8, 2004 (69 FR 70895).

Based on the information summarized above, Pennsylvania has adequately

demonstrated that the improvements in air quality in the Pittsburgh Area are due to permanent and enforceable emissions reductions. The reductions result from Federal and State requirements and regulation of precursors within Pennsylvania that affect the Pittsburgh Area.

B. Maintenance Plan

On December 22, 2014, PADEP submitted a combined maintenance plan for the Pittsburgh Area for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS, as required by section 175A of the CAA. EPA's analysis for proposing approval of the maintenance plan is provided in this section.

1. Attainment Emissions Inventory

An attainment inventory is comprised of the emissions during the time period associated with the monitoring data showing attainment. PADEP determined that the appropriate attainment inventory year for the maintenance plan for the 1997 annual NAAQS is 2007, one of the years in the periods during which the Pittsburgh Area monitored attainment of the 1997 annual PM_{2.5} NAAQS. PADEP determined that the appropriate attainment inventory year for the maintenance plan for the 2006 24-hour PM_{2.5} NAAQS is 2011, one of the years in the periods during which the Pittsburgh Area monitored attainment of the 2006 24-hour PM_{2.5} NAAQS. The 2007 and 2011 inventories included in the maintenance plan contain primary PM_{2.5} emissions (including condensables), SO₂, NO_x, VOC, and NH₃.

In its redesignation request and maintenance plan for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS, PADEP described the methods used for developing its 2007 and 2011 comprehensive emissions inventories. EPA reviewed the procedures used to develop the inventories and found them to be reasonable. EPA has reviewed the documentation provided by PADEP and found the 2007 and 2011 emissions inventories submitted with the maintenance plan to be approvable. For more information on EPA's analysis of the 2007 and 2011 emissions inventories, see EPA's Inventory TSDs, dated April 22, 2015, available in the docket for this rulemaking action at www.regulations.gov.

2. Maintenance Demonstration

Section 175A requires a state seeking redesignation to attainment to submit a SIP revision to provide for the maintenance of the NAAQS in the area "for at least 10 years after the redesignation." EPA has interpreted this

as a showing of maintenance "for a period of ten years following redesignation." The Federal and State measures described in Section V.A.3 of this proposed rulemaking action demonstrate that the reductions in emissions from point, area, and mobile sources in the Area have occurred and will continue to occur through 2025. In addition, the following State and Federal regulations and programs ensure the continuing decline of SO₂, NO_x, PM_{2.5}, and VOC emissions in the Area during the maintenance period and beyond:

Non-EGUs Previously Covered Under the NO_x SIP Call

Pennsylvania established NO_x emission limits for the large industrial boilers that were previously subject to the NO_x SIP Call, but were not subject to CAIR. For these units, Pennsylvania established an allowable ozone season NO_x limit based on the unit's previous ozone season's heat input. A combined NO_x ozone season emissions cap of 3,418 tons applies for all of these units.

CSAPR (August 8, 2011, 76 FR 48208)

EPA promulgated CSAPR to replace CAIR as an emission trading program for EGUs. As discussed previously, pursuant to the D.C. Circuit Court's October 23, 2014 Order, the stay of CSAPR has been lifted and implementation of CSAPR commenced in January 2015. EPA expects that the implementation of CSAPR will preserve the reductions achieved by CAIR and result in additional SO₂ and NO_x emission reductions throughout the maintenance period.

Regulation of Cement Kilns

On July 19, 2011 (76 FR 52558), EPA approved amendments to 25 Pa. Code Chapter 145 Subchapter C to further reduce NO_x emissions from cement kilns. The amendments established NO_x emission rate limits for long wet kilns, long dry kilns, and preheater and precalciner kilns that are lower by 35 percent to 63 percent from the previous limit of 6 pounds of NO_x per ton of clinker that applied to all kilns. The amendments were effective on April 15, 2011.

Consumer Products Regulation

Amendments to Pennsylvania regulation 25 Pa. Code Chapter 130, Subchapter B (Consumer Products) established, effective January 1, 2009, new or more stringent VOC standards for consumer products. The amendments were approved into the Pennsylvania SIP on October 18, 2010 (75 FR 63717).

Pennsylvania's Clean Vehicle Program

The Pennsylvania Clean Vehicles Program (formerly, New Motor Vehicle Control Program) incorporates by reference the California Low Emission Vehicle program (CA LEVII), although it allowed automakers to comply with the National Low Emission Vehicle (NLEV) program as an alternative to this program until Model Year (MY) 2006. The Clean Vehicles Program, codified in 25 Pa. Code Chapter 126, Subchapter D, was modified to require CA LEVII to apply to MY 2008 and beyond, and was approved into the Pennsylvania SIP on January 24, 2012 (77 FR 3386). The Clean Vehicles Program incorporates by reference the emission control standards of CA LEVII, which, among other requirements, reduces emissions of NO_x by requiring that passenger car emission standards and fleet average emission standards also apply to light duty vehicles. Model year 2008 and newer passenger cars and light duty trucks are required to be certified for emissions by the California Air Resource Board (CARB), in order to be sold, leased, offered for sale or lease, imported, delivered, purchased, rented, acquired, received, titled or registered in Pennsylvania. In addition, manufacturers are required to demonstrate that the California fleet average standard is met based on the number of new light-duty vehicles delivered for sale in the Commonwealth. The Commonwealth's submittal for the January 24, 2012 rulemaking projected that, by 2025, the program will achieve approximately 285 tons more NO_x reductions than Tier II for the counties in the Pittsburgh Area.

Two Pennsylvania regulations—the Diesel-Powered Motor Vehicle Idling Act (August 1, 2011, 76 FR 45705) and the Outdoor Wood-Fired Boiler regulation (September 20, 2011, 76 FR 58114)—were not included in the projection inventories, but may also assist in maintaining the standard. Also, the Tier 3 Motor Vehicle Emission and Fuel Standards (79 FR 23414, April 29, 2014) establishes more stringent vehicle emissions standards and will reduce the sulfur content of gasoline beginning in 2017. The fuel standard will achieve NO_x reductions by further increasing the effectiveness of vehicle emission controls for both existing and new vehicles.

Natural Gas Activities

The emissions growth due to a new emissions source, development of natural gas resources from Marcellus Shale (and other deep formations), is included in the area source inventory.

PADEP requires annual emission reporting under 25 Pa. Code Chapter 135 (relating to reporting of sources) of unconventional natural gas development companies. The initial annual source reporting for unconventional natural gas operations began in 2012 for emissions during the 2011 calendar year. Emissions were projected to 2017 and 2025 based on the most recent emissions inventory reports available (2013 for compressor engines and 2012 for all other sources). See

Appendix B–3 of Pennsylvania’s submittal for more details on the methodology used for estimating Marcellus Shale development activity and for the emission totals by pollutant. Starting January 2015, Federal regulations (40 CFR part 60, subpart OOOO) require wells to capture gas at the wellhead. EPA estimates that VOC emissions from hydraulically fractured well completions will decrease by 95 percent as a result of this regulation.

The State and Federal regulations and programs described above ensure the continuing decline of SO₂, NO_x, PM_{2.5}, and VOC emissions in the Pittsburgh Area during the maintenance period and beyond. A summary of the projected reductions from these measures from 2007 to 2025 is shown in Table 7, and from 2011 to 2025 is shown in Table 8. The future year inventories include potential emissions increases from natural gas activities.

TABLE 7—EMISSION REDUCTIONS FROM 2007 TO 2025 DUE TO CONTROL MEASURES IN TPY

	PM _{2.5}	NO _x	SO ₂	VOC	NH ₃
Point	54	– 3,095	340,699	– 293	– 12
Area	672	– 23	2,515	2,961	– 136
On-Road	1,155	38,343	260	15,069	405
Non-Road	611	11,370	588	4,697	– 3
Natural Gas Activities	– 397	– 8,716	– 37	– 8,502	0
Totals	2,095	37,879	343,995	13,932	254

TABLE 8—EMISSION REDUCTIONS FROM 2011 TO 2025 DUE TO CONTROL MEASURES IN TPY

	PM _{2.5}	NO _x	SO ₂	VOC	NH ₃
Point	– 1,572	– 15,099	24,494	– 146	– 274
Area	1,735	11,698	– 6,461	– 18	499
On-Road	430	18,475	31	9,688	171
Non-Road	127	– 2,695	– 86	1,695	0
Natural Gas Activities	– 397	– 8,716	– 37	– 8,502	0
Totals	323	3,663	17,941	2,717	387

Where the emissions inventory method of showing maintenance is used, its purpose is to show that emissions during the maintenance period will not increase over the attainment year inventory. See 1992 Calcagni Memorandum, pages 9–10. For a demonstration of maintenance, emissions inventories are required to be projected to future dates to assess the influence of future growth and controls; however, the demonstration need not be based on modeling. See *Wall v. EPA*, *supra*; *Sierra Club v. EPA*, *supra*. See also 66 FR 53099–53100 and 68 FR 25430–32. PADEP uses projection inventories to show that the Pittsburgh Area will remain in attainment and

developed projection inventories for an interim year of 2017 and a maintenance plan end year of 2025 to show that future emissions of NO_x, SO₂, PM_{2.5}, VOC, and NH₃ will remain at or below the attainment year 2007 for the 1997 annual and 2011 for the 2006 24-hour PM_{2.5} NAAQS, respectively, throughout the Pittsburgh Area through the year 2025.

EPA has reviewed the documentation provided by PADEP for developing annual 2017 and 2025 emissions inventories for the Pittsburgh Area. See Appendix C–2 and C–3 of Pennsylvania’s submittal. EPA has determined that the 2017 and 2025 projected emissions inventories

provided by PADEP are approvable. For more information on EPA’s analysis of the emissions inventories, see EPA’s Inventory TSDs, dated April 22, 2015, available in the docket for this rulemaking action at www.regulations.gov.

Table 9 provides a summary of the PM_{2.5}, NO_x, SO₂, VOC, and NH₃ emissions inventories in tpy, for the Pittsburgh Area for the 2007 attainment year for the 1997 annual PM_{2.5} NAAQS and the 2011 attainment year for the 2006 24-hour PM_{2.5} NAAQS, as compared to the projected inventories for the 2017 interim year, and the 2025 maintenance plan end year for the Pittsburgh Area.

TABLE 9—COMPARISON OF 2007 AND 2011 ATTAINMENT YEARS AND 2017 AND 2025 PROJECTED PM_{2.5} EMISSIONS IN THE PITTSBURGH AREA

Year	PM _{2.5}	NO _x	SO ₂	NH ₃	VOC
2007 (attainment)	18,148	170,923	452,605	3,932	63,205
2011 (attainment)	16,376	136,707	126,551	4,065	51,990
2017 (interim)	15,932	132,236	100,867	3,625	49,860
2007–2017 (projected decrease)	2,216	38,687	351,738	307	13,345
2011–2017 (projected decrease)	444	4,471	25,644	440	2,130
2025 (maintenance)	16,053	133,044	108,610	3,678	49,273
2007–2025 (projected decrease)	2,095	37,879	343,995	254	13,932

TABLE 9—COMPARISON OF 2007 AND 2011 ATTAINMENT YEARS AND 2017 AND 2025 PROJECTED PM_{2.5} EMISSIONS IN THE PITTSBURGH AREA—Continued

Year	PM _{2.5}	NO _x	SO ₂	NH ₃	VOC
2011–2025 (projected decrease)	323	3,663	17,941	387	2,717

As shown in Table 9, the projected levels of PM_{2.5}, NO_x, SO₂, VOC, and NH₃ are under the 2007 and 2011 attainment year levels for each of these pollutants. Pennsylvania has adequately demonstrated that the Area will continue to maintain the 1997 annual and the 2006 24-hour PM_{2.5} NAAQS.

3. Monitoring Network

Pennsylvania's maintenance plan includes a commitment to operate its EPA-approved monitoring network, as necessary to demonstrate ongoing compliance with the NAAQS. Pennsylvania currently operates a PM_{2.5} monitor in the Pittsburgh Area. In its December 22, 2014 submittal, Pennsylvania stated that it will consult with EPA prior to making any necessary changes to the network and will continue to operate the monitoring network in accordance with the requirements of 40 CFR part 58.

4. Verification of Continued Attainment

To provide for tracking of the emission levels in the Area, PADEP will: (a) Evaluate annually the vehicle miles travelled (VMT) data and the annual emissions reported from stationary sources to compare them with the assumptions used in the maintenance plan, and (b) evaluate the periodic emissions inventory for all PM_{2.5} precursors prepared every three years in accordance with EPA's Air Emissions Reporting Requirements (AERR) to determine whether there is an exceedance of more than ten percent over the 2007 and 2011 inventories. Also, as noted in the previous subsection, PADEP has stated that it will continue to operate its monitoring system in accordance with 40 CFR part 58 and remains obligated to quality-assure monitoring data and enter all data into the AQS in accordance with Federal requirements. PADEP has stated that it will use this data in considering whether additional control measures are needed to assure continuing attainment in the Area.

5. Contingency Measures

The contingency plan provisions are designed to promptly correct any violation of the 1997 annual and/or the 2006 24-hour PM_{2.5} NAAQS that occurs in the Pittsburgh Area after redesignation. Section 175A of the CAA

requires that a maintenance plan include such contingency measures as EPA deems necessary to ensure that a state will promptly correct a violation of the NAAQS that occurs after redesignation. The maintenance plan should identify the events that would "trigger" the adoption and implementation of a contingency measure(s), the contingency measure(s) that would be adopted and implemented, and the schedule indicating the time frame by which the state would adopt and implement the measure(s).

Pennsylvania's maintenance plan describes the procedures for the adoption and implementation of contingency measures to reduce emissions should a violation occur. Pennsylvania's contingency measures include a first level response and a second level response. A first level response is triggered when the annual mean PM_{2.5} concentration exceeds 15.5 µg/m³ in a single calendar year within the Area, when the 98th percentile 24-hour PM_{2.5} concentration exceeds 35.0 µg/m³ in a single calendar year within the area, or when the periodic emissions inventory for the Area exceeds the attainment year inventory (2007 and 2011) by more than ten percent. The first level response will consist of a study to determine if the emissions trends show increasing concentrations of PM_{2.5}, and whether this trend is likely to continue. If it is determined through the study that action is necessary to reverse a trend of emissions increases, Pennsylvania will, as expeditiously as possible, implement necessary and appropriate control measures to reverse the trend.

A second level response will be prompted if the two-year average of the annual mean concentration exceeds 15.0 µg/m³ or if the two-year average of the 98th percentile 24-hour PM_{2.5} concentration exceeds 35.0 µg/m³ within the Area. This would trigger an evaluation of the conditions causing the exceedance, whether additional emission control measures should be implemented to prevent a violation of the standard, and analysis of potential measures that could be implemented to prevent a violation. Pennsylvania would then begin its adoption process to implement the measures as

expeditiously as practicable. If a violation of the PM_{2.5} NAAQS occurs, PADEP will propose and adopt necessary additional control measures in accordance with the implementation schedule in the maintenance plan.

Pennsylvania's candidate contingency measures include the following: (1) A regulation based on the Ozone Transport Commission (OTC) Model Rule to update requirements for consumer products; (2) a regulation based on the Control Techniques Guidelines (CTG) for industrial cleaning solvents; (3) voluntary diesel projects such as diesel retrofit for public or private local onroad or offroad fleets, idling reduction technology for Class 2 yard locomotives, and idling reduction technologies or strategies for truck stops, warehouses, and other freight-handling facilities; (4) promotion of accelerated turnover of lawn and garden equipment, focusing on commercial equipment; and (5) promotion of alternative fuels for fleets, home heating and agricultural use. Pennsylvania's rulemaking process and schedule for adoption and implementation of any necessary contingency measure is shown in the SIP submittals as being 18 months from PADEP's approval to initiate rulemaking. For all of the reasons discussed in this section, EPA is proposing to approve Pennsylvania's 1997 annual and 2006 24-hour PM_{2.5} maintenance plan for the Pittsburgh Area as meeting the requirements of section 175A of the CAA.

C. Motor Vehicle Emissions Budgets

Section 176(c) of the CAA requires Federal actions in nonattainment and maintenance areas to "conform to" the goals of SIPs. This means that such actions will not cause or contribute to violations of a NAAQS, worsen the severity of an existing violation, or delay timely attainment of any NAAQS or any interim milestone. Actions involving Federal Highway Administration (FHWA) or Federal Transit Administration (FTA) funding or approval are subject to the transportation conformity rule (40 CFR part 93, subpart A). Under this rule, metropolitan planning organizations (MPOs) in nonattainment and maintenance areas coordinate with state air quality and transportation agencies,

EPA, and the FHWA and FTA to demonstrate that their long range transportation plans and transportation improvement programs (TIP) conform to applicable SIPs. This is typically determined by showing that estimated emissions from existing and planned highway and transit systems are less than or equal to the MVEBs contained in the SIP.

On December 22, 2014, Pennsylvania submitted a SIP revision that contains the 2017 and 2025 PM_{2.5} and NO_x onroad mobile source budgets for Beaver, Butler, Washington, and Westmoreland Counties and portions of Allegheny, Armstrong, Green and Lawrence Counties. Pennsylvania did not provide emission budgets for SO₂, VOC, and NH₃ because it concluded, consistent with the presumptions regarding these precursors in the Transportation Conformity Rule at 40 CFR 93.102(b)(2)(v), which predated and were not disturbed by the litigation on the 1997 PM_{2.5} Implementation Rule, that emissions of these precursors from motor vehicles are not significant contributors to the Area's PM_{2.5} air quality problem. EPA issued conformity regulations to implement the 1997 annual PM_{2.5} NAAQS in July 2004 and May 2005 (69 FR 40004, July 1, 2004 and 70 FR 24280, May 6, 2005). The D.C. Circuit Court's January 2013 decision does not affect EPA's proposed approval of the MVEBs for the Area. The MVEBs are presented in Table 10.

TABLE 10—MVEBS FOR THE PITTSBURGH AREA FOR THE 1997 ANNUAL AND 2006 24-HOUR PM_{2.5} NAAQS IN TPY

Year	PM _{2.5}	NO _x
2017	700	17,584
2025	537	10,709

EPA's substantive criteria for determining adequacy of MVEBs are set out in 40 CFR 93.118(e)(4). Additionally, to approve the MVEBs, EPA must complete a thorough review of the SIP, in this case the PM_{2.5} maintenance plan, and conclude that with the projected level of motor vehicle and all other emissions, the SIPs will achieve its overall purpose, in this case providing for maintenance of the 1997 annual and the 2006 24-hour PM_{2.5} NAAQS. EPA's process for determining adequacy of a MVEB consists of three basic steps: (1) Providing public notification of a SIP submission; (2) providing the public the opportunity to comment on the MVEB during a public comment period; and (3) EPA taking action on the MVEB.

In this proposed rulemaking action, EPA is also initiating the process for determining whether or not the MVEBs are adequate for transportation conformity purposes. The publication of this rulemaking starts a 30-day public comment period on the adequacy of the submitted MVEBs. This comment period is concurrent with the comment period on this proposed action and comments should be submitted to the docket for this rulemaking. EPA may choose to make its determination on the adequacy of the budgets either in the final rulemaking on this maintenance plan and redesignation request or by informing Pennsylvania of the determination in writing, publishing a notice in the **Federal Register** and posting a notice on EPA's adequacy Web page (<http://www.epa.gov/otaq/state/resources/transconf/adequacy.htm>).¹⁵

EPA has reviewed the MVEBs and finds that the submitted MVEBs are consistent with the maintenance plan and that the budgets meet the criteria for adequacy and approval. Therefore, EPA is proposing to approve the 2017 and 2025 PM_{2.5} and NO_x MVEBs for the Pittsburgh Area for transportation conformity purposes. Additional information pertaining to the review of the MVEBs can be found in the Adequacy Findings TSD dated April 23, 2015, available on line at www.regulations.gov, Docket ID No. EPA-R03-OAR-2014-0902.

VI. Proposed Actions

EPA is proposing to approve Pennsylvania's request to redesignate the Pittsburgh Area from nonattainment to attainment for the 1997 annual and the 2006 24-hour PM_{2.5} NAAQS. EPA has evaluated Pennsylvania's redesignation request and determined that upon approval of the 2007 and 2011 comprehensive emissions inventories for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS, respectively, proposed as part of this rulemaking action, it would meet the redesignation criteria set forth in section 107(d)(3)(E) of the CAA. The monitoring data demonstrates that the Pittsburgh Area attained as determined by EPA in a prior rulemaking and for reasons discussed herein, that it will continue to attain both NAAQS. Final approval of this redesignation request would change the designation of the Pittsburgh Area from nonattainment to attainment for the 1997 annual and the 2006 24-hour PM_{2.5} NAAQS. EPA is also proposing to

¹⁵ For additional information on the adequacy process, please refer to 40 CFR 93.118(f) and the discussion of the adequacy process in the preamble to the 2004 final transportation conformity rule. See 69 FR at 40039-40043.

approve the associated maintenance plan for the Pittsburgh Area as a revision to the Pennsylvania SIP for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS because it meets the requirements of section 175A of the CAA as described previously in this proposed rulemaking. In addition, EPA is proposing to approve the 2007 and 2011 comprehensive emissions inventories as meeting the requirement of section 172(c)(3) of the CAA for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS, respectively. Furthermore, EPA is proposing to approve the 2017 and 2025 PM_{2.5} and NO_x MVEBs for the Pittsburgh Area for transportation conformity purposes. EPA is soliciting public comments on the issues discussed in this document. These comments will be considered before taking final action.

VII. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable Federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely proposes to approve state law as meeting Federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Order 12866 (58 FR 51735, October 4, 1993);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104-4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);

- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and

- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule proposing to approve Pennsylvania's redesignation request, maintenance plan, 2007 and 2011 comprehensive emissions inventories for the 1997 annual and 2006 24-hour PM_{2.5} NAAQS, respectively, and MVEBs for transportation conformity purposes for the Pittsburgh Area for both NAAQS, does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects

40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen oxides, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

40 CFR Part 81

Air pollution control, National parks, Wilderness areas.

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

Dated: May 11, 2015.

William C. Early,

Acting, Regional Administrator, Region III.

[FR Doc. 2015-12237 Filed 5-19-15; 8:45 am]

BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 174 and 180

[EPA-HQ-OPP-2015-0032; FRL-9927-39]

Receipt of Several Pesticide Petitions Filed for Residues of Pesticide Chemicals in or on Various Commodities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of filing of petitions and request for comment.

SUMMARY: This document announces the Agency's receipt of several initial filings of pesticide petitions requesting the establishment or modification of regulations for residues of pesticide chemicals in or on various commodities.

DATES: Comments must be received on or before June 19, 2015.

ADDRESSES: Submit your comments, identified by docket identification (ID) number and the pesticide petition number (PP) of interest as shown in the body of this document, 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:* OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 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: Susan Lewis, Registration Division (RD) (7505P), main telephone number: (703) 305-7090; email address:

RDfRNNotices@epa.gov. The mailing address for each contact person is: Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001. As part of the mailing address, include the contact person's name, division, and mail code. The division to contact is listed at the end of each pesticide petition summary.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. 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:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).

- Food manufacturing (NAICS code 311).

- Pesticide manufacturing (NAICS code 32532).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT** for the division listed at the end of the pesticide petition summary of interest.

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

1. *Submitting CBI.* Do not submit this information to EPA through 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 disk or CD-ROM that you mail to EPA, mark the outside of the disk or CD-ROM 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.

2. *Tips for preparing your comments.* When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

3. *Environmental justice.* EPA seeks to achieve environmental justice, the fair treatment and meaningful involvement of any group, including minority and/or low-income populations, in the development, implementation, and enforcement of environmental laws, regulations, and policies. To help address potential environmental justice issues, the Agency seeks information on any groups or segments of the population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. What action is the agency taking?

EPA is announcing its receipt of several pesticide petitions filed under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 346a, requesting the establishment or modification of regulations in 40 CFR part 174 and/or part 180 for residues of pesticide chemicals in or on various food commodities. The Agency is taking

public comment on the requests before responding to the petitioners. EPA is not proposing any particular action at this time. EPA has determined that the pesticide petitions described in this document contain the data or information prescribed in FFDCA section 408(d)(2), 21 U.S.C. 346a(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data support granting of the pesticide petitions. After considering the public comments, EPA intends to evaluate whether and what action may be warranted. Additional data may be needed before EPA can make a final determination on these pesticide petitions.

Pursuant to 40 CFR 180.7(f), a summary of each of the petitions that are the subject of this document, prepared by the petitioner, is included in a docket EPA has created for each rulemaking. The docket for each of the petitions is available at <http://www.regulations.gov>.

As specified in FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), EPA is publishing notice of the petition so that the public has an opportunity to comment on this request for the establishment or modification of regulations for residues of pesticides in or on food commodities. Further information on the petition may be obtained through the petition summary referenced in this unit.

New Tolerances

1. *PP 4F8339.* (EPA-HQ-OPP-2015-0215). Monsanto Company, 1300 I Street NW., Suite 450 East, Washington, DC 20005, requests to establish a tolerance in 40 CFR part 180 for residues of the sum of the nematocide, tioxazafen (MON 102100) (3-phenyl-5-(2-thienyl)-1,2,4-oxadiazole) and its metabolite, benzamidine (benzenecarboximidamide) in or on the following raw agricultural and processed commodities: Corn, field, forage at 0.01 parts per million (ppm); Corn, field, grain at 0.01 ppm; Corn, field, stover at 0.02 ppm; Cotton, gin byproducts at 0.02 ppm; Cotton, undelinted seed at 0.01 ppm; Soybean, forage at 0.15 ppm; Soybean, hay at 0.3 ppm; Soybean, meal at 0.05 ppm; Soybean, seed at 0.04 ppm; and in or on the following food commodities: Cattle, fat at 0.01 ppm; Cattle, meat at 0.01 ppm; Cattle, meat byproducts at 0.01 ppm; Goat, fat at 0.01 ppm; Goat, meat at 0.01 ppm; Goat, meat byproducts at 0.01 ppm; Horse, fat at 0.01 ppm; Horse, meat at 0.01 ppm; Horse, meat byproducts at 0.01 ppm; Milk at 0.01 ppm; Sheep, fat at 0.01 ppm; Sheep, meat at 0.01 ppm; and Sheep, meat

byproducts at 0.01 ppm. The Monsanto Company has submitted an independently validated analytical method for the residue analysis of parent tioxazafen and its metabolite, benzamidine, in crop and processed commodities for corn, cotton, and soybean. Additionally, an independently validated method has been used in cattle and hen feeding studies for the analysis of residues in the food commodities animal meat, fat, liver, kidney, cream, and milk, and poultry meat, fat, liver, and eggs, and is proposed for enforcement of requested tolerances in animal food commodities. Contact: RD.

2. *PP 4E8334.* (EPA-HQ-OPP-2015-0035). Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201W, Princeton, NJ 08540, requests to establish a tolerance in 40 CFR part 180 for residues of the herbicide clethodim, including its metabolites and degradates, determined by measuring only the sum of clethodim, 2-[(1E)-1-[[[(2E)-3-chloro-2-propenyl]oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one, and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones, calculated as the stoichiometric equivalent of clethodim, in or on the raw agricultural commodities: Onion, bulb subgroup 3-07A at 0.2 parts per million (ppm), Vegetable, fruiting group 08-10 at 1.0 ppm, Fruit, pome group 11-10 at 0.2 ppm, Fruit, stone group 12-12 at 0.2 ppm, Berry, low growing, subgroup 13-07G, except cranberry at 3.0 ppm, Rapeseed subgroup 20A, except flax at 0.5 ppm, Sunflower subgroup 20B at 5.0 ppm, Cottonseed subgroup 20C at 1.0 ppm and Stevia at 12 ppm. Analytical methodology has been developed and validated for enforcement purposes. The limit of quantitation (LOQ) of clethodim in the method(s) is 0.2 ppm, which will allow monitoring of food with residues at the levels proposed for the tolerances. Contact: RD.

3. *PP 5E8349.* (EPA-HQ-OPP-2015-0197). Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201W, Princeton, NJ 08540, requests to establish a tolerance in 40 CFR part 180 for residues of the fungicide fluazinam (3-chloro-N-[3-chloro-2,6-dinitro-4-(trifluoromethyl)phenyl]-5-(trifluoromethyl)-2-pyridinamine), including its metabolites and degradates in or on mayhaw at 2.0 parts per million (ppm); cabbage at 3.0 ppm; the squash/

cucumber subgroup 9B at 0.05 ppm; and vegetable, tuberous and corm, subgroup 1C at 0.02 ppm. An analytical method using LC-MS/MS for the determination of fluazinam and AMGT residues on cabbage, squash and cucumbers has been developed and validated. Contact: RD.

4. *PP 5F8352.* (EPA-HQ-OPP-2015-0263). ISK Biosciences Corporation, 7470 Auburn Road, Suite A, Concord, Ohio 44077, requests to establish a tolerance in 40 CFR part 180.601 for residues of the fungicide, cyazofamid, in or on Bulb Vegetables (Crop Group 3-07) at 2.0 parts per million (ppm). The residues are extracted with acetonitrile. After shaking and centrifugation, the extracts are diluted 4 fold with a 50% acetonitrile/water and filtered through a PTFE filter. The filtrate is diluted 5 fold with 50/50 acetonitrile/water. LC/MS/MS is used to measure and evaluate the chemicals cyazofamid and CCIM. Contact: RD.

5. *PP 5E8350.* (EPA-HQ-OPP-2015-0263). Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201W, Princeton, NJ 08540, requests to establish a tolerance in 40 CFR part 180 for residues of the fungicide cyazofamid, 4-chloro-2-cyano-N,N-dimethyl-5-(4-methylphenyl)-1H-imidazole-1-sulfonamide and its metabolite 4-chloro-5-(4-methylphenyl)-1H-imidazole-2-carbonitrile, calculated as the stoichiometric equivalent of cyazofamid in or on the following raw agricultural commodity: Herb subgroup 19A at 90 parts per million (ppm). Analytical methodology has been developed and validated for enforcement purposes. Contact: RD.

6. *PP 4E8337.* (EPA-HQ-OPP-2015-0030). Interregional Research Project Number 4 (IR-4), 500 College Road East, Suite 201W, Princeton, NJ 08540, requests to establish a tolerance in 40 CFR part 180 for residues of carfentrazone-ethyl (ethyl-alpha-2-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]-4-fluorobenzene-propanoate) and the metabolite carfentrazone-ethyl chloropropionic acid (α ,2-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]-4-fluorobenzene-propanoic acid)] in or on the raw agricultural commodity artichoke at 0.1 parts per million (ppm); asparagus at 0.25 ppm; peppermint, tops at 0.25 ppm; spearmint, tops at 0.25 ppm; teff, grain at 0.25 ppm; teff, forage at 1.00 ppm; teff, hay at 0.30 ppm; teff, straw at 0.10 ppm; vegetable, bulb, group 3-07 at 0.10 ppm; vegetable, fruiting, group 8-10 at 0.10 ppm; fruit, citrus, group 10-10 at 0.10 ppm; fruit, pome, group 11-10 at

0.10 ppm; fruit, stone, group 12–12 at 0.10 ppm; caneberry subgroup 13–07A at 0.10 ppm; bushberry subgroup 13–07B at 0.10 ppm; fruit, small vine climbing, subgroup 13–07F, except fuzzy kiwi fruit at 0.10 ppm; berry, low growing, subgroup 13–07G at 0.10 ppm; nut, tree, group 14–12 at 0.10 ppm; oilseed group 20 at 0.20 ppm; grain, cereal forage group 16 at 1.0 ppm; grain, cereal, hay, group 16 at 0.30 ppm; grain cereal, stover, group 16 at 0.80 ppm; and grain, cereal, straw, group 16 at 3.0 ppm. There is a practical analytical method for detecting and measuring levels of carfentrazone-ethyl and its metabolite in or on food with a limit of quantitation that allows monitoring of food with residues at or above the levels set or proposed in the tolerances.

Contact: RD.

7. *PP* 4F8291. (EPA–HQ–OPP–2015–0012). Bayer CropScience, 2 T.W. Alexander Drive, P.O. Box 12014, Research Triangle Park, NC 27709, requests to establish a tolerance in 40 CFR part 180 for residues of the fungicide, pyrimethanil, in or on caneberry (subgroup 13–07A) at 15.0 parts per million (ppm) and bushberry (subgroup 13–07B) at 8.0 ppm. The HPLC/MS/MS is used to measure and evaluate the chemical pyrimethanil. Contact: RD.

Amended Tolerances

1. *PP* 5E8349. (EPA–HQ–OPP–2015–0197). Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201W, Princeton, New Jersey 08540, requests to amend the tolerances in 40 CFR 180.574 for residues of the fungicide fluazinam (3-chloro-N-[3-chloro-2,6-dinitro-4-(trifluoromethyl)phenyl]-5-(trifluoromethyl)-2-pyridinamine), including its metabolites and degradates, in or on the vegetable, brassica leafy, group 5 at 0.01 by changing it to read “vegetable, brassica leafy, group 5, except cabbage” at 0.01 ppm and by removing the existing tolerance on potato at 0.02 ppm upon approval of the requested tolerance on the tuberous and corm subgroup 1C. An analytical method using LC–MS/MS for the determination of fluazinam and AMGT residues on cabbage, squash and cucumbers has been developed and validated. Contact: RD.

2. *PP* 4E8334. (EPA–HQ–OPP–2015–0035). IR–4, 500 College Road East, Suite 201W, Princeton, NJ 08540, requests to remove the existing tolerances in 40 CFR part 180.458 for residues of the herbicide clethodim, including its metabolites and degradates, determined by measuring only the sum of clethodim, 2-[(1E)-1-

[[[(2E)-3-chloro-2-propenyl]oxy]imino]propyl]-5-[2-(ethylthio)propyl]-3-hydroxy-2-cyclohexen-1-one, and its metabolites containing the 5-(2-ethylthiopropyl)cyclohexene-3-one and 5-(2-ethylthiopropyl)-5-hydroxycyclohexene-3-one moieties and their sulphoxides and sulphones, calculated as the stoichiometric equivalent of clethodim, in or on the raw agricultural commodities: Canola seed, at 0.5 ppm, cotton, undelinted seed at 1.0 ppm, peach at 0.2 ppm, onion, bulb at 0.2 ppm, strawberry at 3.0 ppm, and sunflower, seed at 5.0 ppm, upon establishment of the aforementioned tolerances under “New Tolerances” above for this petition. Analytical methodology has been developed and validated for enforcement purposes. The limit of quantitation (LOQ) of clethodim in the method(s) is 0.2 ppm, which will allow monitoring of food with residues at the levels proposed for the tolerances. Contact: RD.

3. *PP* 5E8350. (EPA–HQ–OPP–2015–0263). Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201W, Princeton, NJ 08540, requests to remove the existing tolerances in 40 CFR part 180.601 for residues of the fungicide cyazofamid, 4-chloro-2-cyano-N,N-dimethyl-5-(4-methylphenyl)-1H-imidazole-1-sulfonamide and its metabolite 4-chloro-5-(4-methylphenyl)-1H-imidazole-2-carbonitrile (CA), calculated as the stoichiometric equivalent of cyazofamid in or on basil, dried leaves at 90 parts per million (ppm); and basil, fresh leaves at 30 ppm, upon approval of the aforementioned tolerance on herb subgroup 19A. Analytical methodology has been developed and validated for enforcement purposes. Contact: RD.

4. *PP* 4E8337. (EPA–HQ–OPP–2015–0030). Interregional Research Project Number 4 (IR–4), 500 College Road East, Suite 201W, Princeton, NJ 08540, requests to amend the tolerances in 40 CFR 180.515 for residues of carfentrazone-ethyl (ethyl-alpha-2-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]-4-fluorobenzene-propanoate) and the metabolite carfentrazone-ethyl chloropropionic acid (α ,2-dichloro-5-[4-(difluoromethyl)-4,5-dihydro-3-methyl-5-oxo-1H-1,2,4-triazol-1-yl]-4-fluorobenzene-propanoic acid) as follows: (1) To modify the existing tolerance for banana from 0.20 ppm to 0.10 ppm and (2) to remove the following established tolerances: Vegetable, bulb group 3 at 0.10 ppm; vegetable, fruiting, group 8 at 0.10 ppm; fruit, citrus, group 10 at 0.10 ppm; fruit,

pome, group 11 at 0.10 ppm; fruit, stone, group 12 at 0.10 ppm; berry group 13 at 0.10 ppm; borage at 0.10 ppm; grape at 0.10 ppm; caneberry subgroup 13A at 0.10 ppm; nut, tree group 14 at 0.10 ppm; pistachio at 0.10 ppm; pummelo at 0.10 ppm; kiwi fruit at 0.10 ppm; canola at 0.10 ppm; cotton, undelinted seed at 0.20 ppm; crambe, seed at 0.10 ppm; flax, seed at 0.10 ppm; rapeseed, seed at 0.10 ppm; okra at 0.10 ppm; safflower seed at 0.10 ppm; salal at 0.10 ppm; sunflower seed at 0.10 ppm; strawberry at 0.10 ppm; juneberry at 0.10 ppm; lingonberry at 0.10 ppm; mustard, seed at 0.10 ppm; barley bran at 0.80 ppm; barley, flour at 0.80 ppm; corn, field, forage at 0.20 ppm; corn, sweet, forage at 0.20 ppm, corn, sweet, kernel plus cob with husk removed at 0.10 ppm; grain, cereal, forage, fodder and straw group 16, except corn and sorghum; forage at 1.0 ppm; grain, cereal, forage, fodder and straw, group 16, hay at 0.30 ppm; grain, cereal, forage, fodder and straw, group 16, stover at 0.30 ppm; grain, cereal, forage, fodder and straw, group 16, except rice; straw at 0.10 ppm; grain, cereal, group 15 at 0.10 ppm; grain, cereal, stover at 0.80 ppm; grain, cereal, straw at 3.0 ppm; millet, flour at 0.80 ppm; oat, flour at 0.80 ppm; rice, straw at 1.0 ppm; rye, bran at 0.80 ppm; rye, flour at 0.80 ppm; sorghum, forage at 0.20 ppm; sorghum, sweet at 0.10 ppm; wheat, bran at 0.80 ppm; wheat, flour at 0.80 ppm; wheat, germ at 0.80 ppm; wheat, middlings at 0.80 ppm; and wheat, shorts at 0.80 ppm. There is a practical analytical method for detecting and measuring levels of carfentrazone-ethyl and its metabolite in or on food with a limit of quantitation that allows monitoring of food with residues at or above the levels set or proposed in the tolerances. Contact: RD.

New Tolerance Exemptions

1. *PP* IN–10753. (EPA–HQ–OPP–2015–0214). Drexel Chemical Company, P.O. Box 13327, Memphis, TN 38113–0327, requests to establish an exemption from the requirement of a tolerance for residues of tetraethylene glycol (CAS Reg. No. 112–60–7) when used as an inert ingredient in pesticide formulations applied to growing crops only under 40 CFR 180.920. The petitioner believes no analytical method is needed because it is not required for an exemption from the requirement of a tolerance. Contact: RD.

2. *PP* IN–10759. (EPA–HQ–OPP–2015–0232). Cytec Industries Inc., 5 Garret Mountain Plaza Woodland Park, NJ 07424, requests to establish an exemption from the requirement of a tolerance for residues of poly(oxy-1,2-

ethanediy), α -(3-carboxy-1-oxosulfopropyl)- ω -hydroxy, alkyl ethers, disodium salts (CAS Reg. Nos. 68815-56-5, 68954-91-6, 1013906-64-3, 1024612-24-5), when used as an inert ingredient in pesticide formulations applied to growing crops and raw agricultural commodities under 40 CFR 180.910. The petitioner believes no analytical method is needed because it is not required for an exemption from the requirement of a tolerance. Contact: RD.

3. *PP IN-10760*. (EPA-HQ-OPP-2015-0213). Cytec Industries, Inc., 5 Garret Mountain Plaza, Woodland Park, NJ 07424, requests to establish an exemption from the requirement of a tolerance for residues of butanedioic acid, 2-sulfo-, C-C9-11-isoalkyl esters, C10-rich, disodium salts (CAS. Reg. No. 815583-91-6), when used as an inert ingredient in pesticide formulations applied to growing crops and raw agricultural commodities under 40 CFR 180.910. The petitioner believes no analytical method is needed because it is not required for an exemption from the requirement of a tolerance. Contact: RD.

4. *PP IN-10792*. (EPA-HQ-OPP-2015-0249). Clariant Corporation, 4000 Monroe Road, Charlotte, NC 28205, requests to establish an exemption from the requirement of a tolerance for residues, D-Glucitol, 1-deoxy-1-(methylamino)-, N-C8-10 acyl derivs. (CAS Reg. No. 1591782-62-5), when used as an inert ingredient in pesticide formulations applied to growing crops only under 40 CFR 180.920. The petitioner believes no analytical method is needed because it is not required for an exemption from the requirement of a tolerance. Contact: RD.

Authority: 21 U.S.C. 346a.

Dated: May 8, 2015.

G. Jeffrey Herndon,

Acting Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2015-12238 Filed 5-19-15; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 54

[WC Docket Nos. 10-90, 14-259 and 14-93; FCC 14-98, DA 15-383; Report No. 3021]

Petitions for Reconsideration of Action in Rulemaking Proceeding

AGENCY: Federal Communications Commission.

ACTION: Petition for reconsideration.

SUMMARY: Petitions for Reconsideration (Petitions) have been filed in the Commission's Rulemaking proceeding by Kevin L. Tucker, on behalf of AirNorth Communications, Inc.; Michael D. Donnell on behalf of Michael D. Donnell d/b/a San Joaquin Broadband; and Hamid Vahdatipour, on behalf of Lake Region Technology & Communications, LLC.

DATES: Oppositions to the Petitions must be filed on or before June 4, 2015. Replies to an opposition must be filed on or before June 15, 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, TTY (202) 418-0484.

SUPPLEMENTARY INFORMATION: This is a summary of Commission's document, Report No. 3021, released May 11, 2015. The full text of the Petitions 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 *Notice* pursuant to the Congressional Review Act, 5 U.S.C. 801(a)(1)(A) because this notice does not have an impact on any rules of particular applicability.

Subject: FCC Launches Rural Broadband Expansion Experiments, published at 79 FR 45705, August 6, 2014, in WC Docket Nos. 10-90 and 14-58, and published pursuant to 47 CFR 1.429(e). *See also* § 1.4(b)(1) of the Commission's rules.

Number of Petitions Filed: 3.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2015-12134 Filed 5-19-15; 8:45 am]

BILLING CODE 6712-01-P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

49 CFR Chapter X

[Docket No. EP 726]

On-Time Performance Under Section 213 of the Passenger Rail Investment and Improvement Act of 2008

AGENCY: Surface Transportation Board.

ACTION: Notice of commencement of proceeding.

SUMMARY: The Surface Transportation Board (the Board) is commencing a proceeding to define "on-time performance" for purposes of Section 213 of the Passenger Rail Investment and Improvement Act of 2008.

DATES: May 20, 2015.

FOR FURTHER INFORMATION CONTACT:

Scott M. Zimmerman at (202) 245-0386. Assistance for the hearing impaired is available through the Federal Information Relay Service (FIRS) at (800) 877-8339.

SUPPLEMENTARY INFORMATION:

The Association of American Railroads (AAR) submitted a conditional petition for rulemaking to define "on-time performance" for purposes of Section 213 of the Passenger Rail Investment and Improvement Act of 2008 (PRIIA), 49 U.S.C. 24308(f). The Board concludes that it is appropriate to institute a rulemaking proceeding to define on-time performance for purposes of PRIIA Section 213 and invite public participation. The Board intends to issue a notice of proposed rulemaking and a procedural schedule in a subsequent decision.

Additional information is contained in the Board's decision, which is available on our Web site at www.stb.dot.gov. Copies of the decision may also be purchased by contacting the Board's Office of Public Assistance, Governmental Affairs, and Compliance at (202) 245-0238.

This action will not significantly affect either the quality of the human environment or the conservation of energy resources.

Decided: May 13, 2015.

By the Board, Acting Chairman Miller and Vice Chairman Begeman.

Kenyatta Clay,

Clearance Clerk.

[FR Doc. 2015-12174 Filed 5-19-15; 8:45 am]

BILLING CODE 4915-01-P

Notices

Federal Register

Vol. 80, No. 97

Wednesday, May 20, 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

May 14, 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 June 19, 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 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.

Office of the Secretary, White House Liaison Office

Title: Advisory Committee and Research and Promotion Board Membership Background Information.
OMB Control Number: 0505-0001.

Summary of Collection: The Department is required under Section 1804 of the Food and Agriculture Act of 1977 (7 U.S.C. 2281, *et seq.*) to provide information concerning advisory committee members' principal place of residence, persons or companies by whom employed, and other major sources of income. The Agriculture and Food Act of 1981 (Pub. L. 97-98) reiterates this requirement. Similar information will be required of research and promotion boards/committees/councils in addition to the supplemental commodity specific questions. The Secretary appoints board members under each program. Some of the information contained on form AD-755 is used by the Department to conduct background clearances of prospective board members required by departmental regulations. The clearance is required for all committee members who are appointed by the Secretary. The White House Liaison Office (WHLO) will collect information using form AD-755, "Advisory Committee and Research and Promotion Board Membership Background Information".

Need And Use of the Information: The WHLO will collect information on the background of the nominees to make sure there are no delinquent loans to the United States Department of Agriculture, (USDA), as well as making sure they have no negative record that could be a negative reflection to the USDA. The information obtained from the form is used in the compilation of an annual report to Congress. Failure of the Department to provide this information would require the Secretary to terminate the pertinent committee or board.

Description of Respondents: Individuals or households.

Number of Respondents: 2,419.

Frequency of Responses: Reporting: Annually.

Total Burden Hours: 1,210.

Ruth Brown,

*Departmental Information Collection
Clearance Officer.*

[FR Doc. 2015-12165 Filed 5-19-15; 8:45 am]

BILLING CODE 3410-01-P

DEPARTMENT OF AGRICULTURE

Submission for OMB Review; Comment Request

May 15, 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 June 19, 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 20503. Commenters are encouraged to submit their comments to OMB via email to: 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) 720-8681.

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.

National Agricultural Statistics Service

Title: Agricultural Resource Management, Chemical Use, and Post-harvest Chemical Use Surveys.

OMB Control Number: 0535-0218.

Summary of Collection: The primary objectives of the National Agricultural Statistics Service (NASS) are to provide the public with timely and reliable agricultural production and economic statistics, as well as environmental and specialty agricultural related statistics. The surveys—the Agricultural Resource Management Study (ARMS), the Vegetable Chemical Use Surveys, the Fruit Chemical Use Surveys, and the new Microbial Food Safety Practices—Packer Survey—are critical to NASS' ability to fulfill these objectives and to build the congressionally mandated database on agricultural chemical use and related farm practices. NASS uses a variety of survey instruments to collect the information in conjunction with these studies.

Need and Use of the Information: The ARMS provides a robust data base of information to address varied needs of policy makers. There are many uses for the information from this study including an evaluation of the safety of the nation's food supply; input to the farm sector portion of the gross domestic product; and to provide a barometer on the financial condition of farm businesses. ARMS is the only annual source of whole farm information available for objective evaluation of many critical issues related to agriculture and the rural economy, such as: whole farm finance data, marketing information, input usage, production practices, and crop substitution possibilities. Without these data, decision makers cannot analyze and report on critical issues that affect farms and farm households when pesticide regulatory actions are being considered.

Description of Respondents: Farms.

Number of Respondents: 91,916.

Frequency of Responses: Reporting: Annually.

Total Burden Hours: 91,208.

Charlene Parker,

Departmental Information Collection Clearance Officer.

[FR Doc. 2015-12258 Filed 5-19-15; 8:45 am]

BILLING CODE 3410-20-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

[Docket No. FSIS-2015-0028]

National Advisory Committee on Microbiological Criteria for Foods

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Notice of public meeting.

SUMMARY: This notice is announcing a meeting of the National Advisory Committee on Microbiological Criteria for Foods (NACMCF), that will be held on June 10, 2015, by audio conference call that is open to the public. The Committee will continue its discussions, from its November 17, 2014 meeting, on microbiological criteria as indicators of poor process control or insanitary conditions. After further discussion, the committee plans to adopt its final recommendations.

DATES: Wednesday, June 10, 2015.

Time: 1:00 to 4:00 p.m. E.S.T.

Call-in Phone Number: The June 10, 2015, meeting will be held by telephone. The call-in number for the audio conference will be provided after registration is completed. Please contact Karen Thomas-Sharp at the address, telephone or fax numbers below to register for the meeting: USDA, FSIS, Office of Public Health Science, Stop 3777, Patriots Plaza 3, Floor 9, 1400 Independence Avenue SW., Washington, DC 20250, or by phone (202) 690-6620, fax (202) 690-6334, or email: Karen.thomas-sharp@fsis.usda.gov.

All documents related to the full Committee meeting will be available for public inspection in the FSIS Docket Room, USDA, at Patriots Plaza 3, 355 E. Street SW., Room 8-164, Washington, DC 20250 between 8:30 a.m. and 4:30 p.m., Monday through Friday, as soon as they become available. The NACMCF documents also will be available on the Internet at <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/federal-register-notices>.

FSIS will finalize the agenda on or before the date of the meeting and will post it on the FSIS Web page at <http://www.fsis.usda.gov/wps/portal/fsis/newsroom/meetings>. Please note that the meeting time schedule is subject to change due to the time required for Committee discussions; thus, sessions could end earlier or later than anticipated. Please plan accordingly if you would like to attend or participate in a public comment period.

The official meeting minutes of the June 10, 2015 full Committee meeting,

when they become available, will be located in the FSIS Docket Room at the above address and also will be posted on <http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/nacmcf/meetings/nacmcf-meetings>.

Further Information for Participants:

Persons interested in registering for the audio conference, making a presentation, submitting technical papers, or providing comments at the June 10, 2015 plenary session should contact Karen Thomas-Sharp, phone (202) 690-6620, fax (202) 690-6334, email: Karen.thomas-sharp@fsis.usda.gov or at the mailing address above. Persons requiring special accommodations for this phone conference (voice and TTY) should notify Ms. Thomas-Sharp by June 5, 2015.

SUPPLEMENTARY INFORMATION:

Background

The NACMCF was established in 1988 in response to a recommendation of the National Academy of Sciences for an interagency approach to microbiological criteria for foods and in response to a recommendation of the U.S. House of Representatives Committee on Appropriations, as expressed in the Rural Development, Agriculture, and Related Agencies Appropriation Bill for fiscal year 1988. The charter for the NACMCF is available on the FSIS Web page at <http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/nacmcf/committee-charter/charter>.

The NACMCF provides scientific advice and recommendations to the Secretary of Agriculture and the Secretary of Health and Human Services on issues related to the safety and wholesomeness of the U.S. food supply, including development of microbiological criteria, as well as the review and evaluation of epidemiological and risk assessment data and methodologies for assessing microbiological hazards in foods. The Committee also provides scientific advice and recommendations to the Food and Drug Administration, the Centers for Disease Control and Prevention, and the Departments of Commerce and Defense.

Mr. Brian Ronholm, Deputy Under Secretary for Food Safety, USDA, is the Committee Chair; Dr. Susan T. Mayne, Director of the Food and Drug Administration's Center for Food Safety and Applied Nutrition (CFSAN), is the Vice-Chair; and Dr. James Rogers, FSIS, is the Executive Secretary.

Documents Reviewed by NACMCF

FSIS will make all materials reviewed and considered by NACMCF regarding its deliberations available to the public. Generally, these materials will be made available as soon as possible after the full Committee meeting. Further, FSIS intends to make these materials available in electronic format on the FSIS Web page (www.fsis.usda.gov), as well as in hard copy format in the FSIS Docket Room. Often, an attempt is made to make the materials available at the start of the full Committee meeting when sufficient time is allowed in advance to do so.

Disclaimer: NACMCF documents and comments posted on the FSIS Web site are electronic conversions from a variety of source formats. In some cases, document conversion may result in character translation or formatting errors. The original document is the official, legal copy.

In order to meet the electronic and information technology accessibility standards in Section 508 of the Rehabilitation Act, NACMCF may add alternate text descriptors for non-text elements (graphs, charts, tables, multimedia, etc.). These modifications only affect the Internet copies of the documents.

Copyrighted documents will not be posted on the FSIS Web site, but will be available for inspection in the FSIS Docket Room.

Additional Public Notification

FSIS will announce this notice online through the FSIS Web page located at <http://www.fsis.usda.gov/wps/portal/fsis/topics/regulations/federal-register/federal-register-notices>.

FSIS also will make copies of this **Federal Register** publication available through the FSIS Constituent Update, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to constituents and stakeholders. The Update is communicated via Listserv, a free electronic mail subscription service for industry, trade groups, consumer interest groups, health professionals, and other individuals who have asked to be included. The Update also is available on the FSIS Web page. In addition, FSIS offers an electronic mail subscription service, which provides automatic and customized access to selected food safety news and information. This service is available at <http://www.fsis.usda.gov/wps/portal/fsis/programs-and-services/email>

subscription-service. Options range from recalls to export information to regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

USDA Nondiscrimination Statement

USDA prohibits discrimination in all of its programs and activities on the basis of race, color, national origin, gender, religion, age, disability, political beliefs, sexual orientation, and marital or family status (Not all prohibited bases apply to all programs).

Persons with disabilities who require alternative means for communication of program information (Braille, large print, and audiotape) should contact USDA's Target Center at (202) 720-2600 (voice and TTY).

To file a written complaint of discrimination, write USDA, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW., Washington, DC 20250-9410 or call (202) 720-5964 (voice and TTY). USDA is an equal opportunity provider and employer.

Done at Washington, DC, on: May 15, 2015.

Alfred V. Almanza,

Acting Administrator.

[FR Doc. 2015-12192 Filed 5-19-15; 8:45 am]

BILLING CODE 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food and Nutrition Service

Agency Information Collection Activities: Proposed Collection; Comment Request—Evaluation of Supplemental Nutrition Assistance Program (SNAP) Employment and Training (E&T) Pilots

AGENCY: Food and Nutrition Service (FNS), USDA.

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice invites the public and other public agencies to comment on this proposed information collection. This is a new collection for the purpose of evaluating the Fiscal Year 2015 Pilot Projects to Reduce Dependency and Increase Work Requirements and Work Effort Under the Supplemental Nutrition Assistance Program (SNAP).

DATES: Written comments must be received on or before July 20, 2015.

ADDRESSES: Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the

agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions that were used; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on those who are to respond, including use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments may be sent to: Wesley R. Dean, Food and Nutrition Service, U.S. Department of Agriculture, 3101 Park Center Drive, Room 1014, Alexandria, VA 22302. Comments may also be submitted via fax to the attention of Wesley R. Dean at 703-305-2576 or via email to wesley.dean@fns.usda.gov. Comments will also be accepted through the Federal eRulemaking Portal. Go to <http://www.regulations.gov>, and follow the online instructions for submitting comments electronically.

All written comments will be open for public inspection at the Office of the Food and Nutrition Service during regular business hours (8:30 a.m. to 5 p.m. Monday through Friday) at 3101 Park Center Drive, Room 1014, Alexandria, Virginia 22302.

All responses to this notice will be summarized and included in the request for Office of Management and Budget approval. All comments will be a matter of public record.

FOR FURTHER INFORMATION CONTACT:

Requests for additional information or copies of this information collection should be directed to Wesley R. Dean, Office of Policy Support, Food and Nutrition Service, USDA, 3101 Park Center Drive, Room 1014, Alexandria, VA 22302.

SUPPLEMENTARY INFORMATION:

Title: Evaluation of SNAP E&T Pilots.

OMB Number: 0584-NEW.

Expiration Date: Not Yet Determined.

Type of Request: New Collection.

Abstract: The Supplemental Nutrition Assistance Program (SNAP) is a critical work support for low-income people and families. SNAP benefits help eligible low-income families put food on the table in times of need. It also supports critical and needed skills and job training so that recipients can obtain good jobs that lead to self-sufficiency. SNAP's long-standing mission of helping unemployed and underemployed people is challenging. To help them and their families achieve self-sufficiency, strategies are needed to

impart the skills employers want, and to help address other barriers to employment. Some participants need assistance developing a resume and accessing job leads, others need education and training, and still others need help overcoming barriers that prevent them from working steadily. The SNAP Employment and Training (E&T) program provides assistance to unemployed and underemployed clients in the form of job search, job skills training, education (basic, post-secondary, vocational), work experience or training and workfare, but limited information exists on what is most effective in connecting these participants to gainful employment.

The Agriculture Act of 2014 (Pub. L. 113–79, Section 4022), otherwise known as the 2014 Farm Bill authorized grants for up to 10 pilot sites to develop and rigorously test innovative SNAP E&T strategies for engaging more SNAP work registrants in unsubsidized employment, increasing participants' earnings and reducing reliance on public assistance. The pilots' significant funding can expand the reach of employment and training services and enable States to experiment with promising strategies to increase engagement and promote employment. An evaluation of the pilot sites will be critical in helping Congress and FNS identify strategies that effectively assist SNAP participants to succeed in the labor market and become self-sufficient.

The 10 States receiving grants to fund pilot projects are California, Delaware, Georgia, Kansas, Kentucky, Illinois, Mississippi, Vermont, Virginia and Washington State. The evaluation will collect data from all 10 pilot sites in 2015–2016 (baseline), 2016–2017 (12-month follow-up) and 2018–2019 (36-month follow-up). The data collected for this evaluation will be used for implementation, impact, participant and cost-benefit analyses for each pilot site. Research objectives include: (1) Documenting the context and operations of each pilot, identify lessons learned, and to help interpret and understand impacts within each pilot and across pilots, (2) identifying the impacts on employment, earnings, and reliance on public assistance and food security and other outcomes, to determine what works, and what works for whom, (3) examine the characteristics of service paths of pilot

participants and the control group to assess whether the mere presence of the pilots and their offer of services or participation requirements influence whether people apply for SNAP (entry effects), and (4) estimate the total and component costs of each pilot and provide an estimate of the return to each dollar invested in the pilot services. Primary outcomes will be employment, earnings, and participation in public assistance programs, which will be measured through state administrative records, a baseline survey administered during enrollment into the study, and through follow-up telephone surveys conducted at approximately 12 months and 36 months. Impacts on secondary outcomes, such as food security, health status, and self-esteem, will be measured through the follow-up telephone surveys as well. The end products (interim and final reports) will provide scientifically valid evidence of the pilot project impacts.

Affected Public: Members of the public affected by the data collection include individuals and households; State and local governments; and Businesses from the Private sector (for-profit and not-for-profit). Respondent types identified include (1) individuals and households eligible for SNAP E&T participation; (2) directors and managers from State and local government agencies supporting the SNAP E&T programs; (3) staff from State and local government agencies providing direct services to SNAP E&T participants; (4) directors and managers from private sector for-profit businesses providing SNAP E&T services; and (5) directors and managers from private sector not-for-profit agencies providing SNAP E&T services.

Estimated Number of Respondents: The total estimated number of respondents is 50,758. This includes 50,018 individuals, 280 State and local government directors/managers and staff, and 460 private sector for-profit business and not-for-profit agency directors/managers. Of the 50,000 individuals completing a baseline survey when applying for services, FNS will contact 25,000 out of which 18,240 individuals in the treatment and comparison groups will complete a 12-month follow-up telephone survey (6,760 will be non-responders). Of 18,240 respondents to the 12-month follow-up, 11,090 will complete a 36-

month follow-up telephone survey (7,150 non-respondents). Among the individuals contacted for the telephone surveys, 120 may also be contacted for a focus group, 67 for an in-depth interview, and 27 for a case study on topics of special interest to FNS. Of the individuals contacted for the focus groups, in-depth interviews, and case studies, 214 participants will participate and 86 will decline and be considered nonrespondents. 18 individuals will be contacted separately to pretest surveys, interviews, and focus groups. 170 State and local government agency directors/managers will be contacted for in-person interviews. 150 of those will be interviewed two additional times; 10 of the directors/managers will provide case study data and 10 will provide cost data. A separate group of 100 directors/managers will be sampled to participate in a time use survey, and 10 data director/managers will be contacted for administrative data. 200 Private sector not-for-profit and for-profit agency directors/managers and staff will be contacted for cost/benefit interviews. These individuals will also be contacted for in-person interviews, and the directors and managers for the case study will be recruited from this group.

160 individuals will be contacted for a time-use survey. This sample will also be used to recruit staff to participate in the case study. 100 staff members responsible for data management will also be contacted for the provision of administrative data.

Estimated Frequency of Responses per Respondent: Average of 1 response for individuals per instrument or activity and 1.59 for all activities, 4.36 responses for State and local government representatives for all contacts, and 21.07 responses for private sector representatives for all contacts. The number of contacts per activity range from 1 to 20 across all participants.

Estimated Total Annual Responses: 106,159.

Estimated Time per Response: About 0.35 hours (21.6 minutes). The estimated time of response varies from 0.08 to 8 hours depending on the respondent group and data collection activity, as shown in the table below.

Estimated Total Annual Burden on Respondents: The total annual burden is 32,260 hours.

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			RESPONDENTS						NON-RESPONDENTS						
Affected public	Respondents type	Instrument	Sample size	Estimated number of respondents	Frequency of response	Total responses	Average time per response (hours)	Total Estimated annual burden (hours)	Estimated number of non-respondents	Frequency of response	Total responses	Average time per response (hours)	Total Estimated annual burden (hours)	Grand Total burden estimate	
Individuals/households															
Individuals	Participant	Baseline survey	50,000	50,000	1	50,000	0.08	4,000.00	0	0	0	0	0.00	4,000.00	
	Participant	Pretest	18	9	1	9	0.50	4.50	9	1	9	0.05	0.45	4.95	
	Participant	Telephone survey (12-mon follow-up)	25,000	18,240	1	18,240	0.50	9,120.00	6,760	1	6,760	0.05	338.00	9,458.00	
	Participant	Telephone survey (36-mon follow-up)	18,240	11,090	1	11,090	0.50	5,545.00	7,150	1	7,150	0.05	357.50	5,902.50	
	Participant	Focus Group	120	80	1	80	1.67	133.33	40	1	40	0.08	3.33	136.67	
	Participant	Indepth interview	67	33	1	33	2.17	72.22	33	1	33	0.08	2.78	75.00	
	Participant	Case Study	27	13	1	13	3.17	42.22	13	1	13	0.08	1.11	43.33	
Subtotal of unique individuals/households			50,018	50,009	1.59	79,466	0.24	18,917	14,006	-	14,006	-	703	19,620	
State and local government															
State or local government	State or local director /manager	In-person interview (round 1) and Cost/benefit interviews	170	170	1	170	1.00	170.00	0	0	0	0.08	0.00	170.00	
	State or local director /manager	In-person interview (round 2)	150	150	1	150	1.00	150.00	0	0	0	0.08	0.00	150.00	

	State or local direct service staff	In-person interview (round 3)	150	150	1	150	1.00	150.00	0	0	0	0.08	0.00	150.00
	State or local direct service staff	Case Study	10	10	1	10	1.00	10.00	0	0	0	0.08	0.00	10.00
	State or local data director/manager	Provide administrative data	10	10	12	120	8.00	960.00	0	0	0	0.08	0.00	960.00
	State or local director/manager	Cost/benefit interviews (after visit 1)	10	10	19	190	1.00	190.00	0	0	0	0.08	0.00	190.00
	State or local data director/manager	Provide cost data	10	10	13	130	2.00	260.00	0	0	0	0.08	0.00	260.00
	State or local director/manager	Time Use Survey	100	100	3	300	1.00	300.00	0	0	0	0.08	0.00	300.00
Subtotal unique State, local, and Tribal government			280	280	4.36	1,220	1.80	2,190.00	0	-	0	-	0.00	2,190.00
Business for-not-for profit														
Private sector	Private sector for-profit business director/manager	In-person interview (round 1)	75	75	1	75	1.00	75.00	0	0	0	0	0.00	75.00
	Private sector for-profit business director/manager	In-person interview (round 2)	75	75	1	75	1.00	75.00	0	0	0	0	0.00	75.00
	Private sector for-profit business director/manager	In-person interview (round 3)	75	75	1	75	1.00	75.00	0	0	0	0	0.00	75.00
	Private sector for-profit business director/manager & staff	Case Study	60	60	1	60	1.00	60.00	0	0	0	0	0.00	60.00

Private sector for-profit business data staff	Provide administrative data	50	50	12	600	4.00	2,400.00	0	0	0	0	0.00	2,400.00
Private sector for-profit business director/manager	Cost/benefit interviews	100	100	20	2,000	0.50	1,000.00	0	0	0	0	0.00	1,000.00
Private sector for-profit business director/manager	Provide cost data	100	100	13	1,300	1.00	1,300.00	0	0	0	0	0.00	1,300.00
Private sector for-profit business staff	Time Use Survey	80	80	3	240	1.00	240.00	0	0	0	0	0.00	240.00
Private sector not-for-profit agency director/manager	In-person interview (round 1)	75	75	1	75	1.00	75.00	0	0	0	0	0.00	75.00
Private sector not-for-profit agency director/manager	In-person interview (round 2)	75	75	1	75	1.00	75.00	0	0	0	0	0.00	75.00
Private sector not-for-profit agency director/manager	In-person interview (round 3)	75	75	1	75	1.00	75.00	0	0	0	0	0.00	75.00
Private sector for-profit business director/manager & staff	Case Study	60	60	1	60	1.00	60.00	0	0	0	0	0.00	60.00
Private sector not-for-profit data staff	Provide administrative data	50	50	12	600	4.00	2,400.00	0	0	0	0	0.00	2,400.00
Private sector not-for-profit agency	Cost/benefit interviews	100	100	20	2,000	0.50	1,000.00	0	0	0	0	0.00	1,000.00

director/ manager														
Private sector not-for-profit agency director/ manager	Provide cost data	100	100	13	1,300	1.00	1,300.00	0	0	0	0	0.00	1,300.00	
Private sector not-for-profit staff	Time Use Survey	80	80	3	240	1.00	240.00	0	0	0	0	0.00	240.00	
Subtotal unique private/business sector		460	420	21.07	8,850	1.18	10,450	0	-	0	-	0.00	10,450.00	
Grand total		50,758	50,709	1.77	89,536	0.35	31,557.28	14,006	1.00	14,006	0.05	703.17	32,260.45	

* Nonrespondents are part of the total individuals who completed the baseline information form.

** Sources: Bureau of Labor Statistics, National Compensation Survey, 2010. May, 2011, Bulletin 2753. (<http://www.bls.gov/ncs/ncswage2010.htm>): Individual/Participant: National minimum wage. State, local, or Tribal agency director/manager: Average hourly earnings of State and local government workers in management occupations; Private sector for-profit business director/manager: Average hourly earnings of private industry management occupations; Private sector not-for-profit agency director/manager: Average hourly earnings of private sector social and community services managers

Dated: May 12, 2015.

Audrey Rowe,

Administrator, Food and Nutrition Service.

[FR Doc. 2015-12205 Filed 5-19-15; 8:45 am]

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DEPARTMENT OF AGRICULTURE**Rural Business-Cooperative Service****Inviting Applications for Socially-Disadvantaged Groups Grants**

AGENCY: Rural Business-Cooperative Service, USDA.

ACTION: Notice.

SUMMARY: The Rural Business-Cooperative Service announces the availability of \$3,000,000 in competitive grant funds for the FY 2015 Socially-Disadvantaged Groups Grant (SDGG) program, formerly known as the Small Socially-Disadvantaged Producer Grant program, as authorized by the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113–235). We are requesting proposals from applicants who will provide technical assistance to socially-disadvantaged groups in rural areas. The Agency is encouraging applications that direct grants to projects based in or serving census tracts with poverty rates greater than or equal to 20 percent. This emphasis will support Rural Development's (RD) mission of improving the quality of life for rural Americans and commitment to directing resources to those who most need them. Eligible applicants include Cooperatives, Groups of Cooperatives, and Cooperative Development Centers.

DATES: Completed applications for grants must be submitted on paper or electronically according to the following deadlines:

Paper copies must be postmarked and mailed, shipped, or sent overnight no later than July 20, 2015. You may also hand carry your application to one of our field offices, but it must be received by close of business on the deadline date.

Electronic copies must be received by <http://www.grants.gov> no later than midnight Eastern time July 14, 2015. Late applications are not eligible for funding under this Notice and will not be evaluated.

ADDRESSES: You should contact the USDA Rural Development State Office (State Office) located in the State where you are headquartered if you have questions. Contact information for State Offices can be found at: <http://www.rd.usda.gov/contact-us/state-offices>. You are encouraged to contact your State Office well in advance of the application deadline to discuss your project and ask any questions about the application process. Program guidance as well as application templates may be obtained at <http://www.rurdev.usda.gov/>

[BCP_SDGG.html](#) or by contacting your USDA Rural Development State Office.

If you want to submit an electronic application, follow the instructions for the SDGG funding announcement located at <http://www.grants.gov>. Please review the Grants.gov Web site at http://grants.gov/applicants/organization_registration.jsp for instructions on the process of registering your organization as soon as possible to ensure you are able to meet the electronic application deadline. You are strongly encouraged to file your application early and allow sufficient time to manage any technical issues that may arise. If you want to submit a paper application, send it to the State Office located in the State where you are headquartered. If you are headquartered in Washington, DC, please contact the Grants Division, Cooperative Programs, Rural Business-Cooperative Service, at (202) 690–1376 for guidance on where to submit your application.

FOR FURTHER INFORMATION CONTACT: Grants Division, Cooperative Programs, Rural Business-Cooperative Service, United States Department of Agriculture, 1400 Independence Avenue SW., MS 3253, Room 4208-South, Washington, DC 20250–3250, or call 202–690–1376.

SUPPLEMENTARY INFORMATION:**Overview**

Federal Agency Name: USDA Rural Business Cooperative Service.

Funding Opportunity Title: Socially-Disadvantaged Groups Grant.

Announcement Type: Initial funding request.

Catalog of Federal Domestic Assistance Number: 10.871.

Dates: Application Deadline. You must submit your complete application by July 20, 2015, or it will not be considered for funding. Electronic applications must be received by <http://www.grants.gov> no later than midnight Eastern Time July 14, 2015, or it will not be considered for funding.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act, the paperwork burden associated with this Notice has been approved by the Office of Management and Budget (OMB) under OMB Control Number 0570–0052.

A. Program Description

The SDGG Program is authorized by 310B (e)(11) of the Consolidated Farm and Rural Development Act (7 U.S.C. 1932 (e)(11)). The primary objective of the SDGG program is to provide Technical Assistance to Socially-

Disadvantaged Groups. Grants are available for Cooperative Development Centers, individual Cooperatives, or Groups of Cooperatives that serve Socially-Disadvantaged Groups and where a majority of the boards of directors or governing board is comprised of individuals who are members of Socially-Disadvantaged Groups.

Definitions

The definitions you need to understand are as follows:

Agency—Rural Business-Cooperative Service, an agency of the United States Department of Agriculture (USDA) Rural Development or a successor agency.

Conflict of Interest—A situation in which a person or entity has competing personal, professional, or financial interests that make it difficult for the person or business to act impartially. Federal procurement standards prohibit transactions that involve a real or apparent conflict of interest for owners, employees, officers, agents, or their immediate family members having a financial or other interest in the outcome of the project; or that restrict open and free competition for unrestrained trade. Specifically, project funds may not be used for services or goods going to, or coming from, a person or entity with a real or apparent conflict of interest, including, but not limited to, owner(s) and their immediate family members. Examples of conflicts of interest include using grant funds to pay a member of the applicant's board of directors to provide proposed technical assistance to socially-disadvantaged groups; pay a cooperative member to provide proposed technical assistance to other members of the same cooperative; and pay an immediate family member of the applicant to provide proposed technical assistance to socially-disadvantaged groups.

Cooperative—A business or organization owned by and operated for the benefit of those using its services and where a majority of the board of directors or governing board is comprised of individuals who are members of Socially-Disadvantaged Groups. Profits and earnings generated by the cooperative are distributed among the members, also known as user-owners.

Cooperative Development Center—A nonprofit corporation or institution of higher education operated by the grantee for cooperative or business development and where a majority of the board of directors or governing board is comprised of individuals who are members of Socially-Disadvantaged

Groups. It may or may not be an independent legal entity separate from the grantee. The Center's main objective is to provide Technical Assistance to existing Cooperatives and to groups that want to form Cooperatives.

Feasibility Study—An analysis of the economic, market, technical, financial, and management feasibility of a proposed Project.

Group of Cooperatives—A group of Cooperatives whose primary focus is to provide assistance to Socially-Disadvantaged Groups and where a majority of the board of directors or governing board is comprised of individuals who are members of Socially-Disadvantaged Groups.

Operating Cost—The day-to-day expenses of running a business; for example: utilities, rent on the office space a business occupies, salaries, depreciation, marketing and advertising, and other basic overhead items.

Participant Support Costs—Direct costs for items such as stipends or subsistence allowances, travel allowances, and registration fees paid to or on behalf of participants or trainees (but not employees) in connection with conferences, or training projects.

Project—Includes all activities to be funded by the Socially-Disadvantaged Groups Grant.

Rural and Rural Area—Any area of a State:

(1) Not in a city or town that has a population of more than 50,000 inhabitants, according to the latest decennial census of the United States; and

(2) The contiguous and adjacent urbanized area,

(3) Urbanized areas that are rural in character as defined by 7 U.S.C. 1991 (a) (13).

(4) For the purposes of this definition, cities and towns are incorporated population centers with definite boundaries, local self-government, and legal powers set forth in a charter granted by the State. Notwithstanding any other provision of this paragraph, within the areas of the County of Honolulu, Hawaii, and the Commonwealth of Puerto Rico, the Secretary may designate any part of the areas as a rural area if the Secretary determines that the part is not urban in character, other than any area included in the Honolulu census designated place (CDP) or the San Juan CDP.

Rural Development—A mission area within USDA consisting of the Office of Under Secretary for Rural Development, Rural Business-Cooperative Services, Rural Housing Service, and Rural Utilities Service and any successors.

Socially-Disadvantaged Group—A group whose members have been subjected to racial, ethnic, or gender prejudice because of their identity as members of a group without regard to their individual qualities.

State—Includes each of the 50 states, the Commonwealth of Puerto Rico, the Virgin Islands of the United States, Guam, American Samoa, the Commonwealth of the Northern Mariana Islands, and, as may be determined by the Secretary to be feasible, appropriate and lawful, the Federated States of Micronesia, the Republic of the Marshall Islands and the Republic of Palau.

Technical Assistance—An advisory service performed for the benefit of a Socially-Disadvantaged Group such as market research, product and/or service improvement, legal advice and assistance, Feasibility Study, business plan, marketing plan development, and training.

B. Federal Award Information

Type of Award: Competitive Grant.

Fiscal Year Funds: FY 2015.

Total Funding: \$3,000,000.

Maximum Award: \$175,000.

Project Period: 1 year.

Anticipated Award Date: September 30, 2015.

C. Eligibility Information

Applicants must meet all of the following eligibility requirements. Applications which fail to meet any of these requirements by the application deadline will be deemed ineligible and will not be evaluated further.

1. *Eligible Applicants.* Grants may be made to individual Cooperatives, Groups of Cooperatives, and Cooperative Development Centers that serve socially disadvantaged groups and where a majority of the board of directors or governing board is comprised of individuals who are members of Socially-Disadvantaged Groups. Federally-recognized Tribes and tribal entities must demonstrate that they meet all definition requirements for one of the three eligible applicant types. You must be able to verify your legal structure in the State in which you are incorporated. Grants may not be made to public bodies or to individuals.

(a) An applicant is ineligible if they have been debarred or suspended or otherwise excluded from or ineligible for participation in Federal assistance programs under Executive Order 12549, "Debarment and Suspension." In addition, an applicant will be considered ineligible for a grant due to an outstanding judgment obtained by the U.S. in a Federal Court (other than

U.S. Tax Court), is delinquent on the payment of Federal income taxes, or is delinquent on Federal debt.

(b) Any corporation (i) that has been convicted of a felony criminal violation under any Federal law within the past 24 months or (ii) that has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability, is not eligible for financial assistance provided with funds appropriated by the Consolidated and Further Continuing Appropriations Act, 2015, unless a Federal agency has considered suspension or debarment of the corporation and has made a determination that this further action is not necessary to protect the interests of the Government.

2. *Cost Sharing or Matching.* No matching funds are required.

3. *Other Eligibility Requirements.*

Use of Funds: Your application must propose Technical Assistance that will benefit Socially-Disadvantaged Groups. Please review section D (6) of this Notice, "Funding Restrictions," carefully.

Project Area Eligibility: The proposed Project must take place in a Rural Area as defined in this Notice.

Grant Period Eligibility: If awarded, grant funds must be used within 12 months. Applications must have a time frame of one year or less. Your proposed time frame should begin no earlier than the grant award date and end no later than December 31, 2016. However, you should note that the anticipated award date is September 30, so your proposed start date should be after September 30, 2015. Projects must be completed within the 12-month time frame. The Agency may approve requests to extend the grant period for up to an additional 12 months at its discretion. Further guidance on grant period extensions will be provided in the award document.

However, you may not have more than one active SDGG during the same grant period. If you receive another SDGG during the next grant cycle, the first grant must be closed before funds can be obligated for the new grant. Applications that request funds for a time period ending after December 31, 2016, will not be considered for funding.

If you have an existing Small Socially-Disadvantaged Producer Grant award, you must be performing satisfactorily to be considered eligible for a new SDGG award. Satisfactory performance

includes being up-to-date on all financial and performance reports and being current on all tasks as approved in the work plan. The Agency will use its discretion to make this determination.

Completeness Eligibility: Your application must provide all of the information requested in Section D (2) of this Notice. Applications lacking sufficient information to determine eligibility and scoring will be considered ineligible.

Multiple Grant Eligibility: You may only submit one SDGG grant application each funding cycle.

D. Application and Submission Information

1. Address To Request Application Package

The application template for applying on paper for this funding opportunity is located at http://www.rurdev.usda.gov/BCP_SDGG.html. Use of the application template is strongly recommended to assist you with the application process. You may also contact your USDA Rural Development State Office for more information. Contact information for State Offices is located at <http://www.rd.usda.gov/contact-us/state-offices>. You may also obtain an application package by calling 202-690-1376.

2. Content and Form of Application Submission

You may submit your application in paper form or electronically through Grants.gov. Your application must contain all required information.

To submit an application electronically, you must follow the instructions for this funding announcement at <http://www.grants.gov>. Please note that we cannot accept emailed or faxed applications.

You can locate the Grants.gov downloadable application package for this program by using a keyword, the program name, or the Catalog of Federal Domestic Assistance Number for this program.

When you enter the Grants.gov Web site, you will find information about submitting an application electronically through the site, as well as the hours of operation.

To use Grants.gov, you must already have a DUNS number and you must also be registered and maintain registration in SAM. We strongly recommend that you do not wait until the application deadline date to begin the application process through Grants.gov.

You must submit all of your application documents electronically

through Grants.gov. Applications must include electronic signatures. Original signatures may be required if funds are awarded.

After electronically submitting an application through Grants.gov, you will receive an automatic acknowledgement from Grants.gov that contains a Grants.gov tracking number.

If you want to submit a paper application, send it to the State Office located in the State where you are headquartered. You can find State Office contact information at: <http://www.rd.usda.gov/contact-us/state-offices>.

Your application must also contain the following required forms and proposal elements:

a. Form SF-424, "Application for Federal Assistance," to include your DUNS number and SAM Commercial and Government Entity (CAGE) code and expiration date. Because there are no specific fields for a CAGE code and expiration date, you may identify them anywhere you want to on the form. If you do not include the CAGE code and expiration date and the DUNS number in your application, it will not be considered for funding.

b. Form SF-424A, "Budget Information-Non-Construction Programs." This form must be completed and submitted as part of the application package.

c. Form SF-424B, "Assurances—Non-Construction Programs." This form must be completed, signed, and submitted as part of the application package.

d. Form AD-3030, "Representations Regarding Felony Conviction and Tax Delinquent Status for Corporate Applicants," if you are a corporation. A corporation is any entity that has filed articles of incorporation in one of the 50 States, the District of Columbia, the Federated States of Micronesia, the Republic of Palau, and the Republic of the Marshall Islands, or the various territories of the United States including American Samoa, Guam, Midway Islands, the Commonwealth of the Northern Mariana Islands, Puerto Rico, or the U.S. Virgin Islands. Corporations include both for profit and non-profit entities.

e. You must certify that there are no current outstanding Federal judgments against your property and that you will not use grant funds to pay for any judgment obtained by the United States. To satisfy the Certification requirement, you should include this statement in your application: "[INSERT NAME OF APPLICANT] certifies that the United States has not obtained an unsatisfied judgment against its property and will not use grant funds to pay any

judgments obtained by the United States." A separate signature is not required.

f. Table of Contents. Your application must contain a detailed Table of Contents (TOC). The TOC must include page numbers for each part of the application. Page numbers should begin immediately following the TOC.

g. Executive Summary. A summary of the proposal, not to exceed one page, must briefly describe the Project, tasks to be completed, and other relevant information that provides a general overview of the Project.

h. Eligibility Discussion. A detailed discussion, not to exceed four pages, must describe how you meet the following requirements:

(i) Applicant Eligibility. You must describe how you meet the definition of a Cooperative, Group of Cooperatives, or Cooperative Development Center. Your application must show that your individual Cooperative, Group of Cooperatives or Cooperative Development Center serves socially disadvantaged groups and a majority of the board of directors or governing board is comprised of individuals who are members of Socially-Disadvantaged Groups. Your application must include a list of your board of directors/governing board and the percentage of board of directors/governing board that are members of Socially-Disadvantaged Groups. NOTE: Your application will not be considered for funding if you fail to show that a majority of your board of directors/governing board is comprised of individuals who are members of Socially-Disadvantaged Groups.

If applying as a Cooperative or a Group of Cooperatives, you must verify your incorporation and status in the State that you have applied by providing the State's Certificate of Good Standing and your Articles of Incorporation. If applying as a nonprofit corporation, you must provide evidence of your status as a nonprofit corporation in good standing and your Articles of Incorporation. If applying as an institution of higher education, you must qualify as an Institution of Higher Education as defined at 20 U.S.C. 1001. You must apply as only one type of applicant. If the requested verification documents are not included, your application will not be considered for funding.

(ii) Use of Funds. You must provide a detailed discussion on how the proposed Project activities meet the definition of Technical Assistance and identify the socially-disadvantaged groups that will be assisted.

(iii) Project Area. You must provide specific information that details the

location of the Project area and explain how the area meets the definition of "Rural Area."

(iv) Grant Period. You must provide a time frame for the proposed Project and discuss how the Project will be completed within that time frame. You must have a time frame of one year or less.

i. Scoring Criteria. Each of the scoring criteria in this Notice must be addressed in narrative form, with a maximum of two pages for each individual scoring criterion, unless otherwise specified. Failure to address each scoring criteria will result in the application being determined ineligible.

j. The Agency has established annual performance evaluation measures to evaluate the SDGG program. You must provide estimates on the following performance evaluation measures as part of your narrative:

- Number of businesses assisted;
 - Number of cooperatives assisted;
- and
- Number of socially disadvantaged groups assisted.

3. DUNS Number and SAM

In order to be eligible (unless you are excepted under 2 CFR 25.110(b), (c) or (d), you are required to:

(a) Provide a valid DUNS number in your application, which can be obtained at no cost via a toll-free request line at (866) 705-5711;

(b) Register in SAM before submitting your application. You may register in SAM at no cost at <https://www.sam.gov/portal/public/SAM/>; and

(c) Continue to maintain an active SAM registration with current information at all times during which you have an active Federal award or an application or plan under consideration by a Federal awarding agency.

The Agency may not make a Federal award to you until you have complied with all applicable DUNS and SAM requirements. If you have not fully complied with requirements by the time the Agency is ready to make a Federal award, the Agency may determine that the applicant is not qualified to receive a Federal award and the Agency may use this determination as a basis for making an award to another applicant.

4. Submission Dates and Times

Application Deadline Date: July 20, 2015.

Explanation of Deadlines: Paper applications must be postmarked and mailed, shipped, or sent overnight by July 20, 2015. The Agency will determine whether your application is late based on the date shown on the postmark or shipping invoice. You may

also hand carry your application to one of our field offices, but it must be received by close of business on the deadline date. If the due date falls on a Saturday, Sunday, or Federal holiday, the reporting package is due the next business day. Late applications are not eligible for funding and will not be evaluated further.

Electronic applications must be RECEIVED by <http://www.grants.gov> by midnight Eastern time July 14, 2015, to be eligible for funding. Please review the Grants.gov Web site at http://grants.gov/applicants/organization_registration.jsp for instructions on the process of registering your organization as soon as possible to ensure you are able to meet the electronic application deadline. Grants.gov will not accept applications submitted after the deadline.

5. Intergovernmental Review

Executive Order (EO) 12372, Intergovernmental Review of Federal Programs, applies to this program. This EO requires that Federal agencies provide opportunities for consultation on proposed assistance with State and local governments. Many States have established a Single Point of Contact (SPOC) to facilitate this consultation. A list of States that maintain a SPOC may be obtained at http://www.whitehouse.gov/omb/grants_spoc. If your State has a SPOC, you may submit your application directly for review. Any comments obtained through the SPOC must be provided to Rural Development for consideration as part of your application. If your State has not established a SPOC or you do not want to submit your application to the SPOC, Rural Development will submit your application to the SPOC or other appropriate agency or agencies.

You are also encouraged to contact Cooperative Programs at 202-690-1376 or cpgrants@wdc.usda.gov if you have questions about this process.

6. Funding Restrictions

Grant funds must be used for Technical Assistance. No funds made available under this solicitation shall be used to:

- a. Plan, repair, rehabilitate, acquire, or construct a building or facility, including a processing facility;
- b. Purchase, rent, or install fixed equipment, including processing equipment;
- c. Purchase vehicles, including boats;
- d. Pay for the preparation of the grant application;
- e. Pay expenses not directly related to the funded Project;
- f. Fund political or lobbying activities;

g. To fund any activities considered unallowable by the applicable grant cost principles, including 2 CFR part 200, subpart E and the Federal Acquisition Regulation.

h. Fund architectural or engineering design work for a specific physical facility;

i. Fund any direct expenses for the production of any commodity or product to which value will be added, including seed, rootstock, labor for harvesting the crop, and delivery of the commodity to a processing facility;

j. Fund research and development;

k. Purchase land;

l. Duplicate current activities or activities paid for by other funded grant programs.

m. Pay costs of the Project incurred prior to the date of grant approval;

n. Pay for assistance to any private business enterprise that does not have at least 51 percent ownership by those who are either citizens of the United States or reside in the United States after being legally admitted for permanent residence;

o. Pay any judgment or debt owed to the United States;

p. Pay any Operating Costs of the Cooperative, Group of Cooperatives, or Cooperative Development Center not directly related to the Project;

q. Pay expenses for applicant employee training; or

r. Pay for any goods or services from a person who has a Conflict of Interest with the grantee.

In addition, your application will not be considered for funding if it does any of the following:

- Requests more than the maximum grant amount;
- Proposes ineligible costs that equal more than 10 percent of total grant funds requested; or
- Proposes Participant Support Costs that equal more than 10 percent of total grant funds requested.

We will consider your application for funding if it includes ineligible costs of 10 percent or less of total grant funds requested, as long as it is determined eligible otherwise. However, if your application is successful, those ineligible costs must be removed and replaced with eligible costs before the Agency will make the grant award or the amount of the grant award will be reduced accordingly. If we cannot determine the percentage of ineligible costs, your application will not be considered for funding.

7. Other Submission Requirements

(a) You should not submit your application in more than one format. You must choose whether to submit

your application in hard copy or electronically. Applications submitted in hard copy should be mailed or hand-delivered to the State Office located in the State where you are headquartered. You can find State Office contact information at: <http://www.rd.usda.gov/contact-us/state-offices.your State Office>. To submit an application electronically, you must follow the instructions for this funding announcement at <http://www.grants.gov>. A password is not required to access the Web site.

(b) National Environmental Policy Act. This NOFA has been reviewed in accordance with 7 CFR part 1940, subpart G, "Environmental Program." We have determined that an Environmental Impact Statement is not required because the issuance of regulations and instructions, as well as amendments to them, describing administrative and financial procedures for processing, approving, and implementing the Agency's financial programs is categorically excluded in the Agency's National Environmental Policy Act (NEPA) regulation found at 7 CFR 1940.310(e)(3) of subpart G, "Environmental Program." We have determined that this NOFA does not constitute a major Federal action significantly affecting the quality of the human environment. Individual awards under this NOFA are hereby classified as Categorical Exclusions according to 7 CFR 1940.310(e), the award of financial assistance for planning purposes, management and feasibility studies, or environmental impact analyses, which do not require any additional documentation.

(c) Civil Rights Compliance Requirements. All grants made under this Notice are subject to Title VI of the Civil Rights Act of 1964 as required by the USDA (7 CFR part 15, subpart A) and Section 504 of the Rehabilitation Act of 1973.

E. Application Review Information

1. Scoring Criteria

All eligible and complete applications will be evaluated based on the following criteria. Failure to address any one of the following criteria by the application deadline will result in the application being determined ineligible and the application will not be considered for funding. Evaluators will base scores only on the information provided or cross-referenced by page number in each individual scoring criterion. The total points possible for the criteria are 60.

I. *Technical Assistance (maximum score of 15 points)*. A panel of USDA

employees will evaluate your application to determine your ability to assess the needs of Socially-Disadvantaged Groups. You must explain why the proposed Technical Assistance is needed and provide a detailed plan that describes your method of providing assistance. You must also identify the expected outcomes of the proposed Technical Assistance.

Higher points are awarded if you identify specific needs of the Socially-Disadvantaged Groups to be assisted; clearly explain a logical and detailed plan of assistance for addressing those needs; and discuss realistic outcomes of planned assistance.

II. *Experience (maximum score of 15 points)*. A panel of USDA employees will evaluate your length of experience for identified staff or consultants in providing Technical Assistance, as defined in this Notice. You must describe the specific type of Technical Assistance experience for each identified staff member or consultant, as well as years of experience in providing that assistance. In addition, resumes for each individual staff member or consultant must be included as an attachment, listing their experience for the type of Technical Assistance proposed. The attachments will not count toward the maximum page total. We will compare the described experience to the work plan to determine relevance of the experience. Applications that do not include the attached resumes will not be considered for funding.

Higher points will be awarded if a majority of identified staff or consultants demonstrate 5 or more years of experience in providing relevant Technical Assistance in accordance with the work plan. Maximum points will be awarded if all of the identified staff or consultants demonstrate 5 or more years of experience in providing relevant Technical Assistance.

III. *Commitment (maximum of 10 points)*. A panel of USDA employees will evaluate your commitment to providing Technical Assistance to Socially-Disadvantaged Groups in Rural Areas. You must list the number and location of Socially-Disadvantaged Groups that will directly benefit from the assistance provided. If you define and describe the underserved and economically distressed areas within your service area and provide current and relevant statistics that support your description of the service area, you will score higher on this factor.

IV. *Work Plan/Budget (maximum of 15 points)—Four page limit*. Your work plan must provide specific and detailed

descriptions of the tasks and the key project personnel that will accomplish the project's goals. Budget will be reviewed for completeness. You must list what tasks are to be done, when it will be done, who will do it, and how much it will cost. Reviewers must be able to understand what is being proposed and how the grant funds will be spent. The budget must be a detailed breakdown of estimated costs. These costs should be allocated to each of the tasks to be undertaken. The amount of grant funds requested will be reduced if the applicant does not have justification for all costs.

A panel of USDA employees will evaluate your work plan for detailed actions and an accompanying timetable for implementing the proposal. Clear, logical, realistic, and efficient plans will result in a higher score. You must discuss at a minimum:

- a. Specific tasks to be completed using grant funds;
- b. How customers will be identified;
- c. Key personnel; and
- d. The evaluation methods to be used to determine the success of specific tasks and overall project objectives. Please provide qualitative methods of evaluation. For example, evaluation methods should go beyond quantitative measurements of completing surveys or number of evaluations.

V. *Local support (maximum of 5 points)*. A panel of USDA employees will evaluate your application for local support of the Technical Assistance activities. Applicants that demonstrate strong support from potential beneficiaries and other developmental organizations will receive more points than those not showing such support.

(i) 0 points are awarded if you do not address this criterion.

(ii) 1 point is awarded if you provide 2–3 support letters that show support from potential beneficiaries and/or support from local organizations.

(iii) 2 points are awarded if you provide 4–5 support letters that show support from potential beneficiaries and/or support from local organizations.

(iv) 3 points are awarded if you provide 6–7 support letters that show support from potential beneficiaries and/or support from local organizations.

(v) 4 points are awarded if you provide 8–9 support letters that show support from potential beneficiaries and/or support from local organizations.

(vi) 5 points are awarded if you provide 10 support letters that show support from potential beneficiaries and/or support from local organizations.

You may submit a maximum of 10 letters of support. Support letters should come from potential beneficiaries and

other local organizations. Letters received from Technical Assistance providers and Congressional members will not be included in the count of support letters received. Support letters should be included as an attachment to the application and will not count against the maximum page total. Additional letters from industry groups, commodity groups, Congressional members, and similar organizations should be referenced, but not included in the application package. When referencing these letters, provide the name of the organization, date of the letter, the nature of the support, and the name and title of the person signing the letter.

2. Review and Selection Process

The State Offices will review applications to determine if they are eligible for assistance based on requirements in this Notice, and other applicable Federal regulations. If determined eligible, your application will be scored by a panel of USDA employees in accordance with the point allocation specified in this Notice. The panel will consist of USDA employees with expertise in providing Technical Assistance to Socially-Disadvantaged Groups. The review panel will convene to reach a consensus on the scores for each of the eligible applications. A recommendation will be submitted to the Administrator to fund applications in highest ranking order. Applications that cannot be fully funded may be offered partial funding at the Agency's discretion. If your application is ranked and not funded, it will not be carried forward into the next competition.

F. Federal Award Administration Information

1. Federal Award Notices

If you are selected for funding, you will receive a signed notice of Federal award by postal mail, containing instructions on requirements necessary to proceed with execution and performance of the award.

If you are not selected for funding, you will be notified in writing via postal mail and informed of any review and appeal rights. Funding of successfully appealed applications will be limited to available FY 2015 funding.

2. Administrative and National Policy Requirements

Additional requirements that apply to grantees selected for this program can be found in 7 CFR part 4284, subpart A, and 2 CFR parts 200, 215, 400, 415, 417, 418, and 421. All recipients of Federal financial assistance are required to

report information about first-tier subawards and executive compensation (See 2 CFR part 170). You will be required to have the necessary processes and systems in place to comply with the Federal Funding Accountability and Transparency Act reporting requirements (See 2 CFR 170.200(b), unless you are exempt under 2 CFR 170.110(b)). These regulations may be obtained at <http://www.gpoaccess.gov/cfr/index.html>.

The following additional requirements apply to grantees selected for this program:

- Agency approved Grant Agreement.
- Letter of Conditions.
- Form RD 1940-1, "Request for Obligation of Funds."
- Form RD 1942-46, "Letter of Intent to Meet Conditions."
- Form AD-1047, "Certification Regarding Debarment, Suspension, and Other Responsibility Matters-Primary Covered Transactions."
- Form AD-1048, "Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion-Lower Tier Covered Transactions."
- Form AD-1049, "Certification Regarding a Drug-Free Workplace Requirement (Grants)."
- Form AD-3031, "Assurance Regarding Felony Conviction or Tax Delinquent Status for Corporate Applicants." Must be signed by corporate applicants who receive an award under this Notice.
- Form RD 400-4, "Assurance Agreement."
- SF LLL, "Disclosure of Lobbying Activities," if applicable.

3. Reporting

After grant approval and through grant completion, you will be required to provide the following:

- a. A SF-425, "Federal Financial Report," and a project performance report will be required on a semiannual basis (due 30 working days after end of the semiannual period). For the purposes of this grant, semiannual periods end on March 31st and September 30th. The project performance reports shall include the following: A comparison of actual accomplishments to the objectives established for that period;
- b. Reasons why established objectives were not met, if applicable;
- c. Reasons for any problems, delays, or adverse conditions, if any, which have affected or will affect attainment of overall project objectives, prevent meeting time schedules or objectives, or preclude the attainment of particular objectives during established time periods. This disclosure shall be

accompanied by a statement of the action taken or planned to resolve the situation; and

d. Objectives and timetable established for the next reporting period.

e. Provide a final project and financial status report within 90 days after the expiration or termination of the grant.

f. Provide outcome project performance reports and final deliverables.

G. Agency Contacts

For general questions about this announcement and for program Technical Assistance, please contact the appropriate State Office as indicated in the **ADDRESSES** section of this Notice. You may also contact National Office staff: Melinda Martin, SDGG Program Lead, Melinda.C.Martin@wdc.usda.gov, or call 202-690-1376.

H. Other Information

Non Discrimination Statement

USDA prohibits discrimination against its customers, employees, and applicants for employment on the bases of race, color, national origin, age, disability, sex, gender identify, religion, reprisal, and where applicable, political beliefs, marital status, familial or parental status, sexual orientation, or all or part of an individual's income is derived from any public assistance program, or protected genetic information in employment or in any program or activity conducted or funded by the Department. (Not all prohibited bases will apply to all programs and/or employment activities.)

To File a Program Complaint

If you wish to file a Civil Rights program complaint of discrimination, complete the USDA Program Discrimination Complaint Form (PDF), found online at http://www.ascr.usda.gov/complain_filing_cust.html, or at any USDA office, or call (866) 632-9992 to request the form. You may also write a letter containing all of the information requested in the form. Send your completed complaint form or letter to us by mail at U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250-9410, by fax (202) 690-7442 or email at program.intake@usda.gov.

Persons With Disabilities

Individuals who are deaf, hard of hearing or have speech disabilities and who wish to file either an EEO or program complaint, please contact USDA through the Federal Relay

Service at (800) 877-8339 or (800) 845-6136 (in Spanish).

Persons with disabilities, who wish to file a program complaint, please see information above on how to contact us by mail directly or by email. If you require alternative means of communication for program information (e.g., Braille, large print, audiotape, etc.), please contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Dated: May 14, 2015.

Lillian Salerno,

Administrator, Rural Business-Cooperative Service.

[FR Doc. 2015-12225 Filed 5-19-15; 8:45 am]

BILLING CODE 3410-XY-P

DEPARTMENT OF AGRICULTURE

Rural Housing Service

Notice of Solicitation of Applications (NOSA) for the Section 533 Housing Preservation Grants for Fiscal Year (FY) 2015

ACTION: Notice.

SUMMARY: The Rural Housing Service (RHS), an agency within Rural Development, announces that it is soliciting competitive applications under its Housing Preservation Grant (HPG) program. This action is taken to comply with Agency regulations found in 7 CFR part 1944, subpart N, which requires the Agency to announce the opening and closing dates for receipt of pre-applications for HPG funds from eligible applicants.

DATES: The closing deadline for receipt of all pre-applications in response to this Notice is 5:00 p.m., local time for each Rural Development State Office on July 6, 2015. Rural Development State Office locations can be found at: <http://www.rd.usda.gov/contact-us/state-offices>. The application should be submitted to the Rural Development State Office where the project will be located. If submitting the pre-application in electronic format, the closing deadline for receipt is 5:00 p.m. Eastern Daylight Time on July 6, 2015. The application closing deadline is firm as to *date and hour*. RHS will not consider any application that is received after the closing deadline. Applicants intending to mail applications must provide sufficient time to permit delivery on or before the closing deadline date and time. Acceptance by the United States Postal Service or private mailer does not constitute delivery. Facsimile (FAX) and postage due applications will not be accepted.

FOR FURTHER INFORMATION CONTACT: For general information, applicants may contact Bonnie Edwards-Jackson, Finance and Loan Analyst, Multi-Family Housing Preservation and Direct Loan Division, USDA Rural Development, Stop 0781, 1400 Independence Avenue SW., Washington, DC 20250-0781, telephone (202) 690-0759 (voice) (this is not a toll free number) or (800) 877-8339 (TDD-Federal Information Relay Service) or via email at, Bonnie.Edwards@wdc.usda.gov.

SUPPLEMENTARY INFORMATION:

Overview

Federal Agency Name: USDA Rural Housing Service.

Funding Opportunity Title: Housing Preservation Grants.

Announcement Type: Notice.

Catalog of Federal Domestic

Assistance Number: 10.433.

Dates: July 6, 2015.

Paperwork Reduction Act

The reporting requirements contained in this Notice have been approved by the Office of Management and Budget under Control Number 0575-0115.

A. Program Description

The HPG program is a grant program, authorized under 42 U.S.C. 1490m and implemented at 7 CFR part 1944, subpart N, which provides qualified public agencies, private non-profit organizations including, but not limited to, faith-based and neighborhood partnerships, and other eligible entities, grant funds to assist low- and very low-income homeowners in repairing and rehabilitating their homes in rural areas. In addition, the HPG program assists rental property owners and cooperative housing complexes in rural areas in repairing and rehabilitating their units if they agree to make such units available to low- and very low-income persons.

B. Federal Award Information

The funding instrument for the HPG program will be a grant agreement. The term of the grant can vary from 1 to 2 years, depending on available funds and demand. No maximum or minimum grant levels have been established at the National level. In accordance with 7 CFR 1944.652, coordination and leveraging of funding for repair and rehabilitation activities with housing and community development organizations or activities operating in the same geographic area are expected, but not required. You should contact the Rural Development State Office to determine the allocation. HPG applicants who were previously

selected for HPG funds are eligible to submit new applications to apply for FY 2015 HPG program funds. New HPG applications must be submitted for the renewal or supplementation of existing HPG repair and/or rehabilitation projects that will be completed with FY 2015 HPG funds.

For Fiscal Year 2015, the amount of funding available for the HPG Program can be found at the following link: <http://www.rd.usda.gov/newsroom/notices-solicitation-applications-nosas#nosa>. Priorities such as Rural Economic Area Partnership Zones and other funds will be distributed under a formula allocation to states pursuant to 7 CFR part 1940, subpart L, "Methodology and Formulas for Allocation of Loan and Grant Program Funds." Decisions on funding will be based on pre-application scores. Anyone interested in submitting an application for funding under this program is encouraged to consult the Rural Development Web site periodically for updated information regarding the status of funding authorized for this program.

The commitment of program dollars will be made to selected applicants that have fulfilled the necessary requirements for obligation.

C. Eligibility Information

1. *Eligible Applicants.* Eligible entities for these competitively awarded grants include state and local governments, non-profit corporations, which may include, but not be limited to faith-based and community organizations, Federally recognized Indian tribes, and consortia of eligible entities. HPG applicants who were previously selected for HPG funds are eligible to submit new applications to apply for FY 2015 HPG program funds. More eligibility requirements can be found at 7 CFR 1944.658, 1944.661, and 1944.662.

2. *Cost Sharing or Matching.* Pursuant to 7 CFR 1944.652, grantees are expected to coordinate and leverage funding for repair and rehabilitation activities, as well as replacement housing, with housing and community development organizations or activities operating in the same geographic area. While HPG funds may be leveraged with other resources, cost sharing or matching is not a requirement that the HPG applicant do so as the HPG applicant would not be denied an award of HPG funds if all other project selection criteria have been met.

3. *Other.* Awards made under this Notice are subject to the provisions contained in the Consolidated and Further Appropriations Act 2015, Public

Law 113–235, sections 738 and 739 regarding corporate felony convictions and corporate Federal tax delinquencies. To comply with these provisions, only selected applicants that are or propose to be corporations will submit this form as part of their pre-application. Form AD–3030 can be found here: <http://www.ocio.usda.gov/document/ad3030>.

D. Application and Submission Information

1. *Address to Request Application Package.* Applicants wishing to submit a paper application in response to this Notice must contact the Rural Development State Office serving the state of the proposed HPG housing project in order to receive further information and copies of the paper application package. You may find the addresses and contact information for each state office following this web link, <http://www.rd.usda.gov/contact-us/state-offices>. Rural Development will date and time stamp incoming paper applications to evidence timely receipt and, upon request, will provide the applicant with a written acknowledgment of receipt. You may access the electronic grant pre-application for Housing Preservation Grants at: <http://www.grants.gov>.

2. *Content and Form of Application:* 7 CFR part 1944, subpart N provides details on what information must be contained in the pre-application package. Entities wishing to apply for assistance should contact the Rural Development State Office to receive further information, the State allocation of funds, and copies of the pre-application package. Unless otherwise noted, applicants wishing to apply for assistance must make its statement of activities available to the public for comment. The applicant(s) must announce the availability of its statement of activities for review in a newspaper of general circulation in the project area and allow at least 15 days for public comment. The start of this 15-day period must occur no later than 16 days prior to the last day for acceptance of pre-applications by USDA Rural Development. Federally recognized Indian tribes, pursuant to 7 CFR 1944.674, are exempt from the requirement to consult with local leaders including announcing the availability of its statement of activities for review in a newspaper.

All applicants will file an original and two copies of Standard Form (SF) 424, “Application for Federal Assistance,” and supporting information with the appropriate Rural Development State Office. A pre-application package,

including SF–424, is available in any Rural Development State Office. All pre-applications shall be accompanied by the following information which Rural Development will use to determine the applicant’s eligibility to undertake the HPG program and to evaluate the pre-application under the project selection criteria of 7 CFR 1944.679.

(a) A statement of activities proposed by the applicant for its HPG program as appropriate to the type of assistance the applicant is proposing, including:

(1) A complete discussion of the type of and conditions for financial assistance for housing preservation, including whether the request for assistance is for a homeowner assistance program, a rental property assistance program, or a cooperative assistance program;

(2) The process for selecting recipients for HPG assistance, determining housing preservation needs of the dwelling, performing the necessary work, and monitoring/inspecting work performed;

(3) A description of the process for identifying potential environmental impacts in accordance with 7 CFR 1944.672 and the provisions for compliance with Stipulation I, A–G of the Programmatic Memorandum of Agreement, also known as PMOA, (RD Instruction 2000–FF, available in any Rural Development State Office) in accordance with 7 CFR 1944.673(b);

(4) The development standard(s) the applicant will use for the housing preservation work; and, if not the Rural Development standards for existing dwellings, the evidence of its acceptance by the jurisdiction where the grant will be implemented;

(5) The time schedule for completing the program;

(6) The staffing required to complete the program;

(7) The estimated number of very low- and low-income minority and nonminority persons the grantee will assist with HPG funds; and, if a rental property or cooperative assistance program, the number of units and the term of restrictive covenants on their use for very low- and low-income;

(8) The geographical area(s) to be served by the HPG program;

(9) The annual estimated budget for the program period based on the financial needs to accomplish the objectives outlined in the proposal. The budget should include proposed direct and indirect administrative costs, such as personnel, fringe benefits, travel, equipment, supplies, contracts, and other cost categories, detailing those costs for which the grantee proposes to use the HPG grant separately from non-

HPG resources, if any. The applicant budget should also include a schedule (with amounts) of how the applicant proposes to draw HPG grant funds, *i.e.*, monthly, quarterly, lump sum for program activities, etc.;

(10) A copy of an indirect cost proposal when the applicant has another source of Federal funding in addition to the Rural Development HPG program;

(11) A brief description of the accounting system to be used;

(12) The method of evaluation to be used by the applicant to determine the effectiveness of its program which encompasses the requirements for quarterly reports to Rural Development in accordance with 7 CFR 1944.683(b) and the monitoring plan for rental properties and cooperatives (when applicable) according to 7 CFR 1944.689;

(13) The source and estimated amount of other financial resources to be obtained and used by the applicant for both HPG activities and housing development and/or supporting activities;

(14) The use of program income, if any, and the tracking system used for monitoring same;

(15) The applicant’s plan for disposition of any security instruments held by them as a result of its HPG activities in the event of its loss of legal status;

(16) Any other information necessary to explain the proposed HPG program; and

(17) The outreach efforts outlined in 7 CFR 1944.671(b).

(b) Complete information about the applicant’s experience and capacity to carry out the objectives of the proposed HPG program.

(c) Evidence of the applicant’s legal existence, including, in the case of a private non-profit organization, which may include, but not be limited to, faith-based and community organizations, a copy of, or an accurate reference to, the specific provisions of State law under which the applicant is organized; a certified copy of the applicant’s Articles of Incorporation and Bylaws or other evidence of corporate existence; certificate of incorporation for other than public bodies; evidence of good standing from the State when the corporation has been in existence 1 year or more; and the names and addresses of the applicant’s members, directors and officers. If other organizations are members of the applicant-organization, or the applicant is a consortium, pre-applications should be accompanied by the names, addresses, and principal purpose of the other organizations. If the

applicant is a consortium, documentation showing compliance with paragraph (4)(ii) under the definition of "organization" in 7 CFR 1944.656 must also be included.

(d) For a private non-profit entity, which may include, but not be limited to, faith-based and community organizations, the most recent audited statement and a current financial statement dated and signed by an authorized officer of the entity showing the amounts and specific nature of assets and liabilities together with information on the repayment schedule and status of any debt(s) owed by the applicant.

(e) A brief narrative statement which includes information about the area to be served and the need for improved housing (including both percentage and the actual number of both low-income and low-income minority households and substandard housing), the need for the type of housing preservation assistance being proposed, the anticipated use of HPG resources for historic properties, the method of evaluation to be used by the applicant in determining the effectiveness of its efforts.

(f) A statement containing the component for alleviating any overcrowding as defined by 7 CFR 1944.656.

(g) Applicant must submit an original and one copy of Form RD 1940–20, "Request for Environmental Information," prepared in accordance with Exhibit F–1 of RD Instruction 1944–N (available in any Rural Development State Office).

(h) Applicant must also submit a description of its process for:

(1) Identifying and rehabilitating properties listed on or eligible for listing on the National Register of Historic Places;

(2) Identifying properties that are located in a floodplain or wetland;

(3) Identifying properties located within the Coastal Barrier Resources System; and

(4) Coordinating with other public and private organizations and programs that provide assistance in the rehabilitation of historic properties (Stipulation I, D, of the PMOA, RD Instruction 2000–FF, available as an electronic document and in any Rural Development State Office).

(i) The applicant must also submit evidence of the State Historic Preservation Office's, (SHPO), concurrence in the proposal, or in the event of non-concurrence, a copy of SHPO's comments together with evidence that the applicant has received the Advisory Council on Historic

Preservation's advice as to how the disagreement might be resolved, and a copy of any advice provided by the Council.

(j) The applicant must submit written statements and related correspondence reflecting compliance with 7 CFR 1944.674(a) and (c) regarding consultation with local government leaders in the preparation of its program and the consultation with local and state government pursuant to the provisions of Executive Order 12372.

(k) The applicant is to make its statement of activities available to the public for comment prior to submission to Rural Development pursuant to 7 CFR 1944.674(b). The application must contain a description of how the comments (if any were received) were addressed.

(l) The applicant must submit an original and one copy of Form RD 400–1, "Equal Opportunity Agreement," and Form RD 400–4, "Assurance Agreement," in accordance with 7 CFR 1944.676.

Applicants should review 7 CFR part 1944, subpart N for a comprehensive list of all application requirements.

3. *Address unique entity identifier and System for Award Management (SAM).* As part of the application, all applicants, except for individuals or agencies excepted under 2 CFR 25.110(d), must be: (1) Registered in the System for Award Management (SAM); (2) provide a valid unique entity identifier in its applications; and (3) maintain an active SAM registration with current information at all times during which it has an active Federal award or application. An award may not be made to the applicant until the applicant has complied with the unique entity identifier and SAM requirements.

4. *Intergovernmental Review Intergovernmental Review.* The HPG program is subject to the provisions of Executive Order 12372, which requires intergovernmental consultation with State and local officials.

5. *Funding Restrictions.* There are no limits on proposed direct and indirect costs. Expenses incurred in developing pre-applications will be at the applicant's risk.

6. *Other Submission Requirements.* To comply with the President's Management Agenda, the Department of Agriculture is participating as a partner in the Government-wide Grants.gov site. Housing Preservation Grants [Catalog of Federal Domestic Assistance #10.433] is one of the programs included at this Web site. If you are an applicant under the Housing Preservation Grant program, you may submit your pre-application to the Agency in either

electronic or paper format. Please be mindful that the pre-application deadline for electronic format differs from the deadline for paper format. The electronic format deadline will be based on Eastern Standard Time. The paper format deadline is local time for each Rural Development State Office.

Users of Grants.gov will be able to download a copy of the pre-application package, complete it off line, and then upload and submit the application via the Grants.gov site. You may not email an electronic copy of a grant pre-application to USDA Rural Development; however, the Agency encourages your participation in Grants.gov.

The following are useful tips and instructions on how to use the Web site:

- When you enter the Grants.gov site, you will find information about submitting an application electronically through the site as well as the hours of operation. USDA Rural Development strongly recommends that you do not wait until the application deadline date to begin the application process through Grants.gov. To use Grants.gov, applicants must have a DUNS number.

- You may submit all documents electronically through the Web site, including all information typically included on the Application for Rural Housing Preservation Grants, and all necessary assurances and certifications.

- After you electronically submit your application through the Web site, you will receive an automatic acknowledgement from Grants.gov that contains a Grants.gov tracking number.

- RHS may request that you provide original signatures on forms at a later date.

- If you experience technical difficulties on the closing date and are unable to meet the 5:00 p.m. (Eastern Standard Time) deadline, print out your application and submit it to your State Office, you must meet the closing date and local time deadline.

- Please note that you must locate the downloadable application package for this program by the CFDA Number or FedGrants Funding Opportunity Number, which can be found at <http://www.grants.gov>.

In addition to the electronic pre-application at the <http://www.grants.gov> Web site, all applicants must complete and submit the Fiscal Year 2015 pre-application package, detailed later in this Notice, for Section 533 HPG. A copy of a suggested coversheet is included with this Notice. Applicants are encouraged to submit this pre-application coversheet electronically by accessing the Web site: <http://www.rd.usda.gov/programs-services/>

housing-preservation-grants. Click on the Forms & Resources tab to access the “Fiscal Year 2015 Pre-application for Section 533 Housing Preservation Grants (HPG).”

Applicants are encouraged but not required, to also provide an electronic copy of all hard copy forms and documents submitted in the pre-application/application package as requested by this Notice. The forms and documents must be submitted as read-only Adobe Acrobat PDF files on an electronic media such as CDs, DVDs or USB drives. For each electronic device that you submit, you must include a Table of Contents listing all of the documents and forms on that device. The electronic medium must be submitted to the local Rural Development State Office where the project will be located.

Please Note: If you receive a loan or grant award under this Notice, USDA reserves the right to post all information that is not protected by the Privacy Act submitted as part of the pre-application/application package on a public Web site with free and open access to any member of the public.

E. Application Review Information

1. *Criteria.* All paper applications for Section 533 funds must be filed with the appropriate Rural Development State Office and all paper or electronic applications must meet the requirements of this Notice and 7 CFR part 1944, subpart N. Pre-applications determined not eligible and/or not meeting the selection criteria will be notified by the Rural Development State Office.

2. *Review and Selection Process.* The Rural Development State Offices will utilize the following threshold project selection criteria for applicants in accordance with 7 CFR 1944.679:

(a) Providing a financially feasible program of housing preservation assistance. “Financially feasible” is defined as proposed assistance which will be affordable to the intended recipient or result in affordable housing for very low- and low-income persons.

(b) Serving eligible rural areas with a concentration of substandard housing for households with very low- and low-income.

(c) Being an eligible applicant as defined in 7 CFR 1944.658.

(d) Meeting the requirements of consultation and public comment in accordance with 7 CFR 1944.674.

(e) Submitting a complete pre-application as outlined in 7 CFR 1944.676.

3. *Scoring.* For applicants meeting all of the requirements listed above, the Rural Development State Offices will

use weighted criteria in accordance with 7 CFR part 1944, subpart N as selection for the grant recipients. Each pre-application and its accompanying statement of activities will be evaluated and, based solely on the information contained in the pre-application, the applicant’s proposal will be numerically rated on each criteria within the range provided. The highest-ranking applicant(s) will be selected based on allocation of funds available to the state.

(a) Points are awarded based on the percentage of very low-income persons that the applicant proposes to assist, using the following scale:

- (1) More than 80%: 20 points
- (2) 61% to 80%: 15 points
- (3) 41% to 60%: 10 points
- (4) 20% to 40%: 5 points
- (5) Less than 20%: 0 points

(b) The applicant’s proposal may be expected to result in the following percentage of HPG fund use (excluding administrative costs) to total cost of unit preservation. This percentage reflects maximum repair or rehabilitation with the least possible HPG funds due to leveraging, innovative financial assistance, owner’s contribution or other specified approaches. Points are awarded based on the following percentage of HPG funds (excluding administrative costs) to total funds:

- (1) 50% or less: 20 points
- (2) 51% to 65%: 15 points
- (3) 66% to 80%: 10 points
- (4) 81% to 95%: 5 points
- (5) 96% to 100%: 0 points

(c) The applicant has demonstrated its administrative capacity in assisting very low- and low-income persons to obtain adequate housing based on the following:

(1) The organization or a member of its staff has at least one or more years experience successfully managing and operating a rehabilitation or weatherization type program: 10 points.

(2) The organization or a member of its staff has at least one or more years experience successfully managing and operating a program assisting very low- and low-income persons obtain housing assistance: 10 points.

(3) If the organization has administered grant programs, there are no outstanding or unresolved audit or investigative findings which might impair carrying out the proposal: 10 points.

(d) The proposed program will be undertaken entirely in rural areas outside Metropolitan Statistical Areas, also known as MSAs, identified by Rural Development as having populations below 10,000 or in remote parts of other rural areas (*i.e.*, rural areas

contained in MSAs with less than 5,000 population) as defined in 7 CFR 1944.656: 10 points.

(e) The program will use less than 20 percent of HPG funds for administration purposes:

- (1) More than 20%: Not eligible
- (2) 20%: 0 points
- (3) 19%: 1 point
- (4) 18%: 2 points
- (5) 17%: 3 points
- (6) 16%: 4 points
- (7) 15% or less: 5 points

(f) The proposed program contains a component for alleviating overcrowding as defined in 7 CFR 1944.656: 5 points.

In the event more than one pre-application receives the same amount of points, those pre-applications will then be ranked based on the actual percentage figure used for determining the points. Further, in the event that pre-applications are still tied, then those pre-applications still tied will be ranked based on the percentage for HPG fund use (low to high). Further, for applications where assistance to rental properties or cooperatives is proposed, those still tied will be further ranked based on the number of years the units are available for occupancy under the program (a minimum of 5 years is required). For this part, ranking will be based from most to least number of years.

Finally, if there is still a tie, then a lottery system will be used. After the award selections are made, all applicants will be notified of the status of their applications by mail.

F. Federal Award Administration Information

1. *Federal Award Notices.* The Agency will notify, in writing, applicants whose pre-applications have been selected for funding. At the time of notification, the Agency will advise the applicant what further information and documentation is required along with a timeline for submitting the additional information. If the Agency determines it is unable to select the application for funding, the applicant will be so informed in writing. Such notification will include the reasons the applicant was not selected. The Agency will advise applicants, whose pre-applications did not meet eligibility and/or selection criteria, of their review rights or appeal rights in accordance with 7 CFR 1944.682.

2. *Administrative and National Policy Requirements.* Rural Development is encouraging applications for projects that will support rural areas where, according to the American Community Survey data by census tracts, at least 20

percent of the population is living in persistent poverty. This emphasis will support Rural Development's mission of improving the quality of life for Rural Americans and commitment to directing resources to those who most need them. A persistent poverty county is a classification for counties in the United States that have had a relatively high rate of poverty over a long period.

3. *Reporting.* Post-award reporting requirements can be found in the Grant Agreement.

G. Non-Discrimination Statement

The U.S. Department of Agriculture (USDA) prohibits discrimination against its customers, employees, and applicants for employment on the basis of race, color, national origin, age, disability, sex, gender identity, religion, reprisal and where applicable, political beliefs, marital status, familial or parental status, religion, sexual orientation, or all or part of an individual's income is derived from any public assistance program, or protected genetic information in employment or in any program or activity conducted or funded by the Department. (Not all prohibited bases will apply to all programs and/or employment activities.)

If you wish to file a Civil Rights program complaint of discrimination, complete the USDA Program Discrimination Complaint Form (PDF), found online at http://www.ascr.usda.gov/complaint_filing_cust.html, or at any USDA office, or call (866) 632-9992 to request the form. You may also write a letter containing all of the information requested in the form. Send your completed complaint form or letter to us by mail at U.S. Department of Agriculture, Director, Office of Adjudication, 1400 Independence Avenue SW., Washington, DC 20250-9410, by fax (202) 690-7442 or email at program.intake@usda.gov.

Individuals who are deaf, hard of hearing or have speech disabilities and you wish to file either an EEO or program complaint please contact USDA through the Federal Relay Service at (800) 877-8339 or (800) 845-6136 (in Spanish).

Persons with disabilities, who wish to file a program complaint, please see information above on how to contact us by mail directly or by email. If you require alternative means of communication for program information (e.g., Braille, large print, audiotape, etc.) please contact USDA's TARGET Center at (202) 720-2600 (voice and TDD).

Dated: May 14, 2015.

Tony J. Hernandez,

Administrator, Rural Housing Service.

Fiscal Year 2015 Pre-application for Section 533 Housing Preservation Grants (HPG) Instructions

Applicants are encouraged, but not required, to submit this pre-application form electronically by accessing the Web site: <http://www.rd.usda.gov/programs-services/housing-preservation-grants>. Click on the Forms & Resources tab to access the "Fiscal Year 2015 Pre-application for Section 533 Housing Preservation Grants (HPG)." Please note that electronic submittals are not on a secured Web site. If you do not wish to submit the form electronically by clicking on the Send Form button, you may still fill out the form, print it and submit it with your application package to the State Office. You also have the option to save the form, and submit it on an electronic media to the State Office.

Supporting documentation required by this pre-application may be attached to the email generated when you click the Send Form button to submit the form. However if the attachments are too numerous or large in size, the email box will not be able to accept them. In that case, submit the supporting documentation for this pre-application to the State Office with your complete application package under item IX.

Documents Submitted, indicate the supporting documents that you are submitting either with the pre-application or to the State Office.

I. Applicant Information

a. Applicant's Name: _____

b. Applicant's Address: _____

Address, Line 1: _____

Address, Line 2: _____

City: _____ State: _____ Zip: _____

c. Name of Applicant's Contact Person: _____

d. Contact Person's Telephone Number: _____

e. Contact Person's Email Address: _____

f. Entity Type: State Government

Local Government

(Check One) Non-Profit

Corporation Federally

Recognized Indian Tribes

Faith-Based and neighborhood partnership

Community Organization

Other consortia of an eligible entity

II. Project Information

a. Project Name: _____

b. Project Address: _____

Address, Line 1: _____

Address, Line 2: _____

City: _____ State: _____ Zip: _____

c. Organization DUNS number: _____

d. Grant Amount Requested: _____

e. This grant request is for one of the following types of assistance:

- Homeowner assistance program
 Rental property assistance program
 Cooperative assistance program

f. In response to e. above, answer one of the following:

The number of low- and very-low income persons that the grantee will assist in the Homeowner assistance program: O OR

The number of units for low- and very-low income persons in the Rental property or Cooperative assistance program: _____

g. This proposal is for one of the following:

- Housing Preservation Grant (HPG) program (no set-aside)
 Set-aside for Grant located in a Rural Economic Area Partnership (REAP) zone

III. Low-income Assistance

Check the percentage of very low-income persons that this pre-application proposes to assist in relation to the total population of the project:

- More than 80 percent (20 points)
 61 percent to 80 percent (15 points)
 41 percent to 60 percent (10 points)
 20 percent to 40 percent (5 points)
 Less than 20 percent (0 points)
 Points: _____

IV. Percent of HPG Fund Use

Check the percentage of HPG fund use (excluding administrative costs) in comparison to the total cost of unit preservation. This percentage reflects maximum repair or rehabilitation results with the least possible HPG funds due to leveraging, innovative financial assistance, owner's contribution or other specified approaches.

- 50 percent or less of HPG Funds (20 points)
 51 percent to 65 percent of HPG Funds (15 points)
 66 percent to 80 percent of HPG Funds (10 points)
 81 percent to 95 percent of HPG Funds (5 points)
 96 percent to 100 percent of HPG Funds (0 points)
 Points: _____

V. Administrative Capacity

The following three criteria demonstrate your administrative

capacity to assist very low- and low-income persons to obtain adequate housing (30 points maximum).

a. Does this organization or a member of its staff have at least one or more years of experience successfully managing and operating a rehabilitation or weatherization type of program? (10 points) Yes ___ N No ___ P Points: ___

b. Does this organization or a member of its staff have at least one or more years of experience successfully managing and operating a program assisting very low- or low-income persons obtain housing assistance? (10 points) Yes ___ N No ___ P Points: ___

c. If this organization has administered grant programs, are there any outstanding or unresolved audit or investigative findings which might impair carrying out the proposal? (10 points for No) No ___ Y Yes ___ P Points: ___

If Yes, please explain:

VI. Area Served

Will this proposal be undertaken entirely in rural areas outside Metropolitan Statistical Areas, also known as MSAs, and identified by Rural Development as having populations below 10,000 or in remote parts of other rural areas (i.e., rural areas contained in MSAs with a population of less than 5,000) as defined in 7CFR 1944.656? (10 points) Yes ___ N No ___ P Points: ___

VII. Percent of HPG Funds for Administration

Check the percentage of HPG funds that will be used for Administration purposes:

- More than 20 percent (Not eligible)
 - 20 percent (0 points)
 - 19 percent (1 point)
 - 18 percent (2 points)
 - 17 percent (3 points)
 - 16 percent (4 points)
 - 15 percent or less (5 points)
- Points: ___

VIII. Alleviating Overcrowding

Does the proposed program contain a component for alleviating overcrowding as defined in 7 CFR 1944.656? (5 points) Yes ___ N No ___ P Points: ___

IX. Documents Submitted

Check if the following documents are being submitted electronically with this pre-application or will be mailed to the State Office with your complete pre-application package.

NOTE: You are only required to submit supporting documents for programs in which you will be participating as indicated in this pre-application. Points will be assigned for the items that you checked based on a review of the supporting documents.

Please refer to the NOSA for the complete list of documents that you are required to submit with your complete pre-application package.

Reference	Item	Submitted with this Pre-application	Submitted to state office
III	Low Income Assistance.		
IV	Percent of HPG Fund Use.		
V	Administrative Capacity.		
VI	Area Served.		
VII	Percent of HPG Funds for Administration.		
VIII	Alleviating Overcrowding.		

G. HPG 2015 Scoring

PLEASE NOTE: The scoring below is based on the responses that you have provided on this pre-application form

and may not accord with the final score that the Agency assigns upon evaluating the supporting documentation that you submit. Your score may change from

what you see here if the supporting documentation does not adequately support your answer or, if required documentation is missing.

Scoring items for HPG 2015	Points earned
1. Low Income Assistance (5, 10, 15, 20)
2. Percent of HPG Fund Use (5, 10, 15, 20)
3. Administrative Capacity (10, 20, 30)
4. Area Served (10)
5. Percent of HPG Funds for Administration (1, 2, 3, 4, 5)
6. Alleviating Overcrowding (5)
Total Score:	

Important
 By submitting this electronic pre-application form and its supporting documents, you have completed one step of the application process.
 You **must** also complete the electronic application at the <http://www.grants.gov> website.
 Your complete package, with all forms and supporting documents as listed in the NOSA, must be submitted to the local Rural Development State Office where the project is located for your application to be processed.

[FR Doc. 2015-12224 Filed 5-19-15; 8:45 am]

BILLING CODE 3410-XV-P

COMMISSION ON CIVIL RIGHTS**Agenda and Notice of Public Meeting of the New York Advisory Committee****AGENCY:** 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 planning meeting of the New York Advisory Committee to the Commission will convene at 12:00 p.m. (EDT) on Friday, June 12, 2015, at the law offices of Sullivan & Cromwell, 125 Broad Street, New York, NY 10004. The purpose of the planning meeting is for the Advisory Committee to discuss plans to conduct a public meeting on the over-policing of communities of color in New York.

DATES: Friday, June 12, 2015, at 12:00 p.m. EDT.**ADDRESSES:** The meeting will be held at the at law offices of Sullivan & Cromwell, 125 Broad Street, New York, NY 10004.**FOR FURTHER INFORMATION CONTACT:**Barbara de la Viez at bdelaviez@usccr.gov or call 202-376-7533.

SUPPLEMENTARY INFORMATION: Members of the public are invited to make statement during the open comment period at the end of the meeting. Members of the public may also submit written comments for the record. The comments must be received in the regional office by Monday, July 13, 2015. Written comments may be mailed to the Eastern Regional Office, U.S. Commission on Civil Rights, 1331 Pennsylvania Avenue, Suite 1150, Washington, DC 20425, faxed to (202) 376-7548, or emailed to Evelyn Bohor at ero@usccr.gov. Persons who desire additional information may contact the Eastern Regional Office at (202) 376-7533.

Persons needing accessibility services should contact the Eastern Regional Office at least ten (10) working days before the scheduled meeting date. Please contact Evelyn Bohor at ero@usccr.gov.

Records and documents discussed during the meeting will be available for public viewing as they become available at <http://facadatabase.gov/committee/meetings.aspx?cid=265> and clicking on the "Meeting Details" and "Documents" links. Records generated from this meeting may also be inspected and reproduced at the Eastern Regional Office, as they become available, both before and after the meeting. Persons

interested in the work of this advisory committee are advised to go to the Commission's Web site, www.usccr.gov, or to contact the Eastern Regional Office at the above phone number, email or street address.

Agenda

Welcome and Introductions
Alexandra D. Korry, Chair
Discussion of Plans for the Public Meeting on Over-Policing of Communities of Color in New York
New York Advisory Committee
Administrative Matters
Barbara de la Viez, DFO
Open comment
Adjournment

Dated: May 15, 2015.

David Mussatt,*Chief, Regional Programs Unit.*

[FR Doc. 2015-12161 Filed 5-19-15; 8:45 am]

BILLING CODE 6335-01-P**COMMISSION ON CIVIL RIGHTS****Agenda and Notice of Public Meeting of the Wyoming Advisory Committee****AGENCY:** 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 planning meeting of the Wyoming Advisory Committee to the Commission will convene at 10:00 a.m. (MDT) on Thursday, June 11, 2015, via teleconference. The purpose of the planning meeting is for the Advisory Committee to discuss civil rights issues in the state and select issues for further study.

DATES: Thursday, June 11, 2015, at 10:00 a.m. (MDT)**ADDRESSES:** To be held via teleconference:

Conference Call Toll-Free Number: 1-888-523-1228; Conference ID: 6982953.

TDD: Dial Federal Relay Service 1-800-977-8339 and give the operator the above conference call number and conference ID.

FOR FURTHER INFORMATION CONTACT:Malee V. Craft, DFO, mcraft@usccr.gov, 303-866-1040.

SUPPLEMENTARY INFORMATION: Members of the public may listen to the discussion by dialing the following Conference Call Toll-Free Number: 1-888-523-1228, Conference ID: 6982953. An open comment period will be provided to allow members of the public to make a statement at the end of

the meeting. Please be advised that before being placed into the conference call, the operator will ask callers to provide their names, their organizational affiliations (if any), and an email address (if available) prior to placing callers into the conference room. Callers can expect to incur charges for calls they initiate over wireless lines, and the Commission will not refund any incurred charges. Callers will incur no charge for calls they initiate over land-line connections to the toll-free phone number.

Persons with hearing impairments may also follow the discussion by first calling the Federal Relay Service (FRS) at 1-800-977-8339 and provide the FRS operator with the Conference Call Toll-Free Number: 1-888-523-1228; Conference ID: 6982953.

Members of the public are invited to submit written comments; the comments must be received in the regional office by Monday, July 13, 2015. Written comments may be mailed to the Rocky Mountain Regional Office, U.S. Commission on Civil Rights, 1961 Stout Street, Suite 13-201, Denver, CO 80294, faxed to (303) 866-1040, or emailed to Evelyn Bohor at ebohor@usccr.gov. Persons who desire additional information may contact the Rocky Mountain Regional Office at (303) 866-1040.

Records and documents discussed during the meeting will be available for public viewing as they become available at <http://facadatabase.gov/committee/meetings.aspx?cid=283> and clicking on the "Meeting Details" and "Documents" links. Records generated from this meeting may also be inspected and reproduced at the Rocky Mountain Regional Office, as they become available, both before and after the meeting. Persons interested in the work of this advisory committee are advised to go to the Commission's Web site, www.usccr.gov, or to contact the Rocky Mountain Regional Office at the above phone number, email or street address.

Agenda

Welcome and Introductions
Sleeter Dover, Chair
Civil Rights Discussion and Select Issues for Further Study
Wyoming State Advisory Committee
Administrative Matters
Malee V. Craft, Designated Federal Official (DFO)
Open Comment

Dated: May 15, 2015.

David Mussatt,*Chief, Regional Programs Unit.*

[FR Doc. 2015-12162 Filed 5-19-15; 8:45 am]

BILLING CODE 6335-01-P

DEPARTMENT OF COMMERCE**Bureau of the Census**

[Docket Number 150409353–5353–01]

2020 Decennial Census Residence Rule and Residence Situations**AGENCY:** Bureau of the Census, Department of Commerce.**ACTION:** Notice and Request for Comment.

SUMMARY: The Bureau of the Census (U.S. Census Bureau) requests public comment on the 2010 Census Residence Rule and Residence Situations. The Residence Rule is applied to living situations to determine where people should be counted during the decennial Census. Specific Residence Situations have been included with the Residence Rule to illustrate how the Rule is applied. The Census Bureau is currently reviewing the 2010 Residence Rule and Residence Situations, to determine if changes should be made to the Rule and/or if the situations should be updated for the 2020 Census. The Census Bureau anticipates publishing the final 2020 Census Residence Rule and Residence Situations in late 2017.

DATES: To ensure consideration during the decision-making process, comments must be received by July 20, 2015. The Census Bureau anticipates publishing a summary of comments received in response to this **Federal Register** notice in late 2015. The Census Bureau will then publish the final 2020 Census Residence Rule and Residence Situations in late 2017.

ADDRESSES: Direct all written comments regarding the 2010 Census Residence Rule and Residence Situations to Karen Humes, Chief, Population Division, U.S. Census Bureau, Room 5H174, Washington, DC 20233; or Email [POP.2020.Residence.Rule@census.gov].

FOR FURTHER INFORMATION CONTACT: Population and Housing Programs Branch, U.S. Census Bureau, 6H185, Washington, DC 20233, telephone (301) 763–2381; or Email [POP.2020.Residence.Rule@census.gov].

SUPPLEMENTARY INFORMATION:**A. Background**

The Census Bureau is committed to counting every person in the 2020 Census. Just as important, however, is the Census Bureau's commitment to counting every person in the correct place. The fundamental reason that the decennial census is conducted is to fulfill the Constitutional requirement (Article I, Section 2) to apportion the seats in the U.S. House of

Representatives among the states. Thus, for a fair and equitable apportionment, it is crucial that people are counted in the right place during the 2020 Census.

The Census Act of 1790 established the concept of "usual residence" as the main principle in determining where people are to be counted. This concept has been followed in all subsequent censuses. Usual residence has been defined as the place where a person lives and sleeps most of the time. This place is not necessarily the same as the person's voting residence or legal residence.

Every decade the Census Bureau undertakes a review of the decennial residence rule guidance to ensure that the concept of usual residence is interpreted and applied in the decennial census as intended, and that these interpretations are in keeping with the intent of law, which directs the Census Bureau to enumerate people at their usual residence. This review also serves as an opportunity to identify new or changing living situations resulting from societal change, and create or revise the residence rule guidance where those situations are concerned.

Determining usual residence is straightforward for most people. However, given our Nation's wide diversity in types of living arrangements, the usual residence for some people is not as apparent. A few examples are people experiencing homelessness, people with a seasonal/second residence, people in prisons, people in the process of moving, people in hospitals, children in shared custody arrangements, college students, live-in employees, military personnel, and people who live in workers' dormitories. For these "residence situations," the Census Bureau has provided guidance on how to interpret the usual residence concept to determine where to count those people.

The Census Bureau is requesting public comment on the 2010 Residence Rule (section "B") and on the 2010 Residence Situations (section "B," numbers 1–21, including all subparagraphs under each numbered section) to determine if changes should be made to the Rule and/or if the situations should be updated for the 2020 Census. The 2010 Residence Rule and Residence Situations are described in the next sections of this **Federal Register** notice.

B. The Residence Rule and Residence Situations for the 2010 Census of the United States

The Residence Rule was used to determine where people should be

counted during the 2010 Census. The Rule said:

- Count people at their usual residence, which is the place where they live and sleep most of the time.
- People in certain types of facilities or shelters (*i.e.*, places where groups of people live together) on Census Day should be counted at the facility or shelter.
- People who do not have a usual residence, or cannot determine a usual residence, should be counted where they are on Census Day.

The following sections describe how the Residence Rule applied for people in various living situations.

1. People Away From Their Usual Residence on Census Day

a) People away from their usual residence on Thursday, April 1, 2010 (Census Day), such as on a vacation or a business trip, visiting, traveling outside the U.S., or working elsewhere without a usual residence there (for example, as a truck driver or traveling salesperson)—Counted at the residence where they live and sleep most of the time.

2. Visitors on Census Day

a) Visitors on Thursday, April 1, 2010 (Census Day), who will return to their usual residence—Counted at the residence where they live and sleep most of the time.

b) Citizens of foreign countries who are visiting the U.S. on Thursday, April 1, 2010 (Census Day), such as on a vacation or a business trip—Not counted in the census.

3. People Who Live in More Than One Place

(a) People living away most of the time while working, such as people who live at a residence close to where they work and return regularly to another residence—Counted at the residence where they live and sleep most of the time. If there is no residence where they live and sleep most of the time, they are counted where they live and sleep more than anywhere else. If time is equally divided, or if usual residence cannot be determined, they are counted at the residence where they are staying on Thursday, April 1, 2010 (Census Day).

(b) People who live at two or more residences (during the week, month, or year), such as people who travel seasonally between residences (for example, snowbirds)—Counted at the residence where they live and sleep most of the time. If there is no residence where they live and sleep most of the time, they are counted where they live and sleep more than anywhere else. If

time is equally divided, or if usual residence cannot be determined, they are counted at the residence where they are staying on Thursday, April 1, 2010 (Census Day).

(c) *Children in shared custody or other arrangements who live at more than one residence*—Counted at the residence where they live and sleep most of the time. If time is equally divided, they are counted at the residence where they are staying on Thursday, April 1, 2010 (Census Day).

4. People Without a Usual Residence

(a) *People who cannot determine a usual residence*—Counted where they are staying on Thursday, April 1, 2010 (Census Day).

(b) *People at soup kitchens and regularly scheduled mobile food vans*—Counted at the residence where they live and sleep most of the time. If they do not have a place they live and sleep most of the time, they are counted at the soup kitchen or mobile food van location where they are on Thursday, April 1, 2010 (Census Day).

(c) *People at targeted non-sheltered outdoor locations*—Counted at the outdoor location where people experiencing homelessness stay without paying.

5. Students

(a) *Boarding school students living away from their parental home while attending boarding school below the college level, including Bureau of Indian Affairs boarding schools*—Counted at their parental home rather than at the boarding school.

(b) *College students living at their parental home while attending college*—Counted at their parental home.

(c) *College students living away from their parental home while attending college in the U.S. (living either on-campus or off-campus)*—Counted at the on-campus or off-campus residence where they live and sleep most of the time.

(d) *College students living away from their parental home while attending college in the U.S. (living either on-campus or off-campus) but staying at their parental home while on break or vacation*—Counted at the on-campus or off-campus residence where they live and sleep most of the time.

(e) *U.S. college students living outside the U.S. while attending college outside the U.S.*—Not counted in the census.

(f) *Foreign students living in the U.S. while attending college in the U.S. (living either on-campus or off-campus)*—Counted at the on-campus or off-campus residence where they live and sleep most of the time.

6. Movers on Census Day

(a) *People who move into a residence on Thursday, April 1, 2010 (Census Day), who have not been listed on a questionnaire for any residence*—Counted at the residence they move into on Census Day.

(b) *People who move out of a residence on Thursday, April 1, 2010 (Census Day), and have not moved into a new residence on Thursday, April 1, 2010, and who have not been listed on a questionnaire for any residence*—Counted at the residence from which they moved.

(c) *People who move out of a residence or move into a residence on Thursday, April 1, 2010 (Census Day), who have already been listed on a questionnaire for any residence*—If they have already been listed on one questionnaire, do not list them on any other questionnaire.

7. People Who Are Born or Die on Census Day

(a) *Babies born on or before 11:59:59 p.m. on Thursday, April 1, 2010 (Census Day)*—Counted at the residence where they will live and sleep most of the time, even if they are still in the hospital on April 1, 2010 (Census Day).

(b) *Babies born after 11:59:59 p.m. on Thursday, April 1, 2010 (Census Day)*—Not counted in the census.

(c) *People who die before Thursday, April 1, 2010 (Census Day)*—Not counted in the census.

(d) *People who die on Thursday, April 1, 2010 (Census Day)*—Counted in the census if they are alive at any time on April 1, 2010.

8. Nonrelatives of the Householder

(a) *Roomers or boarders*—Counted at the residence where they live and sleep most of the time.

(b) *Housemates or roommates*—Counted at the residence where they live and sleep most of the time.

(c) *Unmarried partners*—Counted at the residence where they live and sleep most of the time.

(d) *Foster children or foster adults*—Counted at the residence where they live and sleep most of the time.

(e) *Live-in employees, such as caregivers or domestic workers*—Counted at the residence where they live and sleep most of the time.

9. U.S. Military Personnel

(a) *U.S. military personnel living in military barracks in the U.S.*—Counted at the military barracks.

(b) *U.S. military personnel living in the U.S. (living either on base or off base) but not in barracks*—Counted at

the residence where they live and sleep most of the time.

(c) *U.S. military personnel on U.S. military vessels with a U.S. homeport*—Counted at the onshore U.S. residence where they live and sleep most of the time. If they have no onshore U.S. residence, they are counted at their vessel's homeport.

(d) *People in military disciplinary barracks and jails in the U.S.*—Counted at the facility.

(e) *People in military treatment facilities with assigned active duty patients in the U.S.*—Counted at the facility if they are assigned there.

(f) *U.S. military personnel living on or off a military installation outside the U.S., including dependents living with them*—Counted as part of the U.S. overseas population. They should not be included on any U.S. census questionnaire.

(g) *U.S. military personnel on U.S. military vessels with a homeport outside the U.S.*—Counted as part of the U.S. overseas population. They should not be included on any U.S. census questionnaire.

10. Merchant Marine Personnel on U.S. Flag Maritime/Merchant Vessels

(a) *Crews of U.S. flag maritime/merchant vessels docked in a U.S. port or sailing from one U.S. port to another U.S. port on Thursday, April 1, 2010 (Census Day)*—Counted at the onshore U.S. residence where they live and sleep most of the time. If they have no onshore U.S. residence, they are counted at their vessel. If the vessel is docked in a U.S. port, crew members with no onshore U.S. residence are counted at the port. If the vessel is sailing from one U.S. port to another U.S. port, crew members with no onshore U.S. residence are counted at the port of departure.

(b) *Crews of U.S. flag maritime/merchant vessels engaged in U.S. inland waterway transportation on Thursday, April 1, 2010 (Census Day)*—Counted at the onshore residence where they live and sleep most of the time.

(c) *Crews of U.S. flag maritime/merchant vessels docked in a foreign port, sailing from one foreign port to another foreign port, sailing from a U.S. port to a foreign port, or sailing from a foreign port to a U.S. port on Thursday, April 1, 2010 (Census Day)*—Not counted in the census.

11. Foreign Citizens in the U.S.

(a) *Citizens of foreign countries living in the U.S.*—Counted at the U.S. residence where they live and sleep most of the time.

(b) *Citizens of foreign countries living in the U.S. who are members of the diplomatic community*—Counted at the embassy, consulate, United Nations' facility, or other residences where diplomats live.

(c) *Citizens of foreign countries visiting the U.S., such as on a vacation or business trip*—Not counted in the census.

12. *U.S. Citizens and Their Dependents Living Outside the U.S.*

(a) *U.S. citizens living outside the U.S. who are employed as civilians by the U.S. Government, including dependents living with them*—Counted as part of the U.S. overseas population. They should not be included on any U.S. census questionnaire.

(b) *U.S. citizens living outside the U.S. who are not employed by the U.S. Government, including dependents living with them*—Not counted in the census.

(c) *U.S. military personnel living on or off a military installation outside the U.S., including dependents living with them*—Counted as part of the U.S. overseas population. They should not be included on any U.S. census questionnaire.

(d) *U.S. military personnel on U.S. military vessels with a homeport outside the U.S.*—Counted as part of the U.S. overseas population. They should not be included on any U.S. census questionnaire.

13. *People in Correctional Facilities for Adults*

(a) *People in correctional residential facilities on Thursday, April 1, 2010 (Census Day)*—Counted at the facility.

(b) *People in federal detention centers on Thursday, April 1, 2010 (Census Day)*—Counted at the facility.

(c) *People in federal and state prisons on Thursday, April 1, 2010 (Census Day)*—Counted at the facility.

(d) *People in local jails and other municipal confinement facilities on Thursday, April 1, 2010 (Census Day)*—Counted at the facility.

14. *People in Group Homes and Residential Treatment Centers for Adults*

(a) *People in group homes intended for adults (non-correctional)*—Counted at the facility.

(b) *People in residential treatment centers for adults (non-correctional)*—Counted at the residence where they live and sleep most of the time. If they do not have a residence where they live and sleep most of the time, they are counted at the facility.

15. *People in Health Care Facilities*

(a) *Patients in general or Veterans Affairs hospitals (except psychiatric units) on Thursday, April 1, 2010 (Census Day), including newborn babies still in the hospital on Census Day*—Counted at the residence where they live and sleep most of the time. Newborn babies should be counted at the residence where they will live and sleep most of the time.

(b) *People in hospitals on Thursday, April 1, 2010 (Census Day), who have no usual home elsewhere*—Counted at the facility.

(c) *People staying in in-patient hospice facilities on Thursday, April 1, 2010 (Census Day)*—Counted at the residence where they live and sleep most of the time. If they do not have a residence where they live and sleep most of the time, they are counted at the facility.

(d) *People in mental (psychiatric) hospitals and psychiatric units for long-term non-acute care in other hospitals on Thursday, April 1, 2010 (Census Day)*—Counted at the facility.

(e) *People in nursing facilities/skilled nursing facilities on Thursday, April 1, 2010 (Census Day)*—Counted at the facility.

16. *People in Juvenile Facilities*

(a) *People in correctional facilities intended for juveniles on Thursday, April 1, 2010 (Census Day)*—Counted at the facility.

(b) *People in group homes for juveniles (non-correctional) on Thursday, April 1, 2010 (Census Day)*—Counted at the facility.

(c) *People in residential treatment centers for juveniles (non-correctional) on Thursday, April 1, 2010 (Census Day)*—Counted at the facility.

17. *People in Residential School-Related Facilities*

(a) *People in college/university student housing*—Counted at the college/university student housing.

(b) *Boarding school students living away from their parental home while attending boarding school below the college level, including Bureau of Indian Affairs boarding schools*—Counted at their parental home rather than at the boarding school.

(c) *People in residential schools for people with disabilities on Thursday, April 1, 2010 (Census Day)*—Counted at the school.

18. *People in Shelters*

(a) *People in emergency and transitional shelters (with sleeping facilities) on Thursday, April 1, 2010*

(Census Day), for people experiencing homelessness—Counted at the shelter.

(b) *People in living quarters for victims of natural disasters*—Counted at the residence where they live and sleep most of the time. If they do not have a residence where they live and sleep most of the time, they are counted at the facility.

(c) *People in domestic violence shelters on Thursday, April 1, 2010 (Census Day)*—Counted at the shelter.

19. *People in Transitory Locations*

(a) *People at transitory locations such as recreational vehicle (RV) parks, campgrounds, hotels and motels (including those on military sites), hostels, marinas, racetracks, circuses, or carnivals*—Counted at the residence where they live and sleep most of the time. If there is no residence where they live and sleep most of the time, they are counted where they live and sleep more than anywhere else. If time is equally divided, or if usual residence cannot be determined, they are counted at the place where they are staying on Thursday, April 1, 2010 (Census Day).

20. *People in Religious-Related Residential Facilities*

(a) *People in religious group quarters such as convents and monasteries*—Counted at the residence where they live and sleep most of the time. If they do not have a residence where they live and sleep most of the time, they are counted at the facility.

21. *People in Workers' Residential Facilities*

(a) *People in workers' group living quarters and Job Corps Centers*—Counted at the residence where they live and sleep most of the time. If they do not have a residence where they live and sleep most of the time, they are counted at the facility.

Dated: May 13, 2015.

John H. Thompson,

Director, Bureau of the Census.

[FR Doc. 2015-12118 Filed 5-19-15; 8:45 am]

BILLING CODE 3510-07-P

DEPARTMENT OF COMMERCE

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Institute of Standards and Technology (NIST).

Title: Manufacturing Extension Partnership (MEP) Management Information Reporting.

OMB Control Number: 0693-0032.

Form Number(s): None.

Type of Request: Regular Submission.

Number of Respondents: 60.

Average Hours Per Response: 160.

Burden Hours: 9,600.

Needs and Uses: NIST MEP offers technical and business assistance to small- and medium-sized manufacturers. This is a major program which links all 50 states and Puerto Rico and the manufacturers through more than 400 affiliated MEP Centers and Field Offices. NIST MEP has a number of legislative and contractual requirements for collecting data and information from the MEP Centers. This information is used for the following purposes: (1) Program Accountability,

(2) Reports to Stakeholders, (3) Continuous Improvement; and (4) Identification of Distinctive Practices.

Affected Public: Business or other for-profit organizations.

Frequency: Quarterly, Bi-yearly, Yearly.

Respondent's Obligation: Required to obtain or retain benefits.

Copies of the above information collection proposal can be obtained by calling or writing Jennifer Jessup, Departmental Paperwork Clearance Officer, (202) 482-0336, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at JJessup@doc.gov).

This information collection request may be viewed at www.reginfo.gov. Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to OIRA *Submission@omb.eop.gov* or fax to (202) 975-5806.

Dated: May 15, 2015.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2015-12177 Filed 5-19-15; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B-01-2015]

Foreign-Trade Zone (FTZ) 174—Pima County, Arizona; Authorization of Production Activity; Global Solar Energy, Inc. (Thin Film Photovoltaic Solar Products); Tucson, Arizona

On January 14, 2015, Tucson Regional Economic Opportunities, Inc., grantee of FTZ 174, submitted a notification of proposed production activity to the Foreign-Trade Zones (FTZ) Board on behalf of Global Solar Energy, Inc. (Global Solar), located in Tucson, Arizona. A separate application for subzone designation at the Global Solar facility is planned and will be processed under Section 400.38 of the FTZ Board's regulations.

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 3952, 01-26-2015). The production activity described in the notification is authorized for a period of five years (until May 14, 2020), subject to the FTZ Act and the Board's regulations, including Section 400.14.

Dated: May 14, 2015.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2015-12249 Filed 5-19-15; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

Bureau Of Industry And Security

In the Matter of: Joseph DeBose, 400 S. Ortonville Road, Ortonville, Michigan 48462; Order Denying Export Privileges

On July 19, 2013, in the U.S. District Court for the Eastern District of New York, Joseph DeBose ("DeBose"), was convicted of violating Section 38 of the Arms Export Control Act (22 U.S.C. 2778 (2012)) ("AECA"). Specifically, DeBose knowingly and willfully exported from the United States to China firearms and firearms barrels, including a Beretta 9mm semi-automatic handgun, which were designated as defense articles on the United States Munitions List, without first obtaining the required license or written approval from the State Department. DeBose was sentenced to 24 months of imprisonment, three years of supervised release, and fined a \$100 assessment.

Section 766.25 of the Export Administration Regulations ("EAR" or "Regulations")¹ provides, in pertinent part, that "[t]he Director of the Office of Exporter Services, in consultation with the Director of the Office of Export Enforcement, may deny the export privileges of any person who has been convicted of a violation of the Export Administration Act ("EAA"), the EAR, or any order, license or authorization issued thereunder; any regulation, license, or order issued under the International Emergency Economic Powers Act (50 U.S.C. 1701-1706); 18 U.S.C. 793, 794 or 798; section 4(b) of the Internal Security Act of 1950 (50 U.S.C. 783(b)), or section 38 of the Arms Export Control Act (22 U.S.C. 2778)." 15 CFR 766.25(a); *see also* Section 11(h) of the EAA, 50 U.S.C. app. § 2410(h). The denial of export privileges under this provision may be for a period of up to 10 years from the date of the conviction. 15 CFR 766.25(d); *see also* 50 U.S.C. app. § 2410(h). In addition, Section 750.8 of the Regulations states that the Bureau of Industry and Security's Office of Exporter Services may revoke any Bureau of Industry and Security ("BIS") licenses previously issued in which the person had an interest in at the time of his conviction.

BIS has received notice of DeBose's conviction for violating the AECA, and has provided notice and an opportunity for DeBose to make a written submission to BIS, as provided in Section 766.25 of the Regulations. BIS has not received a submission from DeBose.

Based upon my review and consultations with BIS's Office of Export Enforcement, including its Director, and the facts available to BIS, I have decided to deny DeBose's export privileges under the Regulations for a period of 10 years from the date of DeBose's conviction. I have also decided to revoke all licenses issued pursuant to the Act or Regulations in which DeBose had an interest at the time of his conviction.

Accordingly, it is hereby *ordered*:

First, from the date of this Order until July 19, 2023, Joseph DeBose, with a last

¹ The Regulations are currently codified in the Code of Federal Regulations at 15 CFR parts 730-774 (2015). The Regulations issued pursuant to the Export Administration Act (50 U.S.C. app. §§ 2401-2420 (2000)) ("EAA"). Since August 21, 2001, the EAA has been in lapse and the President, through Executive Order 13222 of August 17, 2001 (3 CFR, 2001 Comp. 783 (2002)), which has been extended by successive Presidential Notices, the most recent being that of August 7, 2014 (79 FR 46959 (August 11, 2014)), has continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701, *et seq.* (2006 & Supp. IV 2010)).

known address of 400 S. Ortonville Road, Ortonville, Michigan 48462, and when acting for or on his behalf, his successors, assigns, employees, agents or representatives (the “Denied Person”), may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as “item”) exported or to be exported from the United States that is subject to the Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, License Exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations.

Second, no person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of the Denied Person any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by the Denied Person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the Denied Person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the Denied Person of any item subject to the Regulations that has been exported from the United States;

D. Obtain from the Denied Person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the Denied Person, or service any item, of whatever origin, that is owned, possessed or

controlled by the Denied Person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Third, after notice and opportunity for comment as provided in Section 766.23 of the Regulations, any other person, firm, corporation, or business organization related to DeBose by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order in order to prevent evasion of this Order.

Fourth, in accordance with Part 756 of the Regulations, DeBose may file an appeal of this Order with the Under Secretary of Commerce for Industry and Security. The appeal must be filed within 45 days from the date of this Order and must comply with the provisions of Part 756 of the Regulations.

Fifth, a copy of this Order shall be delivered to the DeBose. This Order shall be published in the **Federal Register**.

Sixth, this Order is effective immediately and shall remain in effect until July 19, 2023.

Issued this 11 day of May, 2015.

Karen H. Nies-Vogel,

Director, Office of Exporter Services.

[FR Doc. 2015–12195 Filed 5–19–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

Bureau Of Industry And Security In the Matter of: Wei Jiun Chu, a/k/a Jim Chu, 1530 Silver Rain Drive, Diamond Bar, CA 91765; Order Denying Export Privileges

On August 25, 2014, in the U.S. District Court for the District of Arizona, Wei Jiun Chu, a/k/a Jim Chu (“Chu”), was convicted of violating Section 38 of the Arms Export Control Act (22 U.S.C. 2778 (2012)) (“AECA”). Specifically, Chu knowingly and willfully exported from the United States to Taiwan 40 radiation-hardened adjustable positive voltage regulators, which were designated as defense articles from Category XV(e) of the United States Munitions List, without having first obtained from the United States Department of State, Directorate of Defense Trade Controls, a license for such export or written authorization for such export. Chu was sentenced to 36 months of probation, with no

confinement time and a \$100 assessment.

Section 766.25 of the Export Administration Regulations (“EAR” or “Regulations”)¹ provides, in pertinent part, that “[t]he Director of the Office of Exporter Services, in consultation with the Director of the Office of Export Enforcement, may deny the export privileges of any person who has been convicted of a violation of the Export Administration Act (“EAA”), the EAR, or any order, license or authorization issued thereunder; any regulation, license, or order issued under the International Emergency Economic Powers Act (50 U.S.C. 1701–1706); 18 U.S.C. 793, 794 or 798; section 4(b) of the Internal Security Act of 1950 (50 U.S.C. 783(b)), or section 38 of the Arms Export Control Act (22 U.S.C. 2778).” 15 CFR 766.25(a); *see also* Section 11(h) of the EAA, 50 U.S.C. app. § 2410(h). The denial of export privileges under this provision may be for a period of up to 10 years from the date of the conviction. 15 CFR 766.25(d); *see also* 50 U.S.C. app. § 2410(h). In addition, Section 750.8 of the Regulations states that the Bureau of Industry and Security’s Office of Exporter Services may revoke any Bureau of Industry and Security (“BIS”) licenses previously issued in which the person had an interest in at the time of his conviction.

BIS has received notice of Chu’s conviction for violating the AECA, and has provided notice and an opportunity for Chu to make a written submission to BIS, as provided in Section 766.25 of the Regulations. BIS has not received a submission from Chu.

Based upon my review and consultations with BIS’s Office of Export Enforcement, including its Director, and the facts available to BIS, I have decided to deny Chu’s export privileges under the Regulations for a period of 10 years from the date of Chu’s conviction. I have also decided to revoke all licenses issued pursuant to the Act or Regulations in which Chu had an interest at the time of his conviction.

Accordingly, it is hereby *ordered*:

First, from the date of this Order until August 25, 2024, Wei Jiun Chu, a/k/a

¹ The Regulations are currently codified in the Code of Federal Regulations at 15 CFR parts 730–774 (2015). The Regulations issued pursuant to the Export Administration Act (50 U.S.C. app. §§ 2401–2420 (2000)) (“EAA”). Since August 21, 2001, the EAA has been in lapse and the President, through Executive Order 13222 of August 17, 2001 (3 CFR, 2001 Comp. 783 (2002)), which has been extended by successive Presidential Notices, the most recent being that of August 7, 2014 (79 FR 46959 (August 11, 2014)), has continued the Regulations in effect under the International Emergency Economic Powers Act (50 U.S.C. 1701, *et seq.* (2006 & Supp. IV 2010)).

Jim Chu, with a last known address of 1530 Silver Rain Drive, Diamond Bar, CA 91765, and when acting for or on his behalf, his successors, assigns, employees, agents or representatives (the "Denied Person"), may not, directly or indirectly, participate in any way in any transaction involving any commodity, software or technology (hereinafter collectively referred to as "item") exported or to be exported from the United States that is subject to the Regulations, including, but not limited to:

A. Applying for, obtaining, or using any license, License Exception, or export control document;

B. Carrying on negotiations concerning, or ordering, buying, receiving, using, selling, delivering, storing, disposing of, forwarding, transporting, financing, or otherwise servicing in any way, any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations; or

C. Benefitting in any way from any transaction involving any item exported or to be exported from the United States that is subject to the Regulations, or in any other activity subject to the Regulations.

Second, no person may, directly or indirectly, do any of the following:

A. Export or reexport to or on behalf of the Denied Person any item subject to the Regulations;

B. Take any action that facilitates the acquisition or attempted acquisition by the Denied Person of the ownership, possession, or control of any item subject to the Regulations that has been or will be exported from the United States, including financing or other support activities related to a transaction whereby the Denied Person acquires or attempts to acquire such ownership, possession or control;

C. Take any action to acquire from or to facilitate the acquisition or attempted acquisition from the Denied Person of any item subject to the Regulations that has been exported from the United States;

D. Obtain from the Denied Person in the United States any item subject to the Regulations with knowledge or reason to know that the item will be, or is intended to be, exported from the United States; or

E. Engage in any transaction to service any item subject to the Regulations that has been or will be exported from the United States and which is owned, possessed or controlled by the Denied Person, or service any item, of whatever origin, that is owned, possessed or

controlled by the Denied Person if such service involves the use of any item subject to the Regulations that has been or will be exported from the United States. For purposes of this paragraph, servicing means installation, maintenance, repair, modification or testing.

Third, after notice and opportunity for comment as provided in Section 766.23 of the Regulations, any other person, firm, corporation, or business organization related to Chu by ownership, control, position of responsibility, affiliation, or other connection in the conduct of trade or business may also be made subject to the provisions of this Order in order to prevent evasion of this Order.

Fourth, in accordance with Part 756 of the Regulations, Chu may file an appeal of this Order with the Under Secretary of Commerce for Industry and Security. The appeal must be filed within 45 days from the date of this Order and must comply with the provisions of Part 756 of the Regulations.

Fifth, a copy of this Order shall be delivered to the Chu. This Order shall be published in the **Federal Register**.

Sixth, this Order is effective immediately and shall remain in effect until August 25, 2024.

Issued this 13 day of May, 2015.

Karen H. Nies-Vogel,

Director, Office of Exporter Services.

[FR Doc. 2015-12194 Filed 5-19-15; 8:45 am]

BILLING CODE P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-580-874]

Certain Steel Nails From the Republic of Korea: Final Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce ("the Department") determines that imports of certain steel nails ("nails") from the Republic of Korea ("Korea") are being sold in the United States at less than fair value ("LTFV"), as provided in section 735 of the Tariff Act of 1930, as amended (the "Act"). The final weighted-average dumping margins of sales at LTFV are listed below in the section entitled "Final Determination Margins."

DATES: *Effective Date:* May 20, 2015.

FOR FURTHER INFORMATION CONTACT: Krisha Hill or Drew Jackson, 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) 482-4037 or (202) 482-4406, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 29, 2014, the Department published in the **Federal Register** the preliminary determination in the LTFV investigation of nails from Korea.¹ In the *Preliminary Determination*, we postponed the final determination until no later than 135 days after the date of publication of the *Preliminary Determination* in accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii) and invited parties to comment on our *Preliminary Determination*.

The following events have occurred since the *Preliminary Determination*. Between January 6, 2015, and February 13, 2015, the Department conducted sales and cost verifications of both respondents, Jinheung Steel Corporation ("Jinheung Steel") and Daejin Steel ("Daejin"), as well as the sales verification of Jinheung Steel's affiliate, Illinois Tool Works Inc. ("ITW"). On January 28, 2015, Jinheung Steel requested a hearing. On March 27, 2015, Jinheung Steel, Daejin, ITW, and Mid Continent Steel & Wire, Inc. ("Petitioner") submitted case briefs. On April 2, 2015, Daejin and Petitioner submitted rebuttal case briefs. On April 8, 2015, Jinheung Steel withdrew its hearing request. No hearing was held in this investigation.

Period of Investigation

The period of investigation ("POI") is April 1, 2013, through March 31, 2014.

Scope of the Investigation

The product covered by this investigation is certain steel nails from Malaysia. For a full description of the scope of the investigation, see Appendix I to this notice.

Since the *Preliminary Determination*, several interested parties (*i.e.*, IKEA Supply AG, The Home Depot, Target Corporation, and Petitioner) commented on the scope of these investigations. The Department reviewed these comments and made certain changes. For further discussion, see the Issues and Decision

¹ See *Certain Steel Nails From the Republic of Korea: Affirmative Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination*, 79 FR 78051 (December 29, 2014) (*Preliminary Determination*).

Memorandum.² The scope in Appendix I reflects all modifications to the scope made by the Department for this final determination.

Verification

As provided in section 782(i) of the Act and 19 CFR 351.307(b)(1)(i), from January 2015 through February 2015, we verified the sales and cost information submitted by Jinheung Steel and Daejin, as well as sales information submitted by ITW, for use in our final determination. We used standard verification procedures including an examination of relevant accounting and production records, and original source documents provided by Jinheung Steel, Daejin, and ITW.³

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties in this investigation are addressed in the Issues and Decision Memorandum accompanying this notice, and which is hereby adopted by this notice.⁴ A list of the issues raised and to which the

² See Memorandum to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, from Howard Smith, Acting Office Director, Enforcement and Compliance, Office IV, regarding "Certain Steel Nails From the Republic of Korea: Issues and Decision Memorandum for the Final Determination of Sales at Less Than Fair Value" (Issues and Decision Memorandum), dated concurrently with this determination and hereby adopted by this notice.

³ See Memorandum to the File from Robert Bolling and Drew Jackson, AD/CVD Operations, Office IV, through Charles Riggle, Senior International Trade Compliance Analyst, AD/CVD Operations, Office IV, regarding "Verification of the Sales Questionnaire Responses of Illinois Tool Works: Antidumping Duty Investigation of Certain Steel Nails from Korea" (March 10, 2015); see also Memorandum to the File from Drew Jackson and Krishna Hill, AD/CVD Operations, Office IV, through Robert Bolling, Program Manager, AD/CVD Operations, Office IV, regarding "Verification of the Sales Questionnaire Responses of Daejin Steel: Antidumping Duty Investigation of Certain Steel Nails from the Republic of Korea" (March 11, 2015); see also Memorandum to the File from Ji Young Oh and Kristin Case, Senior Accountants, through Taija Slaughter, Lead Accountant, and Neal M. Halper, Office Director, regarding "Verification of the Cost Response of Daejin Steel Company in the Antidumping Duty Investigation of Certain Steel Nails from Korea" (March 12, 2015); see also Memorandum to the File from Ji Young Oh and Kristin Case, Senior Accountants, through Taija Slaughter, Lead Accountant, and Neal M. Halper, Office Director, regarding "Verification of the Cost Response of Jinheung Steel Corporation in the Antidumping Duty Investigation of Certain Steel Nails from the Republic of Korea" (March 12, 2015); see also Memorandum to the File from Drew Jackson and Krishna Hill, AD/CVD Operations, Office IV, through Robert Bolling, Program Manager, AD/CVD Operations, Office IV, regarding "Verification of the Sales Questionnaire Responses of Jinheung Steel Corporation: Antidumping Duty Investigation of Certain Steel Nails from the Republic of Korea" (March 19, 2015).

⁴ See Issues and Decision Memorandum.

Department responded is attached to this notice as Appendix II. 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>. The memorandum is available to all parties in the Central Records Unit, room 7046 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <http://enforcement.trade.gov>. The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Changes to the Margin Calculations Since the Preliminary Determination

Based on a review of the record and comments received from interested parties regarding our *Preliminary Determination*, we made the following changes to the margin calculations for Jinheung Steel and Daejin:

For Daejin:

- We used an updated sales database submitted by Daejin which reflects minor corrections and findings from the sales verification.⁵
- We adjusted U.S. price for domestic brokerage and handling charges incurred in U.S. dollars ("DBROK2U").⁶
- We used Jinheung Steel's business proprietary home market financial information as the data source to calculate Daejin's CV profit and selling expense.⁷
- We corrected the programming error related to the calculation of total cost of manufacturing ("TOTCOM") for certain control numbers ("CONNUMs").⁸

For Jinheung Steel:

⁵ See Letter from Daejin to the Department, regarding "Certain Steel Nails from Korea; Submission of Daejin Steel Company's Revised U.S. Sales Database," dated March 26, 2015.

⁶ See Issues and Decision Memorandum at comment 1; see also Memorandum from Krishna Hill, International Trade Compliance Analyst, to Robert Bolling, Program Manager, regarding "Analysis Memorandum for the Final Determination of the Antidumping Duty Investigation of Certain Steel Nails from the Republic of Korea: Daejin Steel," dated May 13, 2015.

⁷ See Issues and Decision Memorandum at comment 4; see also Memorandum from Ji Young Oh, Senior Accountant, to Neal M. Halper, Director, Office of Accounting, regarding "Cost of Production and Constructed Value Calculation Adjustments for the Final Determination—Daejin Steel," dated May 13, 2015 ("Daejin Steel Cost Calculation Memorandum").

⁸ See Issues and Decision Memorandum at comment 3; see also Daejin Steel Cost Calculation Memorandum.

- We assigned a single manufacturer code to all home-market and U.S. sales based on our determination to treat Jinheung Steel, Duo-Fast Korea Co. Ltd. ("DFK"), and Jinsco International Corporation ("Jinsco") as a single entity.⁹

- We used updated sales and cost databases submitted by Jinheung Steel and ITW, which reflect minor corrections presented during the verification of these companies.¹⁰
- We revised certain reported product characteristics to reflect changes found during verification of ITW's response.¹¹
- We disallowed Jinheung Steel's duty drawback offset.¹²
- We adjusted Jinheung Steel's reported scrap offset.¹³
- We recalculated Jinheung Steel's general and administrative and financial expenses so that they reflect our adjustment to Jinheung Steel's reported scrap offset.¹⁴
- We reversed an adjustment to Jinheung Steel's reported costs involving work in process that we made at the *Preliminary Determination*.¹⁵

Final Determination Margins

The Department determines that the following weighted-average dumping margins exist for the period April 1, 2013, through March 31, 2014:

⁹ See Issues and Decision Memorandum at comment 5; see also Memorandum to the File from Drew Jackson, International Trade Analyst, AD/CVD Operations Office IV through Robert Bolling, Program Manager, AD/CVD Operations Office IV, regarding "Analysis Memorandum for the Final Determination of the Antidumping Duty Investigation of Certain Steel Nails from the Republic of Korea: Jinheung Steel Corporation and Affiliates" dated May 13, 2015 ("Jinheung Steel Analysis Memorandum").

¹⁰ See Letter from Jinheung Steel to the Department, regarding "Antidumping Investigation of Certain Steel Nails from Korea—Response of Jinheung Steel Corporation, Jinsco International Corporation, and Duo-Fast Korea Co., Ltd. to March 4 Request for Revised Cost Data Files," dated March 9, 2015; see also Letter from Jinheung Steel to the Department, regarding "Antidumping Investigation of Certain Steel Nails from Korea—Response of Jinheung Steel Corporation, Jinsco International Corporation, and Duo-Fast Korea Co., Ltd. to March 20 Request for Revised Sales Data Files," dated March 23, 2015; see also Letter from ITW to the Department, regarding "Certain Steel Nails from Korea: Revised U.S. Sales Databases of Illinois Tool Works Inc.," dated March 23, 2015.

¹¹ See Jinheung Steel Analysis Memorandum.

¹² See Jinheung Steel Analysis Memorandum.

¹³ See Issues and Decision Memorandum at comment 8; see also Jinheung Steel Analysis Memorandum; see also Memorandum to the File regarding "Cost of Production and Constructed Value Calculation Adjustments for the Final Determination—Jinheung Steel Corporation," dated May 13, 2015 ("Jinheung Steel Cost Calculation Memorandum").

¹⁴ See Jinheung Steel Analysis Memo; see also Jinheung Steel Cost Calculation Memorandum.

¹⁵ See Issues and Decision Memorandum at comment 9; see also Jinheung Steel Analysis Memo and Jinheung Steel Cost Calculation Memorandum.

Exporter or producer	Weighted-average dumping margin (percent)
Daejin Steel	11.80
Jinheung Steel Corporation	0.00
Duo-Fast Korea Co., Ltd	
Jinsco International Corporation	
All Others	11.80

All Others Rate

Section 735(c)(5)(A) of the Act provides that the estimated “All Others” rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero or *de minimis* margins, and any margins determined entirely under section 776 of the Act. The weighted-average margin for exporters and producers individually investigated that meets these criteria is that of Daejin. Therefore, the All-Others rate is the rate calculated for Daejin, as indicated in the “Final Determination Margins” section above.

Disclosure

We will disclose to parties in this proceeding the calculations performed for this final determination within five days of the date of public announcement of our final determination, in accordance with 19 CFR 351.224(b).

Suspension of Liquidation

Pursuant to section 735(c)(1)(B) of the Act, the Department will instruct U.S. Customs and Border Protection (“CBP”) to continue to suspend liquidation of all of entries of certain steel nails from Korea, except as noted below, which were entered, or withdrawn from warehouse, for consumption on or after December 29, 2014, the date of publication of the *Preliminary Determination*. For the Jinheung Steel Single Entity, which includes Jinheung Steel, Duo-Fast Korea Co., Ltd., and Jinsco International Corporation, because this entity’s estimated weighted-average final dumping margin is zero, we are directing CBP to terminate suspension of liquidation of entries of certain steel nails produced and exported by this entity.

Pursuant to CFR 351.210(d), we will instruct CBP to require a cash deposit equal to the weighted-average amount by which normal value exceeds U.S. price, as follows: (1) The rate for Daejin will be the rate we determined in this final determination; (2) if the exporter is not a firm identified in this investigation but the producer is, the

rate will be the rate established for the producer of the subject merchandise; and (3) the rate for all other producers or exporters will be 11.80 percent. These suspension of liquidation instructions will remain in effect until further notice.

International Trade Commission Notification

In accordance with section 735(d) of the Act, we notified the U.S. International Trade Commission (“ITC”) of our final determination. As our final determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will determine within 45 days whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports or sales (or the likelihood of sales) for importation of the subject merchandise. If the ITC determines that such injury exists, the Department will issue an antidumping duty order directing CBP to assess, upon further instruction by the Department, antidumping duties on appropriate imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation.

Return or Destruction of Proprietary Information

This notice will serve as a reminder to parties subject to administrative protective order (“APO”) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this determination and notice in accordance with sections 735(d) and 777(i)(1) of the Act.

Dated: May 13, 2015.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix I—Scope of the Investigation

The merchandise covered by this investigation is certain steel nails having a nominal shaft length not exceeding 12 inches.¹⁶ Certain steel nails include, but are

¹⁶ The shaft length of certain steel nails with flat heads or parallel shoulders under the head shall be measured from under the head or shoulder to the tip of the point. The shaft length of all other certain steel nails shall be measured overall.

not limited to, nails made from round wire and nails that are cut from flat-rolled steel. Certain steel nails may be of one piece construction or constructed of two or more pieces. Certain steel nails may be produced from any type of steel, and may have any type of surface finish, head type, shank, point type and shaft diameter. Finishes include, but are not limited to, coating in vinyl, zinc (galvanized, including but not limited to electroplating or hot dipping one or more times), phosphate, cement, and paint. Certain steel nails may have one or more surface finishes. Head styles include, but are not limited to, flat, projection, cupped, oval, brad, headless, double, countersunk, and sinker. Shank styles include, but are not limited to, smooth, barbed, screw threaded, ring shank and fluted. Screw-threaded nails subject to this proceeding are driven using direct force and not by turning the nail using a tool that engages with the head. Point styles include, but are not limited to, diamond, needle, chisel and blunt or no point. Certain steel nails may be sold in bulk, or they may be collated in any manner using any material.

Excluded from the scope of this investigation are certain steel nails packaged in combination with one or more non-subject articles, if the total number of nails of all types, in aggregate regardless of size, is less than 25. If packaged in combination with one or more non-subject articles, certain steel nails remain subject merchandise if the total number of nails of all types, in aggregate regardless of size, is equal to or greater than 25, unless otherwise excluded based on the other exclusions below.

Also excluded from the scope are certain steel nails with a nominal shaft length of one inch or less that are (a) a component of an unassembled article, (b) the total number of nails is sixty (60) or less, and (c) the imported unassembled article falls into one of the following eight groupings: 1) builders’ joinery and carpentry of wood that are classifiable as windows, French-windows and their frames; 2) builders’ joinery and carpentry of wood that are classifiable as doors and their frames and thresholds; 3) swivel seats with variable height adjustment; 4) seats that are convertible into beds (with the exception of those classifiable as garden seats or camping equipment); 5) seats of cane, osier, bamboo or similar materials; 6) other seats with wooden frames (with the exception of seats of a kind used for aircraft or motor vehicles); 7) furniture (other than seats) of wood (with the exception of i) medical, surgical, dental or veterinary furniture; and ii) barbers’ chairs and similar chairs, having rotating as well as both reclining and elevating movements); or 8) furniture (other than seats) of materials other than wood, metal, or plastics (e.g., furniture of cane, osier, bamboo or similar materials). The aforementioned imported unassembled articles are currently classified under the following Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 4418.10, 4418.20, 9401.30, 9401.40, 9401.51, 9401.59, 9401.61, 9401.69, 9403.30, 9403.40, 9403.50, 9403.60, 9403.81 or 9403.89.

Also excluded from the scope of this investigation are steel nails that meet the specifications of Type I, Style 20 nails as

identified in Tables 29 through 33 of ASTM Standard F1667 (2013 revision).

Also excluded from the scope of this investigation are nails suitable for use in powder-actuated hand tools, whether or not threaded, which are currently classified under HTSUS subheadings 7317.00.20.00 and 7317.00.30.00.

Also excluded from the scope of this investigation are nails having a case hardness greater than or equal to 50 on the Rockwell Hardness C scale (HRC), a carbon content greater than or equal to 0.5 percent, a round head, a secondary reduced-diameter raised head section, a centered shank, and a smooth symmetrical point, suitable for use in gas-actuated hand tools.

Also excluded from the scope of this investigation are corrugated nails. A corrugated nail is made up of a small strip of corrugated steel with sharp points on one side.

Also excluded from the scope of this investigation are thumb tacks, which are currently classified under HTSUS subheading 7317.00.10.00.

Certain steel nails subject to this investigation are currently classified under HTSUS subheadings 7317.00.55.02, 7317.00.55.03, 7317.00.55.05, 7317.00.55.07, 7317.00.55.08, 7317.00.55.11, 7317.00.55.18, 7317.00.55.19, 7317.00.55.20, 7317.00.55.30, 7317.00.55.40, 7317.00.55.50, 7317.00.55.60, 7317.00.55.70, 7317.00.55.80, 7317.00.55.90, 7317.00.65.30, 7317.00.65.60 and 7317.00.75.00. Certain steel nails subject to this investigation also may be classified under HTSUS subheading 8206.00.00.00 or other HTSUS subheadings.

While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

Appendix II—List of Topics Discussed in the Issues and Decision Memorandum

I. Summary

II. Background

III. Scope of the Investigation

IV. Scope Comments

V. Discussion of the Issues

Issues Pertaining to Daejin:

Comment 1: Domestic Brokerage and Handling Charges Incurred in U.S. Dollars

Comment 2: Daejin's Audited Financial Statements

Comment 3: TOTCOM Calculation Error for Certain CONNUMs

Comment 4: Constructed Value ("CV") Profit for Daejin

Issues Pertaining to Jinheung Steel:

Comment 5: Cash Deposit Rate for Affiliated Companies

Comment 6: Product Comparison Methodology

Comment 7: Differential Pricing Analysis

Comment 8: Steel Scrap Offset

Comment 9: Change in Work-In-Process and Semi-Finished Goods Inventories

VI. Recommendation

[FR Doc. 2015-12257 Filed 5-19-15; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[C-523-809]

Certain Steel Nails From the Sultanate of Oman: Final Negative Countervailing Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) determines that *de minimis* countervailable subsidies are being provided to producers and exporters of certain steel nails (nails) from the Sultanate of Oman. The period of investigation is January 1, 2013, through December 31, 2013.

DATES: *Effective Date:* May 20, 2015.

FOR FURTHER INFORMATION CONTACT: Dana Mermelstein or Trisha Tran, 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) 482-1391 and (202) 482-4852, respectively.

SUPPLEMENTARY INFORMATION:

Background

Petitioner in this investigation is Mid Continent Steel & Wire, Inc. (Petitioner). This investigation covers 10 subsidy programs. In addition to the Government of the Sultanate of Oman (the GSO), the respondent in this investigation is Oman Fasteners LLC (Oman Fasteners).

Case History

The following events have occurred since we published the *Preliminary Determination* on November 3, 2014.¹

We conducted verification of the GSO's and Oman Fasteners' questionnaire responses from January 11, 2015 through January 15, 2015, and issued verification reports on February 9, 2015 and February 13, 2015. Oman Fasteners, the GSO, and Petitioner submitted case briefs on February 26, 2015. Petitioner, Oman Fasteners, the GSO, and Overseas International Steel Industry, LLC (OISI) submitted rebuttal briefs on March 3, 2015.

Scope of the Investigation

The product covered by this investigation is certain steel nails from Sultanate of Oman. For a full

¹ See *Certain Steel Nails from the Sultanate of Oman: Preliminary Negative Countervailing Duty Determination and Alignment of Final Countervailing Duty Determination with Final Antidumping Duty Determination*, 79 FR 65178 (November 3, 2014) (*Preliminary Determination*).

description of the scope of the investigation, see Appendix I to this notice.

Since the *Preliminary Determination*, several interested parties (*i.e.*, IKEA Supply AG, The Home Depot, Target Corporation, and Petitioner) commented on the scope of these investigations. The Department reviewed these comments and made certain changes. For further discussion, see the Issues and Decision Memorandum.² The scope in Appendix I reflects all modifications to the scope made by the Department for this final determination.

Analysis of Subsidy Programs and Comments Received

The subsidy programs under investigation and the issues raised in the case and rebuttal briefs by parties in this investigation are discussed in the Issues and Decision Memorandum,³ which is concurrently dated with, and hereby adopted by, this notice. A list of topics discussed in the Issues and Decision Memorandum is attached to this notice as Appendix II. The Issues and Decision Memorandum is a public document and is on file electronically via ACCESS. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Internet at <http://enforcement.trade.gov/frn/index.html>. The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Final Determination

The total estimated net countervailable subsidy rate is:

Company	Subsidy rate
Oman Fasteners LLC	0.24 percent (<i>de minimis</i>)

Because the total estimated net countervailable subsidy rate for the

² See Memorandum to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, from Howard Smith, Acting Office Director for Enforcement and Compliance (Office IV) Antidumping and Countervailing Duty Operations, "Issues and Decision Memorandum for the Final Determination of the Countervailing Duty Investigation of Certain Steel Nails from the Sultanate of Oman" (Issues and Decision Memorandum), dated concurrently with this determination and hereby adopted by this notice.

³ Public versions of all business proprietary documents and all public documents are on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). Access to ACCESS is available to registered users at <http://access.trade.gov> and in the Department's Central Records Unit, room 7046 of the main Department building.

examined company is *de minimis*, we determine that countervailable subsidies are not being provided to producers or exporters of nails in Oman. We have not calculated an all-others rate pursuant to sections 705(c)(1)(B) and (c)(5) of the Tariff Act of 1930, as amended (the Act) because we have not reached an affirmative final determination. Because our final determination is negative, this proceeding is terminated in accordance with section 705(c)(2) of the Act.

In the *Preliminary Determination*, the total net countervailable subsidy rate for the individually examined respondent was *de minimis* and, therefore, we did not suspend liquidation of entries of nails from Oman.⁴ Because the estimated subsidy rate for the examined company is *de minimis* in this final determination, we are not directing U.S. Customs and Border Protection to suspend liquidation of entries of nails from the Sultanate of Oman.

United States International Trade Commission (USITC) Notification

In accordance with section 705(d) of the Act, we will notify the USITC of our final determination. Because our final determination is negative, this investigation is terminated.

Return or Destruction of Proprietary Information

This notice serves as the only reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/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 that is subject to sanction.

This determination is issued and published pursuant to sections 705(d) and 777(i) of the Act.

Dated: May 13, 2015.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix I—Scope of the Investigation

The merchandise covered by this investigation is certain steel nails having a nominal shaft length not exceeding 12 inches.⁵ Certain steel nails include, but are not limited to, nails made from round wire

and nails that are cut from flat-rolled steel. Certain steel nails may be of one piece construction or constructed of two or more pieces. Certain steel nails may be produced from any type of steel, and may have any type of surface finish, head type, shank, point type and shaft diameter. Finishes include, but are not limited to, coating in vinyl, zinc (galvanized, including but not limited to electroplating or hot dipping one or more times), phosphate, cement, and paint. Certain steel nails may have one or more surface finishes. Head styles include, but are not limited to, flat, projection, cupped, oval, brad, headless, double, countersunk, and sinker. Shank styles include, but are not limited to, smooth, barbed, screw threaded, ring shank and fluted. Screw-threaded nails subject to this proceeding are driven using direct force and not by turning the nail using a tool that engages with the head. Point styles include, but are not limited to, diamond, needle, chisel and blunt or no point. Certain steel nails may be sold in bulk, or they may be collated in any manner using any material.

Excluded from the scope of this investigation are certain steel nails packaged in combination with one or more non-subject articles, if the total number of nails of all types, in aggregate regardless of size, is less than 25. If packaged in combination with one or more non-subject articles, certain steel nails remain subject merchandise if the total number of nails of all types, in aggregate regardless of size, is equal to or greater than 25, unless otherwise excluded based on the other exclusions below.

Also excluded from the scope are certain steel nails with a nominal shaft length of one inch or less that are (a) a component of an unassembled article, (b) the total number of nails is sixty (60) or less, and (c) the imported unassembled article falls into one of the following eight groupings: (1) Builders' joinery and carpentry of wood that are classifiable as windows, French-windows and their frames; (2) builders' joinery and carpentry of wood that are classifiable as doors and their frames and thresholds; (3) swivel seats with variable height adjustment; (4) seats that are convertible into beds (with the exception of those classifiable as garden seats or camping equipment); (5) seats of cane, osier, bamboo or similar materials; (6) other seats with wooden frames (with the exception of seats of a kind used for aircraft or motor vehicles); (7) furniture (other than seats) of wood (with the exception of (i) medical, surgical, dental or veterinary furniture; and ii) barbers' chairs and similar chairs, having rotating as well as both reclining and elevating movements); or (8) furniture (other than seats) of materials other than wood, metal, or plastics (e.g., furniture of cane, osier, bamboo or similar materials). The aforementioned imported unassembled articles are currently classified under the following Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 4418.10, 4418.20, 9401.30, 9401.40, 9401.51, 9401.59, 9401.61, 9401.69, 9403.30, 9403.40, 9403.50, 9403.60, 9403.81 or 9403.89.

Also excluded from the scope of this investigation are steel nails that meet the specifications of Type I, Style 20 nails as identified in Tables 29 through 33 of ASTM Standard F1667 (2013 revision).

Also excluded from the scope of this investigation are nails suitable for use in powder-actuated hand tools, whether or not threaded, which are currently classified under HTSUS subheadings 7317.00.20.00 and 7317.00.30.00.

Also excluded from the scope of this investigation are nails having a case hardness greater than or equal to 50 on the Rockwell Hardness C scale (HRC), a carbon content greater than or equal to 0.5 percent, a round head, a secondary reduced-diameter raised head section, a centered shank, and a smooth symmetrical point, suitable for use in gas-actuated hand tools.

Also excluded from the scope of this investigation are corrugated nails. A corrugated nail is made up of a small strip of corrugated steel with sharp points on one side.

Also excluded from the scope of this investigation are thumb tacks, which are currently classified under HTSUS subheading 7317.00.10.00.

Certain steel nails subject to this investigation are currently classified under HTSUS subheadings 7317.00.55.02, 7317.00.55.03, 7317.00.55.05, 7317.00.55.07, 7317.00.55.08, 7317.00.55.11, 7317.00.55.18, 7317.00.55.19, 7317.00.55.20, 7317.00.55.30, 7317.00.55.40, 7317.00.55.50, 7317.00.55.60, 7317.00.55.70, 7317.00.55.80, 7317.00.55.90, 7317.00.65.30, 7317.00.65.60 and 7317.00.75.00. Certain steel nails subject to this investigation also may be classified under HTSUS subheading 8206.00.00.00 or other HTSUS subheadings.

While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

Appendix II—List of Topics in the Issues and Decision Memorandum

- I. SUMMARY
- II. BACKGROUND
- III. SCOPE OF THE INVESTIGATION
- IV. SCOPE COMMENTS
- V. SUBSIDIES VALUATION
- VI. ANALYSIS OF PROGRAMS
- VII. ANALYSIS OF COMMENTS
- VIII. RECOMMENDATION

[FR Doc. 2015–12263 Filed 5–19–15; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–583–854]

Certain Steel Nails From Taiwan: Final Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) determines that imports of certain steel nails from Taiwan are being sold in the United States at less than fair value (LTFV), as provided in section 735 of the Tariff Act

⁴ See *Preliminary Determination*, 79 FR at 65179.

⁵ The shaft length of certain steel nails with flat heads or parallel shoulders under the head shall be measured from under the head or shoulder to the tip of the point. The shaft length of all other certain steel nails shall be measured overall.

of 1930, as amended (the Act). The final weighted-average dumping margins of sales at LTFV are listed below in the section entitled "Final Determination Margins."

DATES: *Effective Date:* May 20, 2015.

FOR FURTHER INFORMATION CONTACT:

Victoria Cho or Scott Hoefke, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482-5075 or (202) 482-4947.

SUPPLEMENTARY INFORMATION:

Background

On December 29, 2014, the Department published in the **Federal Register** the preliminary determination in the LTFV investigation of Certain Steel Nails from Taiwan.¹ In the *Preliminary Determination*, we postponed the final determination until no later than 135 days after the publication of the *Preliminary Determination* in accordance with section 735(a)(2)(B) of the Act and 19 CFR 351.210(b)(2)(i) and invited parties to comment on our *Preliminary Determination*.

On the same day, we received timely-filed allegations from Respondents² that the Department made ministerial errors in calculating their dumping margins in this proceeding.³ Also on December 29, 2014, we received allegations from Petitioner⁴ that the Department made significant ministerial errors in calculating the dumping margins for the *Preliminary Determination*.⁵ In addition, Petitioner requested a disclosure meeting.⁶ Subsequently, Respondents also requested to attend

the disclosure meeting.⁷ On January 7, 2015, the Department held disclosure meetings with both parties.⁸

Between January 26, 2015, and February 6, 2015, the Department conducted verifications in Taiwan of the sales and cost information submitted by Quick Advance, Ko, PT and Proteam. In accordance with 19 CFR 351.309(c)(1)(i), we invited parties to comment on our *Preliminary Determination*. On March 30, 2015, the Department released its Ministerial Error Allegation Memo.⁹ On March 31, 2015, Petitioner and Respondents submitted case briefs. Each of these parties submitted rebuttal briefs on April 9, 2015.

Period of Investigation

The period of investigation is April 1, 2013, through March 31, 2014.

Scope of the Investigation

The product covered by this investigation is certain steel nails from Taiwan. For a full description of the scope of the investigation, see Appendix I to this notice.

Since the *Preliminary Determination*, several interested parties (*i.e.*, IKEA Supply AG, The Home Depot, Target Corporation, and Petitioner) commented on the scope of these investigations. The Department reviewed these comments and made certain changes. For further discussion, see the Issues and Decision Memorandum.¹⁰ The scope in Appendix I reflects all modifications to the scope made by the Department for this final determination.

Verification

As provided in section 782(i) of the Act, in January 2015 through February 2015, we conducted verification of the sales and cost information submitted by PT Enterprises, Inc. (PT) and its

affiliated producer Pro-Team Coil Nail Enterprise, Inc. (Proteam), and Quick Advance, Inc. (Quick Advance) and its affiliated producer Ko's Nail, Inc. (Ko) for use in our final determination. We used standard verification procedures including an examination of relevant accounting and production records, and original source documents provided by PT and its affiliate, Proteam, and Quick Advance and its affiliate, Ko.¹¹

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties in this investigation are addressed in the Issues and Decision Memorandum. A list of the issues raised is attached to this notice as Appendix II. 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>; the memorandum is available to all parties in the Central Records Unit, room 7046 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <http://enforcement.trade.gov>. The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Determination

Based on our review and analysis of the comments received from parties, and minor corrections presented at verification, we made certain changes to Respondents' margin calculations since the *Preliminary Determination*. As a result of those changes, the Department is no longer making a negative determination of sales at less than fair value. For a discussion of these changes,

¹ See *Certain Steel Nails From Taiwan: Negative Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination*, 79 FR 78053, 78054 (December 29, 2014) (*Preliminary Determination*).

² The mandatory respondents are PT Enterprise, Inc. (PT) and its affiliated manufacturer, Pro-Team Coil Nail Enterprise, Inc. (Proteam); and Quick Advance, Inc. (Quick Advance) and its affiliated manufacturer, Ko's Nail, Inc. (Ko) (collectively, Respondents).

³ See Letter from Respondents, regarding "PT Enterprise and Quick Advance, Request to Correct Clerical Errors in Preliminary Determination; Antidumping Duty Investigation of Certain Steel Nails from Taiwan," dated December 29, 2014 (Respondents Allegations Letter).

⁴ The petitioner is Mid Continent Steel & Wire, Inc. (Petitioner).

⁵ See Letter from Petitioner, regarding "Certain Steel Nails from Taiwan: Allegations of Significant Ministerial Error and Request for Disclosure Meeting," dated December 29, 2014 (Petitioner Allegations Letter).

⁶ *Id.*

⁷ See Letter from Respondents, regarding "PT Enterprise and Quick Advance, Request to Attend Disclosure Meeting; Antidumping Duty Investigation of Certain Steel Nails from Taiwan," dated January 6, 2014.

⁸ See Memoranda to the file from Scott Hoefke, "Certain Steel Nails from Taiwan," regarding ex parte disclosure meetings with Petitioner and Respondents, dated January 8, 2014.

⁹ See the Department's March 20, 2015, Memorandum to Christian Marsh entitled, "Ministerial Error Allegations in the Preliminary Determination of the Antidumping Duty Investigation of Certain Steel Nails from Taiwan," (Ministerial Error Allegation Memo).

¹⁰ See Memorandum to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, from Abdelali Elouaradia, Office Director, Office VI, Enforcement and Compliance Operations, "Issues and Decision Memorandum for the Affirmative Final Determination in the Less than Fair Value Investigation of Certain Nails from Taiwan," dated concurrently with this determination and hereby adopted by this notice.

¹¹ See Quick Advance's February 26, 2015, Memorandum to the File entitled, "Verification of the Sales Response of Quick Advance, Inc. and Ko's Nail, Inc. in the Investigation of Nails from Taiwan" (Quick Advance's sales verification memo); PT's February 26, 2015, Memorandum to the File entitled, "Verification of the Sales Response of PT Enterprises, Inc. and Proteam Coil Nail Enterprises, Inc. in the Investigation of Nails from Taiwan" (PT's sales verification memo); Memorandum from Gina K. Lee to Neal M. Halper entitled, "Verification of the Cost Response of Quick Advance Inc. and Ko Nail Inc. in the Antidumping Duty Investigation of Certain Steel Nails from Taiwan, dated March 18, 2015 (Ko's Cost Verification Report); and also see Memorandum from Laurens Van Houten to Neal M. Halper entitled, "Verification of the Cost Response of PT Enterprise Inc. in the Antidumping Duty Investigation of Certain Steel Nails from Taiwan," dated March 19, 2015 (PT's Cost Verification Report).

see the Issues and Decision Memorandum.

For Quick Advance:

- We used an updated sales and cost database submitted by Quick Advance which reflects minor corrections and findings from the sales and cost verifications.

- We revised the programing language to reflect the changes to constructed value (CV).

- We revised the calculation of CV.
- We added in lines of code to take into account quantity adjustments.
- We added credit expenses and inventory carrying cost incurred in Taiwan to account for expenses reported in Taiwanese dollars.

- We made changes to Quick Advance's reported cost data as set forth in the Quick Advance's Final Cost Memo.

For PT:

- We used updated sale database by PT which reflect minor corrections presented during the verification of these companies.

- We revised the programing language to reflect the changes to CV.

- We revised the calculation of CV.
- We added in lines of code to take into account quantity adjustments.

- We made changes to PT's reported cost data as set forth in the PT's Final Cost Memo.

Final Determination

The Department determines that the following weighted-average dumping margins exist for the period April 1, 2013, through March 31, 2014:

Exporter or producer	Weighted-average dumping margin (percent)
Quick Advance Inc	0.00
PT Enterprises Inc	2.24
All Others	2.24

All Others Rate

Section 735(c)(5)(A) of the Act provides that the estimated "all others" rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero or *de minimis* margins, and any margins determined entirely under section 776 of the Act. The weighted-average margin for exporters and producers individually investigated that meets these criteria is that of PT. Therefore, the All-Others rate is the rate calculated for PT, as indicated in the "Final Determination Margins" section above.

Disclosure

We will disclose to parties in this proceeding the calculations performed for this final determination within five days of the date of public announcement of our final determination, in accordance with 19 CFR 351.224(b).

Suspension of Liquidation

Pursuant to sections 735(c)(1)(B) and (C) of the Act, the Department will instruct U.S. Customs and Border Protection (CBP) to suspend liquidation of all entries of certain steel nails from Taiwan, except for those from Quick Advance, which are entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final determination. For Quick Advance and Ko, because their estimated weighted-average final dumping margins are zero, we are not directing CBP to suspend liquidation of entries of nails produced and exported by these companies. We will not instruct CBP to suspend liquidation of any entries of certain steel nails from as described in the "Scope of the Investigation" in Appendix I which are entered, or withdrawn from warehouse, for consumption on or after the date of publication of this notice. We will instruct CBP to require a cash deposit equal to the weighted-average amount by which normal value exceeds U.S. price, as follows: (1) The rate for PT will be the rate we determined in this final determination; (2) if the exporter is not a firm identified in this investigation but the producer is, the rate will be the rate established for the producer of the subject merchandise; (3) the rate for all other producers or exporters will be 2.24 percent. These suspension of liquidation instructions will remain in effect until further notice.

International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the U.S. International Trade Commission (ITC) of our final determination. As our final determination is affirmative, in accordance with section 735(b)(3) of the Act, the ITC will determine within 75 days whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports or sales (or the likelihood of sales) for importation of the subject merchandise. If the ITC determines that such injury exists, the Department will issue an antidumping duty order directing CBP to assess, upon further instruction by the Department, antidumping duties on all imports of the

subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation.

Return or Destruction of Proprietary Information

This notice will serve as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this determination and notice in accordance with sections 735(d) and 777(i) of the Act.

Dated: May 13, 2015.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix I

Scope of the Investigation

The merchandise covered by this investigation is certain steel nails having a nominal shaft length not exceeding 12 inches.¹² Certain steel nails include, but are not limited to, nails made from round wire and nails that are cut from flat-rolled steel. Certain steel nails may be of one piece construction or constructed of two or more pieces. Certain steel nails may be produced from any type of steel, and may have any type of surface finish, head type, shank, point type and shaft diameter. Finishes include, but are not limited to, coating in vinyl, zinc (galvanized, including but not limited to electroplating or hot dipping one or more times), phosphate, cement, and paint. Certain steel nails may have one or more surface finishes. Head styles include, but are not limited to, flat, projection, cupped, oval, brad, headless, double, countersunk, and sinker. Shank styles include, but are not limited to, smooth, barbed, screw threaded, ring shank and fluted. Screw-threaded nails subject to this proceeding are driven using direct force and not by turning the nail using a tool that engages with the head. Point styles include, but are not limited to, diamond, needle, chisel and blunt or no point. Certain steel nails may be sold in bulk, or they may be collated in any manner using any material.

Excluded from the scope of this investigation are certain steel nails packaged in combination with one or more non-subject articles, if the total number of nails of all

¹² The shaft length of certain steel nails with flat heads or parallel shoulders under the head shall be measured from under the head or shoulder to the tip of the point. The shaft length of all other certain steel nails shall be measured overall.

types, in aggregate regardless of size, is less than 25. If packaged in combination with one or more non-subject articles, certain steel nails remain subject merchandise if the total number of nails of all types, in aggregate regardless of size, is equal to or greater than 25, unless otherwise excluded based on the other exclusions below.

Also excluded from the scope are certain steel nails with a nominal shaft length of one inch or less that are (a) a component of an unassembled article, (b) the total number of nails is sixty (60) or less, and (c) the imported unassembled article falls into one of the following eight groupings: (1) Builders' joinery and carpentry of wood that are classifiable as windows, French-windows and their frames; (2) builders' joinery and carpentry of wood that are classifiable as doors and their frames and thresholds; (3) swivel seats with variable height adjustment; (4) seats that are convertible into beds (with the exception of those classifiable as garden seats or camping equipment); (5) seats of cane, osier, bamboo or similar materials; (6) other seats with wooden frames (with the exception of seats of a kind used for aircraft or motor vehicles); (7) furniture (other than seats) of wood (with the exception of i) medical, surgical, dental or veterinary furniture; and ii) barbers' chairs and similar chairs, having rotating as well as both reclining and elevating movements); or (8) furniture (other than seats) of materials other than wood, metal, or plastics (e.g., furniture of cane, osier, bamboo or similar materials). The aforementioned imported unassembled articles are currently classified under the following Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 4418.10, 4418.20, 9401.30, 9401.40, 9401.51, 9401.59, 9401.61, 9401.69, 9403.30, 9403.40, 9403.50, 9403.60, 9403.81 or 9403.89.

Also excluded from the scope of this investigation are steel nails that meet the specifications of Type I, Style 20 nails as identified in Tables 29 through 33 of ASTM Standard F1667 (2013 revision).

Also excluded from the scope of this investigation are nails suitable for use in powder-actuated hand tools, whether or not threaded, which are currently classified under HTSUS subheadings 7317.00.20.00 and 7317.00.30.00.

Also excluded from the scope of this investigation are nails having a case hardness greater than or equal to 50 on the Rockwell Hardness C scale (HRC), a carbon content greater than or equal to 0.5 percent, a round head, a secondary reduced-diameter raised head section, a centered shank, and a smooth symmetrical point, suitable for use in gas-actuated hand tools.

Also excluded from the scope of this investigation are corrugated nails. A corrugated nail is made up of a small strip of corrugated steel with sharp points on one side.

Also excluded from the scope of this investigation are thumb tacks, which are currently classified under HTSUS subheading 7317.00.10.00.

Certain steel nails subject to this investigation are currently classified under HTSUS subheadings 7317.00.55.02, 7317.00.55.03, 7317.00.55.05, 7317.00.55.07,

7317.00.55.08, 7317.00.55.11, 7317.00.55.18, 7317.00.55.19, 7317.00.55.20, 7317.00.55.30, 7317.00.55.40, 7317.00.55.50, 7317.00.55.60, 7317.00.55.70, 7317.00.55.80, 7317.00.55.90, 7317.00.65.30, 7317.00.65.60 and 7317.00.75.00. Certain steel nails subject to this investigation also may be classified under HTSUS subheading 8206.00.00.00 or other HTSUS subheadings.

While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

Appendix II

List of Topics Discussed in the Issues and Decision Memorandum

Case Issues:

- I. Summary
- II. General Issues
- III. Background
- IV. Scope of the Investigation
- V. Scope Comments
- VI. Discussion of the Issues
- VII. Conclusion

General Issues

- Comment 1: Taiwan Nails CV Profit and the Use of Financial Statements
- Comment 2: The Department Should Rely on the Average-to-Average Methodology without Zeroing in the Final Determination
- Comment 3: The Department Should Determine that Quick Advance and PT are Affiliated with Their Respective Largest U.S. Customers
- Comment 4: Whether a Middleman Dumping Investigation is Warranted
- Comment 5: The Department's Calculation of Constructed Value for PT and Quick Advance
- Comment 6: The Department's Calculation of Surrogate Credit Expense Ratio
- Comment 7: The Department's Calculation of Indirect and Direct Selling Expense Ratio to Categorize Chun Yu's Works & Co.'s Selling Expenses
- Comment 8: The Department's Calculation of Indirect and Direct Selling Expense Ratio to Properly Account for OFCO's Selling Expenses
- Comment 9: The Department's Treatment of PT's and Quick Advance's U.S. Prices for Commission/Compensation Paid to its Unaffiliated Taiwanese Selling Agent and Unaffiliated Taiwanese Trading Company

Issues Pertaining to PT and Proteam

- Comment 10: The Department Should Assign Partial AFA to PT's Unreported Sales of Subject Merchandise
- Comment 11: Transactions disregarded—Tolling Activities
- Comment 12: Threading Costs
- Comment 13: General and Administrative Expense

Issues Pertaining to Quick Advance and Ko

- Comment 14: The Department Should Rely on Quick Advance/Ko's Section C Database Submitted After Verification
- Comment 15: Ko's Raw Materials
- Comment 16: Ko's Phosphate Coating Costs

[FR Doc. 2015-12247 Filed 5-19-15; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[C-552-819]

Certain Steel Nails From the Socialist Republic of Vietnam: Final Affirmative Countervailing Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (Department) has determined that countervailable subsidies are being provided to producers and exporters of certain steel nails (nails) from the Socialist Republic of Vietnam (Vietnam). For information on the estimated countervailing duty rates, see the "Suspension of Liquidation" section, below.

DATES: *Effective Date:* May 20, 2015.

FOR FURTHER INFORMATION CONTACT: Sergio Balbontin, Thomas Schauer, or Shane Subler, 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) 482-6478, (202) 482-0410, and (202) 482-0189, respectively.

SUPPLEMENTARY INFORMATION:

Background

The petitioner in this investigation is Mid Continent Steel & Wire, Inc. The period for which we are measuring subsidies, or period of investigation, is January 1, 2013, through December 31, 2013.

Case History

The events that have occurred since the Department published the *Preliminary Determination* on November 3, 2014,¹ are discussed in the Issues and Decision Memorandum.² The Issues and Decision Memorandum is a public document and is on file

¹ *Certain Steel Nails From the Socialist Republic of Vietnam: Preliminary Affirmative Countervailing Duty Determination and Alignment of Final Countervailing Duty Determination With Final Antidumping Duty Determination*, 79 FR 65184 (November 3, 2014) (*Preliminary Determination*) and accompanying Memorandum, "Decision Memorandum for the Preliminary Determination in the Countervailing Duty Investigation of Certain Steel Nails from the Socialist Republic of Vietnam" (*Preliminary Decision Memorandum*).

² See Memorandum to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations from James Maeder, Office Director, Office I, "Decision Memorandum for the Final Determination in the Countervailing Duty Investigation of Certain Steel Nails from the Socialist Republic of Vietnam" dated concurrently with this notice (Issues and Decision Memorandum).

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>. The Issues and Decision Memorandum is available to all parties in the Central Records Unit, room 7046 of the main Department of 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 Issues and Decision Memorandum and the electronic versions of the Issues and Decision Memorandum are identical in content.

Scope of the Investigation

The product covered by this investigation is certain steel nails from Vietnam. For a full description of the scope of the investigation, *see* Appendix I to this notice.

Since *the Preliminary Determination*, several interested parties (*i.e.*, IKEA Supply AG, The Home Depot, Target Corporation, and Petitioner) commented on the scope of these investigations. The Department reviewed these comments and made certain changes. For further discussion, *see* the Issues and Decision

Memorandum. The scope in Appendix I reflects all modifications to the scope made by the Department for this final determination.

Analysis of Subsidy Programs and Comments Received

The subsidy programs under investigation and the issues raised in the case and rebuttal briefs by parties to this investigation are addressed in the Issues and Decision Memorandum. Attached as Appendix II is a list of the issues that parties have raised and to which we have responded in the Issues and Decision Memorandum.

Use of Adverse Facts Available

For purposes of this final determination, we have relied on facts available and applied adverse inferences, in accordance with sections 776(a) and (b) of the Act, to determine the subsidy rates for the mandatory respondents. For a full discussion of these issues, *see* the Decision Memorandum, at "Use of Facts Otherwise Available and Adverse Facts Available."

Suspension of Liquidation

In accordance with section 705(c)(1)(B)(i) of the Act, we calculated

a countervailing duty rate for the two individually investigated producers/exporters of the subject merchandise, Region Industries Co., Ltd. (Region) and United Nail Products Co. (United). With respect to the all-others rate, section 705(c)(5)(A)(ii) of the Act provides that if the countervailable subsidy rates established for all exporters and producers individually investigated are determined entirely in accordance with section 776 of the Act, the Department may use any reasonable method to establish an all-others rate for exporters and producers not individually investigated. In this case, the rates calculated for the investigated companies are based entirely on adverse facts available under section 776 of the Act. Because there is no other information on the record, we based the all-others rate on the AFA rates calculated for Region and United, consistent with our practice.³ We calculated the all-others rate using a simple average of Region's and United's rates.

We determine the total estimated net countervailable subsidy rates to be:

Company	Subsidy rate
Region Industries Co., Ltd	288.56 percent
United Nail Products Co. Ltd	313.97 percent
All Others	301.27 percent

As a result of our affirmative *Preliminary Determination*, pursuant to sections 703(d)(1)(B) and (2) of the Act, we instructed U.S. Customs and Border Protection (CBP) to suspend liquidation of entries of subject merchandise from Vietnam which were entered or withdrawn from warehouse, for consumption on or after November 3, 2014, the date of the publication of the *Preliminary Determination* in the **Federal Register**.

In accordance with section 703(d) of the Act, we later issued instructions to CBP to discontinue the suspension of liquidation for countervailing duty purposes for subject merchandise entered, or withdrawn from warehouse, on or after March 3, 2015, but to continue the suspension of liquidation of all entries from November 3, 2014, through March 2, 2015.

We will issue a countervailing duty order and reinstate the suspension of

liquidation under section 706(a) of the Act if the United States International Trade Commission (ITC) issues a final affirmative injury determination, and we will instruct CBP to require a cash deposit of estimated countervailing duties for such entries of merchandise in the amounts indicated above. If the ITC determines that material injury, or threat of material injury, does not exist, this proceeding will be terminated and all estimated duties deposited or securities posted as a result of the suspension of liquidation will be refunded or canceled.

ITC Notification

In accordance with section 705(d) of the Act, we will notify the ITC of our determination. In addition, we are making available to the ITC all non-privileged and non-proprietary information related to this investigation. We will allow the ITC access to all

privileged and business proprietary information in our files, provided the ITC confirms that it will not disclose such information, either publicly or under an administrative protective order (APO), without the written consent of the Assistant Secretary for Enforcement and Compliance.

Return or Destruction of Proprietary Information

In the event that the ITC issues a final negative injury determination, this notice will serve as the only reminder to parties subject to an APO of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/ destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an

³ See *Raw Flexible Magnets from the People's Republic of China: Affirmative Countervailing Duty Determination*, 73 FR 39667 (July 10, 2008); *Final Affirmative Countervailing Duty Determination:*

Certain Hot-Rolled Carbon Steel Flat Products From Argentina, 66 FR 37007, 37008 (July 16, 2001); *Final Affirmative Countervailing Duty Determination: Prestressed Concrete Steel Wire*

Strand From India, 68 FR 68356, 68357 (December 8, 2003).

APO is a violation which is subject to sanction.

This determination is published pursuant to sections 705(d) and 777(i) of the Act.

Dated: May 13, 2015.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix I

Scope of the Investigation

The merchandise covered by this investigation is certain steel nails having a nominal shaft length not exceeding 12 inches.⁴ Certain steel nails include, but are not limited to, nails made from round wire and nails that are cut from flat-rolled steel. Certain steel nails may be of one piece construction or constructed of two or more pieces. Certain steel nails may be produced from any type of steel, and may have any type of surface finish, head type, shank, point type and shaft diameter. Finishes include, but are not limited to, coating in vinyl, zinc (galvanized, including but not limited to electroplating or hot dipping one or more times), phosphate, cement, and paint. Certain steel nails may have one or more surface finishes. Head styles include, but are not limited to, flat, projection, cupped, oval, brad, headless, double, countersunk, and sinker. Shank styles include, but are not limited to, smooth, barbed, screw threaded, ring shank and fluted. Screw-threaded nails subject to this proceeding are driven using direct force and not by turning the nail using a tool that engages with the head. Point styles include, but are not limited to, diamond, needle, chisel and blunt or no point. Certain steel nails may be sold in bulk, or they may be collated in any manner using any material.

Excluded from the scope of this investigation are certain steel nails packaged in combination with one or more non-subject articles, if the total number of nails of all types, in aggregate regardless of size, is less than 25. If packaged in combination with one or more non-subject articles, certain steel nails remain subject merchandise if the total number of nails of all types, in aggregate regardless of size, is equal to or greater than 25, unless otherwise excluded based on the other exclusions below.

Also excluded from the scope are certain steel nails with a nominal shaft length of one inch or less that are (a) a component of an unassembled article, (b) the total number of nails is sixty (60) or less, and (c) the imported unassembled article falls into one of the following eight groupings: (1) builders' joinery and carpentry of wood that are classifiable as windows, French-windows and their frames; (2) builders' joinery and carpentry of wood that are classifiable as doors and their frames and thresholds; (3) swivel seats with variable height adjustment; (4) seats that are convertible into beds (with the exception of those classifiable as garden

seats or camping equipment); (5) seats of cane, osier, bamboo or similar materials; (6) other seats with wooden frames (with the exception of seats of a kind used for aircraft or motor vehicles); (7) furniture (other than seats) of wood (with the exception of i) medical, surgical, dental or veterinary furniture; and ii) barbers' chairs and similar chairs, having rotating as well as both reclining and elevating movements); or (8) furniture (other than seats) of materials other than wood, metal, or plastics (e.g., furniture of cane, osier, bamboo or similar materials). The aforementioned imported unassembled articles are currently classified under the following Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 4418.10, 4418.20, 9401.30, 9401.40, 9401.51, 9401.59, 9401.61, 9401.69, 9403.30, 9403.40, 9403.50, 9403.60, 9403.81 or 9403.89.

Also excluded from the scope of this investigation are steel nails that meet the specifications of Type I, Style 20 nails as identified in Tables 29 through 33 of ASTM Standard F1667 (2013 revision).

Also excluded from the scope of this investigation are nails suitable for use in powder-actuated hand tools, whether or not threaded, which are currently classified under HTSUS subheadings 7317.00.20.00 and 7317.00.30.00.

Also excluded from the scope of this investigation are nails having a case hardness greater than or equal to 50 on the Rockwell Hardness C scale (HRC), a carbon content greater than or equal to 0.5 percent, a round head, a secondary reduced-diameter raised head section, a centered shank, and a smooth symmetrical point, suitable for use in gas-actuated hand tools.

Also excluded from the scope of this investigation are corrugated nails. A corrugated nail is made up of a small strip of corrugated steel with sharp points on one side.

Also excluded from the scope of this investigation are thumb tacks, which are currently classified under HTSUS subheading 7317.00.10.00.

Certain steel nails subject to this investigation are currently classified under HTSUS subheadings 7317.00.55.02, 7317.00.55.03, 7317.00.55.05, 7317.00.55.07, 7317.00.55.08, 7317.00.55.11, 7317.00.55.18, 7317.00.55.19, 7317.00.55.20, 7317.00.55.30, 7317.00.55.40, 7317.00.55.50, 7317.00.55.60, 7317.00.55.70, 7317.00.55.80, 7317.00.55.90, 7317.00.65.30, 7317.00.65.60 and 7317.00.75.00. Certain steel nails subject to this investigation also may be classified under HTSUS subheading 8206.00.00.00 or other HTSUS subheadings.

While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

Appendix II

List of Comments and Issues in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope Comments
- IV. Scope of the Investigation
- V. Subsidies Valuation
- VI. Use of Facts Otherwise Available and

Adverse Facts Available

VII. Analysis of Programs

VIII. Analysis of Comments

Comment 1 Whether the Respondents Cooperated to the Best of their Ability and Should Be Subject to Adverse Facts Available

Comment 2 Whether the Department's Post-Preliminary Application of Adverse Facts Available with Respect to Land Preferences for Enterprises in Encouraged Industries or Industrial Zones was Justified

Comment 3 Whether the Department's Preliminary Application of Adverse Facts Available with Respect to Import Duty Exemptions for Raw Materials was Justified

IX. Recommendation

[FR Doc. 2015-12278 Filed 5-19-15; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[C-583-855]

Certain Steel Nails From Taiwan: Final Negative Countervailing Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) determines that no countervailable subsidies are being provided to producers and exporters of certain steel nails (nails) from Taiwan. The period of investigation is January 1, 2013, through December 31, 2013.

DATES: *Effective Date:* May 20, 2015.

FOR FURTHER INFORMATION CONTACT: Joshua Morris or Dana Mermelstein, 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) 482-1779 and (202) 482-1391, respectively.

SUPPLEMENTARY INFORMATION:

Background

The petitioner in this investigation is Mid Continent Steel & Wire, Inc. (the petitioner). This investigation covers 10 subsidy programs. In addition to the Taiwan Authorities (the TA), the respondents in this investigation are PT Enterprise, Inc. (PT Enterprise) and Quick Advance, Inc. (Quick Advance).

Case History

The following events have occurred since we published the *Preliminary Determination* on November 3, 2014.¹

¹ See *Certain Steel Nails From Taiwan: Preliminary Negative Countervailing Duty*

⁴ The shaft length of certain steel nails with flat heads or parallel shoulders under the head shall be measured from under the head or shoulder to the tip of the point. The shaft length of all other certain steel nails shall be measured overall.

We conducted verification of the TA's, PT Enterprise's, and Quick Advance's questionnaire responses from November 6 through November 13, 2014, and issued verification reports on December 4, 2014. PT Enterprise submitted a case brief on December 12, 2014. Petitioner submitted a rebuttal brief on December 17, 2014. No other parties submitted case or rebuttal briefs.

Scope of the Investigation

The product covered by this investigation is certain steel nails from Taiwan. For a full description of the scope of the investigation, see Appendix I to this notice.

Since the *Preliminary Determination*, several interested parties (*i.e.*, IKEA Supply AG, The Home Depot, Target Corporation, and the petitioner) commented on the scope of these investigations. The Department reviewed these comments and made certain changes. For further discussion, see the Issues and Decision Memorandum.² The scope in Appendix I reflects all modifications to the scope made by the Department for this final determination.

Analysis of Subsidy Programs and Comments Received

The subsidy programs under investigation and the issues raised in the case and rebuttal briefs by parties in this investigation are discussed in the Issues and Decision Memorandum. A list of subsidy programs and the issues that parties raised, and to which we responded in the Issues and Decision Memorandum, is attached to this notice as Appendix II. The Issues and Decision Memorandum is a public document and is on file electronically *via* the Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Internet at <http://enforcement.trade.gov/frn/index.html>. The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

The total estimated net countervailable subsidy rates are:

Company	Subsidy rate
PT Enterprise, Inc	0.00
Quick Advance, Inc	0.00

Because the total estimated net countervailable subsidy rates are zero, we determine that countervailable subsidies are not being provided to producers or exporters of nails in Taiwan. We have not calculated an all-others rate pursuant to sections 705(c)(1)(B) and (c)(5) of the Tariff Act of 1930, as amended (the Act) because we have not reached an affirmative final determination. Because our final determination is negative, this proceeding is terminated in accordance with section 705(c)(2) of the Act.

In the *Preliminary Determination*, the total net countervailable subsidy rates for the individually examined respondents were zero or *de minimis* and, therefore, we did not suspend liquidation of entries of nails from Taiwan.³ Because the estimated subsidy rates for both examined companies are zero in this final determination, we are not directing U.S. Customs and Border Protection to suspend liquidation of entries of nails from Taiwan.

United States International Trade Commission (USITC) Notification

In accordance with section 705(d) of the Act, we will notify the USITC of our final determination. Because our final determination is negative, this investigation is terminated.

Return or Destruction of Proprietary Information

This notice serves as the only reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/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 that is subject to sanction.

This determination is issued and published pursuant to sections 705(d) and 777(i) of the Act.

Dated: May 13, 2015.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix I

Scope of the Investigation

The merchandise covered by this investigation is certain steel nails having a nominal shaft length not exceeding 12 inches.⁴ Certain steel nails include, but are not limited to, nails made from round wire and nails that are cut from flat-rolled steel. Certain steel nails may be of one piece construction or constructed of two or more pieces. Certain steel nails may be produced from any type of steel, and may have any type of surface finish, head type, shank, point type and shaft diameter. Finishes include, but are not limited to, coating in vinyl, zinc (galvanized, including but not limited to electroplating or hot dipping one or more times), phosphate, cement, and paint. Certain steel nails may have one or more surface finishes. Head styles include, but are not limited to, flat, projection, cupped, oval, brad, headless, double, countersunk, and sinker. Shank styles include, but are not limited to, smooth, barbed, screw threaded, ring shank and fluted. Screw-threaded nails subject to this proceeding are driven using direct force and not by turning the nail using a tool that engages with the head. Point styles include, but are not limited to, diamond, needle, chisel and blunt or no point. Certain steel nails may be sold in bulk, or they may be collated in any manner using any material.

Excluded from the scope of this investigation are certain steel nails packaged in combination with one or more non-subject articles, if the total number of nails of all types, in aggregate regardless of size, is less than 25. If packaged in combination with one or more non-subject articles, certain steel nails remain subject merchandise if the total number of nails of all types, in aggregate regardless of size, is equal to or greater than 25, unless otherwise excluded based on the other exclusions below.

Also excluded from the scope are certain steel nails with a nominal shaft length of one inch or less that are (a) a component of an unassembled article, (b) the total number of nails is sixty (60) or less, and (c) the imported unassembled article falls into one of the following eight groupings: (1) Builders' joinery and carpentry of wood that are classifiable as windows, French-windows and their frames; (2) builders' joinery and carpentry of wood that are classifiable as doors and their frames and thresholds; (3) swivel seats with variable height adjustment; (4) seats that are convertible into beds (with the exception of those classifiable as garden seats or camping equipment); (5) seats of cane, osier, bamboo or similar materials; (6) other seats with wooden frames (with the exception of seats of a kind used for aircraft or motor vehicles); (7) furniture (other than seats) of wood (with the exception of i)

⁴ The shaft length of certain steel nails with flat heads or parallel shoulders under the head shall be measured from under the head or shoulder to the tip of the point. The shaft length of all other certain steel nails shall be measured overall.

Determination and Alignment of Final Countervailing Duty Determination With Final Antidumping Duty Determination, 79 FR 65181 (November 3, 2014) (*Preliminary Determination*).

² See Memorandum to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, "Issues and Decision Memorandum for the Final Determination in the Countervailing Duty Investigation of Certain Steel Nails from Taiwan" (Issues and Decision Memorandum), which is dated concurrently with and is hereby adopted by this notice.

³ *Preliminary Determination*, 79 FR at 65181.

medical, surgical, dental or veterinary furniture; and ii) barbers' chairs and similar chairs, having rotating as well as both reclining and elevating movements); or (8) furniture (other than seats) of materials other than wood, metal, or plastics (e.g., furniture of cane, osier, bamboo or similar materials). The aforementioned imported unassembled articles are currently classified under the following Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 4418.10, 4418.20, 9401.30, 9401.40, 9401.51, 9401.59, 9401.61, 9401.69, 9403.30, 9403.40, 9403.50, 9403.60, 9403.81 or 9403.89.

Also excluded from the scope of this investigation are steel nails that meet the specifications of Type I, Style 20 nails as identified in Tables 29 through 33 of ASTM Standard F1667 (2013 revision).

Also excluded from the scope of this investigation are nails suitable for use in powder-actuated hand tools, whether or not threaded, which are currently classified under HTSUS subheadings 7317.00.20.00 and 7317.00.30.00.

Also excluded from the scope of this investigation are nails having a case hardness greater than or equal to 50 on the Rockwell Hardness C scale (HRC), a carbon content greater than or equal to 0.5 percent, a round head, a secondary reduced-diameter raised head section, a centered shank, and a smooth symmetrical point, suitable for use in gas-actuated hand tools.

Also excluded from the scope of this investigation are corrugated nails. A corrugated nail is made up of a small strip of corrugated steel with sharp points on one side.

Also excluded from the scope of this investigation are thumb tacks, which are currently classified under HTSUS subheading 7317.00.10.00.

Certain steel nails subject to this investigation are currently classified under HTSUS subheadings 7317.00.55.02, 7317.00.55.03, 7317.00.55.05, 7317.00.55.07, 7317.00.55.08, 7317.00.55.11, 7317.00.55.18, 7317.00.55.19, 7317.00.55.20, 7317.00.55.30, 7317.00.55.40, 7317.00.55.50, 7317.00.55.60, 7317.00.55.70, 7317.00.55.80, 7317.00.55.90, 7317.00.65.30, 7317.00.65.60 and 7317.00.75.00. Certain steel nails subject to this investigation also may be classified under HTSUS subheading 8206.00.00.00 or other HTSUS subheadings.

While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

Appendix II

List of Comments and Issues in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Investigation
- IV. Scope Comments
- V. Subsidies Valuation
- VI. Analysis of Programs
- VII. Analysis of Comment

Comment: Specificity of Grants Under the Energy Technology Program

VIII. Recommendation

[FR Doc. 2015-12277 Filed 5-19-15; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[C-580-875]

Certain Steel Nails From the Republic of Korea: Final Negative Countervailing Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) determines that *de minimis* countervailable subsidies are being provided to producers and exporters of certain steel nails (nails) from the Republic of Korea (Korea). The period of investigation is January 1, 2013, through December 31, 2013.

DATES: *Effective Date:* May 20, 2015.

FOR FURTHER INFORMATION CONTACT: Dana Mermelstein or Erin Kearney, 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) 482-1391 and (202) 482-0167, respectively.

SUPPLEMENTARY INFORMATION:

Background

The petitioner in this investigation is Mid Continent Steel & Wire, Inc. (Petitioner). This investigation covers 26 subsidy programs. In addition to the Government of Korea (the GOK), the respondents in this investigation are Daejin Steel Company (Daejin) and Jinheung Steel Corporation, including cross-owned affiliates Duo-Fast Korea Co., Ltd. and Jinsco International Corporation (collectively, Jinheung).

Case History

The following events have occurred since we published the *Preliminary Determination* on November 3, 2014.¹

We conducted verification of the questionnaire responses of the GOK, Daejin, and Jinheung between December 8 and December 17, 2014, and issued verification reports between February 4 and February 10, 2015.² No parties submitted case or rebuttal briefs.

¹ See *Certain Steel Nails From the Republic of Korea: Preliminary Negative Countervailing Duty Determination and Alignment of Final Countervailing Duty Determination With Final Antidumping Duty Determination*, 79 FR 65187 (November 3, 2014) (*Preliminary Determination*).

² See Memoranda to the File, through Robert Bolling, Program Manager, Office IV, "Verification of the Questionnaire Responses of Jinheung Steel Corporation, Jinsco International Corporation, and Duo-Fast Korea Co., Ltd." (February 4, 2015); "Countervailing Duty Investigation of Certain Steel Nails from Korea: Verification of Daejin Steel Company" (February 5, 2015); and "Verification of

Scope of the Investigation

The product covered by this investigation is certain steel nails from Korea. For a full description of the scope of the investigation, see Appendix I to this notice.

Since *the Preliminary Determination*, several interested parties (i.e., IKEA Supply AG, The Home Depot, Target Corporation, and Petitioner) commented on the scope of these investigations. The Department reviewed these comments and made certain changes. For further discussion, see the Issues and Decision Memorandum.³ The scope in Appendix I reflects all modifications to the scope made by the Department for this final determination.

Analysis of Subsidy Programs

The subsidy programs under investigation are discussed in the Issues and Decision Memorandum.⁴ A list of topics discussed in the Issues and Decision Memorandum is attached to this notice as Appendix II. The Issues and Decision Memorandum is a public document and is on file electronically via ACCESS. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Internet at <http://enforcement.trade.gov/frn/index.html>. The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Final Determination

The total estimated net countervailable subsidy rates are:

Company	Subsidy rate percent
Daejin Steel Company	* 0.14
Jinheung Steel Corporation	0.18

the Questionnaire Responses of the Government of Korea" (February 10, 2015).

³ See Memorandum to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, from Howard Smith, Acting Director, Office IV, Antidumping and Countervailing Duty Operations, "Issues and Decision Memorandum for the Final Determination in the Countervailing Duty Investigation of Certain Steel Nails from the Republic of Korea" (Issues and Decision Memorandum), dated concurrently with this determination and hereby adopted by this notice.

⁴ Public versions of all business proprietary documents and all public documents are on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). Access to ACCESS is available to registered users at <http://access.trade.gov> and in the Department's Central Records Unit, Room 7046 of the main Department building.

⁵ For a discussion of these entities' cross-ownership, see the Preliminary Decision Memorandum at 8.

Company	Subsidy rate percent
Duo-Fast Korea Co., Ltd. Jinsco International Corporation ⁵	

* *De minimis*.

Because the total estimated net countervailable subsidy rates for the examined companies are *de minimis*, we determine that countervailable subsidies are not being provided to producers or exporters of nails in Korea. We have not calculated an all-others rate pursuant to sections 705(c)(1)(B) and (c)(5) of the Tariff Act of 1930, as amended (the Act) because we have not reached an affirmative final determination. Because our final determination is negative, this proceeding is terminated in accordance with section 705(c)(2) of the Act.

In the *Preliminary Determination*, the total net countervailable subsidy rates for the individually examined respondents were *de minimis* and, therefore, we did not suspend liquidation of entries of nails from Korea.⁶ Because the estimated subsidy rates for the examined companies are *de minimis* in this final determination, we are not directing U.S. Customs and Border Protection to suspend liquidation of entries of nails from Korea.

United States International Trade Commission (USITC) Notification

In accordance with section 705(d) of the Act, we will notify the USITC of our final determination. Because our final determination is negative, this investigation is terminated.

Return or Destruction of Proprietary Information

This notice serves as the only reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/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 that is subject to sanction.

This determination is issued and published pursuant to sections 705(d) and 777(i) of the Act.

⁶ See *Preliminary Determination*, 79 FR at 65188.

Dated: May 13, 2015.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix I—Scope of the Investigation

The merchandise covered by this investigation is certain steel nails having a nominal shaft length not exceeding 12 inches.⁷ Certain steel nails include, but are not limited to, nails made from round wire and nails that are cut from flat-rolled steel. Certain steel nails may be of one piece construction or constructed of two or more pieces. Certain steel nails may be produced from any type of steel, and may have any type of surface finish, head type, shank, point type and shaft diameter. Finishes include, but are not limited to, coating in vinyl, zinc (galvanized, including but not limited to electroplating or hot dipping one or more times), phosphate, cement, and paint. Certain steel nails may have one or more surface finishes. Head styles include, but are not limited to, flat, projection, cupped, oval, brad, headless, double, countersunk, and sinker. Shank styles include, but are not limited to, smooth, barbed, screw threaded, ring shank and fluted. Screw-threaded nails subject to this proceeding are driven using direct force and not by turning the nail using a tool that engages with the head. Point styles include, but are not limited to, diamond, needle, chisel and blunt or no point. Certain steel nails may be sold in bulk, or they may be collated in any manner using any material.

Excluded from the scope of this investigation are certain steel nails packaged in combination with one or more non-subject articles, if the total number of nails of all types, in aggregate regardless of size, is less than 25. If packaged in combination with one or more non-subject articles, certain steel nails remain subject merchandise if the total number of nails of all types, in aggregate regardless of size, is equal to or greater than 25, unless otherwise excluded based on the other exclusions below.

Also excluded from the scope are certain steel nails with a nominal shaft length of one inch or less that are (a) a component of an unassembled article, (b) the total number of nails is sixty (60) or less, and (c) the imported unassembled article falls into one of the following eight groupings: (1) Builders' joinery and carpentry of wood that are classifiable as windows, French-windows and their frames; (2) builders' joinery and carpentry of wood that are classifiable as doors and their frames and thresholds; (3) swivel seats with variable height adjustment; (4) seats that are convertible into beds (with the exception of those classifiable as garden seats or camping equipment); (5) seats of cane, osier, bamboo or similar materials; (6) other seats with wooden frames (with the exception of seats of a kind used for aircraft or motor vehicles); (7) furniture (other than seats) of wood (with the exception of (i) medical, surgical, dental or veterinary

⁷ The shaft length of certain steel nails with flat heads or parallel shoulders under the head shall be measured from under the head or shoulder to the tip of the point. The shaft length of all other certain steel nails shall be measured overall.

furniture; and (ii) barbers' chairs and similar chairs, having rotating as well as both reclining and elevating movements); or (8) furniture (other than seats) of materials other than wood, metal, or plastics (*e.g.*, furniture of cane, osier, bamboo or similar materials). The aforementioned imported unassembled articles are currently classified under the following Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 4418.10, 4418.20, 9401.30, 9401.40, 9401.51, 9401.59, 9401.61, 9401.69, 9403.30, 9403.40, 9403.50, 9403.60, 9403.81 or 9403.89.

Also excluded from the scope of this investigation are steel nails that meet the specifications of Type I, Style 20 nails as identified in Tables 29 through 33 of ASTM Standard F1667 (2013 revision).

Also excluded from the scope of this investigation are nails suitable for use in powder-actuated hand tools, whether or not threaded, which are currently classified under HTSUS subheadings 7317.00.20.00 and 7317.00.30.00.

Also excluded from the scope of this investigation are nails having a case hardness greater than or equal to 50 on the Rockwell Hardness C scale (HRC), a carbon content greater than or equal to 0.5 percent, a round head, a secondary reduced-diameter raised head section, a centered shank, and a smooth symmetrical point, suitable for use in gas-actuated hand tools.

Also excluded from the scope of this investigation are corrugated nails. A corrugated nail is made up of a small strip of corrugated steel with sharp points on one side.

Also excluded from the scope of this investigation are thumb tacks, which are currently classified under HTSUS subheading 7317.00.10.00.

Certain steel nails subject to this investigation are currently classified under HTSUS subheadings 7317.00.55.02, 7317.00.55.03, 7317.00.55.05, 7317.00.55.07, 7317.00.55.08, 7317.00.55.11, 7317.00.55.18, 7317.00.55.19, 7317.00.55.20, 7317.00.55.30, 7317.00.55.40, 7317.00.55.50, 7317.00.55.60, 7317.00.55.70, 7317.00.55.80, 7317.00.55.90, 7317.00.65.30, 7317.00.65.60 and 7317.00.75.00. Certain steel nails subject to this investigation also may be classified under HTSUS subheading 8206.00.00.00 or other HTSUS subheadings.

While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

Appendix II—List Topics in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Investigation
- IV. Scope Comments
- V. Subsidies Valuation
- VI. Analysis of Programs
- VII. Recommendation

[FR Doc. 2015-12246 Filed 5-19-15; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE**International Trade Administration**

[C-557-817]

Certain Steel Nails From Malaysia: Final Negative Countervailing Duty Determination

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) determines that *de minimis* countervailable subsidies are being provided to producers and exporters of certain steel nails (nails) from Malaysia. The period of investigation is January 1, 2013 through December 31, 2013.

DATES: *Effective Date:* May 20, 2015.

FOR FURTHER INFORMATION CONTACT: Yasmin Nair or Ilissa Shefferman, 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) 482-3813 and (202) 482-4684, respectively.

SUPPLEMENTARY INFORMATION:**Background**

The petitioner in this investigation is Mid Continent Steel & Wire, Inc. (Petitioner). The Department has determined two subsidy programs to be countervailable in this investigation. In addition to the Government of Malaysia (the GOM), the respondents to this investigation are Inmax Sdn. Bhd. and Inmax Industries Sdn. Bhd. (collectively, Inmax) and Region System Sdn. Bhd (Region).

Case History

The following events have occurred since we published the *Preliminary Determination* on November 3, 2014.¹

We conducted verification of the GOM's, Inmax's, and Region System's questionnaire responses from January 22 through January 28, 2015, and issued verification reports on March 3, 2015. Petitioner submitted a case brief on March 18, 2015. Inmax and Region System submitted a rebuttal brief on March 23, 2015.

Scope of the Investigation

The product covered by this investigation is certain steel nails from

¹ See *Certain Steel Nails From Malaysia: Preliminary Negative Countervailing Duty Determination and Alignment of Final Countervailing Duty Determination With Final Antidumping Duty Determination*, 79 FR 65179 (November 3, 2014) (*Preliminary Determination*).

Malaysia. For a full description of the scope of the investigation, see Appendix I to this notice.

Since the *Preliminary Determination*, several interested parties (*i.e.*, IKEA Supply AG, The Home Depot, Target Corporation, and Petitioner) commented on the scope of these investigations. The Department reviewed these comments and made certain changes. For further discussion, see the Issues and Decision Memorandum.² The scope in Appendix I reflects all modifications to the scope made by the Department for this final determination.

Analysis of Subsidy Programs and Comments Received

The subsidy programs under investigation and the issues raised in the case and rebuttal briefs by parties in this investigation are discussed in the Memorandum to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, "Issues and Decision Memorandum for the Final Determination in the Countervailing Duty Investigation of Certain Steel Nails from Malaysia" (Issues and Decision Memorandum),³ which is concurrently dated with, and hereby adopted by, this notice. A list of subsidy programs and the issues that parties raised, and to which we responded in the Issues and Decision Memorandum, is attached to this notice as Appendix II. The Issues and Decision Memorandum is a public document and is on file electronically via ACCESS. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly on the Internet at <http://enforcement.trade.gov/frn/index.html>. The signed Issues and Decision Memorandum and the electronic version of the Issues and Decision Memorandum are identical in content.

Final Determination

The total estimated net countervailable subsidy rates are:

² See Memorandum to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, from Abdelali Elouaradia, Acting Office Director for Enforcement and Compliance (Office VI), "Issues and Decision Memorandum for the Final Determination in the Countervailing Duty Investigation of Certain Steel Nails from Malaysia" (Issues and Decision Memorandum), dated concurrently with this determination and hereby adopted by this notice.

³ Public versions of all business proprietary documents and all public documents are on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Service System (ACCESS). Access to ACCESS is available to registered users at <http://access.trade.gov> and in the Department's Central Records Unit, room 7046 of the main Department building.

Company	Subsidy rate (percent)
Inmax Sdn. Bhd and Inmax Industries Sdn. Bhd	* 0.01
Region System Sdn. Bhd	* 0.02

* *De minimis*.

Because the total estimated net countervailable subsidy rates for the examined companies are *de minimis*, we determine that countervailable subsidies are not being provided to producers or exporters of nails in Malaysia. Consistent with section 705(c)(1)(B) of the Tariff Act of 1930, as amended (the Act), we have not calculated an all-others rate because we have not reached an affirmative final determination. Because our final determination is negative, this proceeding is terminated in accordance with section 705(c)(2) of the Act.

In the *Preliminary Determination*, the total net countervailable subsidy rates for the individually examined respondents were *de minimis* and, therefore, we did not suspend liquidation of entries of nails from Malaysia.⁴ Because the estimated subsidy rates for the examined companies are *de minimis* in this final determination, we are not directing U.S. Customs and Border Protection to suspend liquidation of entries of nails from Malaysia.

United States International Trade Commission (USITC) Notification

In accordance with section 705(d) of the Act, we will notify the USITC of our final determination. Because our final determination is negative, this investigation is terminated.

Return or Destruction of Proprietary Information

This notice serves as the only reminder to parties subject to an administrative protective order (APO) of their responsibility concerning the destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the return/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 that is subject to sanction.

This determination is issued and published pursuant to sections 705(d) and 777(i) of the Act.

⁴ See *Preliminary Determination*, 79 FR at 65180.

Dated: May 13, 2015.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix 1

Scope of the Investigation

The merchandise covered by this investigation is certain steel nails having a nominal shaft length not exceeding 12 inches.⁵ Certain steel nails include, but are not limited to, nails made from round wire and nails that are cut from flat-rolled steel. Certain steel nails may be of one piece construction or constructed of two or more pieces. Certain steel nails may be produced from any type of steel, and may have any type of surface finish, head type, shank, point type and shaft diameter. Finishes include, but are not limited to, coating in vinyl, zinc (galvanized, including but not limited to electroplating or hot dipping one or more times), phosphate, cement, and paint. Certain steel nails may have one or more surface finishes. Head styles include, but are not limited to, flat, projection, cupped, oval, brad, headless, double, countersunk, and sinker. Shank styles include, but are not limited to, smooth, barbed, screw threaded, ring shank and fluted. Screw-threaded nails subject to this proceeding are driven using direct force and not by turning the nail using a tool that engages with the head. Point styles include, but are not limited to, diamond, needle, chisel and blunt or no point. Certain steel nails may be sold in bulk, or they may be collated in any manner using any material.

Excluded from the scope of this investigation are certain steel nails packaged in combination with one or more non-subject articles, if the total number of nails of all types, in aggregate regardless of size, is less than 25. If packaged in combination with one or more non-subject articles, certain steel nails remain subject merchandise if the total number of nails of all types, in aggregate regardless of size, is equal to or greater than 25, unless otherwise excluded based on the other exclusions below.

Also excluded from the scope are certain steel nails with a nominal shaft length of one inch or less that are (a) a component of an unassembled article, (b) the total number of nails is sixty (60) or less, and (c) the imported unassembled article falls into one of the following eight groupings: (1) Builders' joinery and carpentry of wood that are classifiable as windows, French-windows and their frames; (2) builders' joinery and carpentry of wood that are classifiable as doors and their frames and thresholds; (3) swivel seats with variable height adjustment; (4) seats that are convertible into beds (with the exception of those classifiable as garden seats or camping equipment); (5) seats of cane, osier, bamboo or similar materials; (6) other seats with wooden frames (with the exception of seats of a kind used for aircraft or motor vehicles); (7) furniture (other than seats) of wood (with the exception of i)

⁵ The shaft length of certain steel nails with flat heads or parallel shoulders under the head shall be measured from under the head or shoulder to the tip of the point. The shaft length of all other certain steel nails shall be measured overall.

medical, surgical, dental or veterinary furniture; and ii) barbers' chairs and similar chairs, having rotating as well as both reclining and elevating movements); or (8) furniture (other than seats) of materials other than wood, metal, or plastics (e.g., furniture of cane, osier, bamboo or similar materials). The aforementioned imported unassembled articles are currently classified under the following Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 4418.10, 4418.20, 9401.30, 9401.40, 9401.51, 9401.59, 9401.61, 9401.69, 9403.30, 9403.40, 9403.50, 9403.60, 9403.81 or 9403.89.

Also excluded from the scope of this investigation are steel nails that meet the specifications of Type I, Style 20 nails as identified in Tables 29 through 33 of ASTM Standard F1667 (2013 revision).

Also excluded from the scope of this investigation are nails suitable for use in powder-actuated hand tools, whether or not threaded, which are currently classified under HTSUS subheadings 7317.00.20.00 and 7317.00.30.00.

Also excluded from the scope of this investigation are nails having a case hardness greater than or equal to 50 on the Rockwell Hardness C scale (HRC), a carbon content greater than or equal to 0.5 percent, a round head, a secondary reduced-diameter raised head section, a centered shank, and a smooth symmetrical point, suitable for use in gas-actuated hand tools.

Also excluded from the scope of this investigation are corrugated nails. A corrugated nail is made up of a small strip of corrugated steel with sharp points on one side.

Also excluded from the scope of this investigation are thumb tacks, which are currently classified under HTSUS subheading 7317.00.10.00.

Certain steel nails subject to this investigation are currently classified under HTSUS subheadings 7317.00.55.02, 7317.00.55.03, 7317.00.55.05, 7317.00.55.07, 7317.00.55.08, 7317.00.55.11, 7317.00.55.18, 7317.00.55.19, 7317.00.55.20, 7317.00.55.30, 7317.00.55.40, 7317.00.55.50, 7317.00.55.60, 7317.00.55.70, 7317.00.55.80, 7317.00.55.90, 7317.00.65.30, 7317.00.65.60 and 7317.00.75.00. Certain steel nails subject to this investigation also may be classified under HTSUS subheading 8206.00.00.00 or other HTSUS subheadings.

While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

Appendix 2

List of Comments and Issues in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Investigation
- IV. Scope Comments
- V. Subsidies Valuation
- VI. Analysis of Programs
- VII. Analysis of Comment

Comment: Countervailability of Sales Tax Exemptions

VIII. Recommendation

[FR Doc. 2015-12252 Filed 5-19-15; 8:45 am]

BILLING CODE 3510-DS-P

DEPARTMENT OF COMMERCE

International Trade Administration

[A-557-816]

Certain Steel Nails From Malaysia; Final Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (the Department) determines that imports of certain steel nails from Malaysia are being sold in the United States at less than fair value (LTFV), as provided in section 735 of the Tariff Act of 1930, as amended (the Act). The final weighted-average dumping margins of sales at LTFV are listed below in the section entitled "Final Determination Margins."

DATES: *Effective Date:* May 20, 2015.

FOR FURTHER INFORMATION CONTACT: Edythe Artman or Steve Bezirganian, AD/CVD Operations, Office VI, Enforcement and Compliance, International Trade Administration, U.S. Department of Commerce, 14th Street and Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482-3931 or (202) 482-1131, respectively.

SUPPLEMENTARY INFORMATION:

Background

On December 29, 2014, the Department published in the **Federal Register** the preliminary determination in the LTFV investigation of certain steel nails from Malaysia.¹ In the *Preliminary Determination*, we postponed the final determination until no later than 135 days after the publication of the *Preliminary Determination* in accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii) and invited parties to comment on our *Preliminary Determination*.

The following events occurred since December 17, 2014, the day on which the *Preliminary Determination* was signed. On December 29, 2014, and January 12, 2015, Region System Sdn. Bhd. and Region International Co., Ltd. (collectively Region), one of the mandatory respondents, submitted responses to additional Department requests for information. On December 31, 2014, January 2, 2015, and January

¹ See *Certain Steel Nails From Malaysia: Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination and Extension of Provisional Measures*, 79 FR 78055 (December 29, 2014) (*Preliminary Determination*).

8, 2015, Inmax Sdn. Bhd. (Inmax), the other mandatory respondent, submitted responses to additional Department requests for information. On January 9, 2015, Petitioner, Mid Continent Steel & Wire, Inc., submitted factual information in rebuttal to information submitted by Inmax in its aforementioned January 2, 2015 response.

Between January 26, 2015, and February 13, 2015, the Department conducted sales and cost verifications of both respondents. See the "Verification," section below. From March 26, 2015, through April 1, 2015, Petitioner, Inmax, and Region submitted case and/or rebuttal briefs. No public hearing was requested from any party.

Period of Investigation

The period of investigation is April 1, 2013, through March 31, 2014.

Scope of the Investigation

The product covered by this investigation is certain steel nails from Malaysia. For a full description of the scope of the investigation, see Appendix I to this notice.

Since the *Preliminary Determination*, several interested parties (*i.e.*, IKEA Supply AG, The Home Depot, Target Corporation, and Petitioner) commented on the scope of these investigations. The Department reviewed these comments and made certain changes. For further discussion, see the Issues and Decision Memorandum.² The scope in Appendix I reflects all modifications to the scope made by the Department for this final determination.

Verification

As provided in section 782(i) of the Act, in January 2015 through February 2015, we conducted verifications of the sales and cost information submitted by Inmax and Region for use in our final determination. We used standard verification procedures including an examination of relevant accounting and production records, and original source documents provided by Inmax and its affiliate, Inmax Industries Sdn. Bhd., and by Region.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties in this

² See Memorandum to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, from Abdelali Elouaradia, Acting Office Director for Enforcement and Compliance (Office VI), "Issues and Decision Memorandum for the Final Determination of the Less-Than-Fair-Value Investigation of Certain Steel Nails from Malaysia" (Issues and Decision Memorandum), dated concurrently with this determination and hereby adopted by this notice.

investigation are addressed in the Issues and Decision Memorandum. A list of the issues raised is attached to this notice as Appendix II. 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>; the memorandum is available to all parties in the Central Records Unit, room 7046 of the main Department of Commerce building. In addition, a complete version of the Issues and Decision Memorandum can be accessed directly at <http://enforcement.trade.gov>. The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Changes Since the Preliminary Determination

Following analysis of the comments submitted by interested parties, we have assigned a margin to Inmax based on adverse facts available (AFA). For Region, we have made the following changes: Revised energy and labor costs; revised common variable overhead; modified the transactions regarded adjustment related to heat treatment service costs; revised U.S. packing expenses for certain packing materials; corrected a billing adjustment for one home market sale; corrected the inland freight expense for several home market sales; corrected product coding for several home market and U.S. sales; and corrected the shipment date and associated imputed credit expense calculations for several U.S. sales. For more details, see the accompanying Issue and Decision Memorandum and the company-specific analysis memoranda for the final determination.

Use of Facts Otherwise Available and AFA

In the *Preliminary Determination*, we stated that because the mandatory respondent Tag Fasteners Sdn. Bhd. (Tag) failed to respond to the Department's questionnaire, we preliminarily determined to apply facts otherwise available with an adverse inference to this respondent pursuant to sections 776(a) and (b) of the Act. Pursuant to section 776 of the Act, the Department continues to find it appropriate to base Tag's rate on AFA. In addition, pursuant to sections 776(a) and (b) of the Act, the Department determines it is appropriate to apply facts otherwise available with an adverse inference to Inmax. In applying AFA, we are assigning Tag and Inmax

the highest margin identified in the petition, 39.35 percent.³

Final Determination Margins

The Department determines that the following weighted-average dumping margins exist for the period April 1, 2013, through March 31, 2014:

Exporter or producer	Weighted-average dumping margin (percent)
Inmax Sdn. Bhd.	39.35%
Region International Co. Ltd. and Region System Sdn. Bhd.	2.61
Tag Fasteners Sdn. Bhd.	39.35
All Others	2.61

All Others Rate

Section 735(c)(5)(A) of the Act provides that the estimated "All Others" rate shall be an amount equal to the weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero or *de minimis* margins, and any margins determined entirely under section 776 of the Act. The weighted-average margin for exporters and producers individually investigated that meets these criteria is that of Region. Therefore, the All-Others rate is the rate calculated for Region, as indicated in the "Final Determination Margins" section above.

Disclosure

We will disclose to parties in this proceeding the calculations performed for this final determination within five days of the date of public announcement of our final determination, in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

Pursuant to sections 735(c)(1)(B) and (C) of the Act, the Department will instruct U.S. Customs and Border Protection (CBP) to suspend liquidation of all entries of certain steel nails from Malaysia which were entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final determination. We will instruct CBP to require a cash deposit equal to the weighted-average amount by which normal value exceeds U.S. price, as follows: (1) The rates for Inmax, Region, and Tag will be the rates we determined in this final determination; (2) if the exporter is not a firm identified in this investigation but the producer is, the rate will be the

³ See the Issues and Decision Memorandum.

rate established for the producer of the subject merchandise; (3) the rate for all other producers or exporters will be 2.61 percent. These suspension of liquidation instructions will remain in effect until further notice.

International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the U.S. International Trade Commission (ITC) of our final determination. As our final determination is affirmative, in accordance with section 735(b)(3) of the Act, the ITC will determine within 45 days whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports or sales (or the likelihood of sales) for importation of the subject merchandise. If the ITC determines that such injury exists, the Department will issue an antidumping duty order directing CBP to assess, upon further instruction by the Department, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation.

Return or Destruction of Proprietary Information

This notice will serve as a reminder to parties subject to administrative protective order (APO) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this determination and notice in accordance with sections 735(d) and 777(i) of the Act.

Dated: May 13, 2015.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix I—Scope of the Investigation

The merchandise covered by this investigation is certain steel nails having a nominal shaft length not exceeding 12 inches.⁴ Certain steel nails include, but are not limited to, nails made from round wire

⁴ The shaft length of certain steel nails with flat heads or parallel shoulders under the head shall be measured from under the head or shoulder to the tip of the point. The shaft length of all other certain steel nails shall be measured overall.

and nails that are cut from flat-rolled steel. Certain steel nails may be of one piece construction or constructed of two or more pieces. Certain steel nails may be produced from any type of steel, and may have any type of surface finish, head type, shank, point type and shaft diameter. Finishes include, but are not limited to, coating in vinyl, zinc (galvanized, including but not limited to electroplating or hot dipping one or more times), phosphate, cement, and paint. Certain steel nails may have one or more surface finishes. Head styles include, but are not limited to, flat, projection, cupped, oval, brad, headless, double, countersunk, and sinker. Shank styles include, but are not limited to, smooth, barbed, screw threaded, ring shank and fluted. Screw-threaded nails subject to this proceeding are driven using direct force and not by turning the nail using a tool that engages with the head. Point styles include, but are not limited to, diamond, needle, chisel and blunt or no point. Certain steel nails may be sold in bulk, or they may be collated in any manner using any material.

Excluded from the scope of this investigation are certain steel nails packaged in combination with one or more non-subject articles, if the total number of nails of all types, in aggregate regardless of size, is less than 25. If packaged in combination with one or more non-subject articles, certain steel nails remain subject merchandise if the total number of nails of all types, in aggregate regardless of size, is equal to or greater than 25, unless otherwise excluded based on the other exclusions below.

Also excluded from the scope are certain steel nails with a nominal shaft length of one inch or less that are (a) a component of an unassembled article, (b) the total number of nails is sixty (60) or less, and (c) the imported unassembled article falls into one of the following eight groupings: (1) Builders' joinery and carpentry of wood that are classifiable as windows, French-windows and their frames; (2) builders' joinery and carpentry of wood that are classifiable as doors and their frames and thresholds; (3) swivel seats with variable height adjustment; (4) seats that are convertible into beds (with the exception of those classifiable as garden seats or camping equipment); (5) seats of cane, osier, bamboo or similar materials; (6) other seats with wooden frames (with the exception of seats of a kind used for aircraft or motor vehicles); (7) furniture (other than seats) of wood (with the exception of i) medical, surgical, dental or veterinary furniture; and ii) barbers' chairs and similar chairs, having rotating as well as both reclining and elevating movements); or (8) furniture (other than seats) of materials other than wood, metal, or plastics (e.g., furniture of cane, osier, bamboo or similar materials). The aforementioned imported unassembled articles are currently classified under the following Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 4418.10, 4418.20, 9401.30, 9401.40, 9401.51, 9401.59, 9401.61, 9401.69, 9403.30, 9403.40, 9403.50, 9403.60, 9403.81 or 9403.89.

Also excluded from the scope of this investigation are steel nails that meet the specifications of Type I, Style 20 nails as identified in Tables 29 through 33 of ASTM Standard F1667 (2013 revision).

Also excluded from the scope of this investigation are nails suitable for use in powder-actuated hand tools, whether or not threaded, which are currently classified under HTSUS subheadings 7317.00.20.00 and 7317.00.30.00.

Also excluded from the scope of this investigation are nails having a case hardness greater than or equal to 50 on the Rockwell Hardness C scale (HRC), a carbon content greater than or equal to 0.5 percent, a round head, a secondary reduced-diameter raised head section, a centered shank, and a smooth symmetrical point, suitable for use in gas-actuated hand tools.

Also excluded from the scope of this investigation are corrugated nails. A corrugated nail is made up of a small strip of corrugated steel with sharp points on one side.

Also excluded from the scope of this investigation are thumb tacks, which are currently classified under HTSUS subheading 7317.00.10.00.

Certain steel nails subject to this investigation are currently classified under HTSUS subheadings 7317.00.55.02, 7317.00.55.03, 7317.00.55.05, 7317.00.55.07, 7317.00.55.08, 7317.00.55.11, 7317.00.55.18, 7317.00.55.19, 7317.00.55.20, 7317.00.55.30, 7317.00.55.40, 7317.00.55.50, 7317.00.55.60, 7317.00.55.70, 7317.00.55.80, 7317.00.55.90, 7317.00.65.30, 7317.00.65.60 and 7317.00.75.00. Certain steel nails subject to this investigation also may be classified under HTSUS subheading 8206.00.00.00 or other HTSUS subheadings.

While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

Appendix II—List of Topics Discussed in the Issues and Decision Memorandum

Issues Pertaining to Inmax

Comment 1: Application of Adverse Facts Available for Inmax

Issues Pertaining to Region

Comment 2: Region System Energy and Labor Costs

Comment 3: Region System Common Variable Overhead

Comment 4: Region System Heat Treatment Service Costs

Comment 5: Region System Financial Expense Rate

Comment 6: Whether to Revise Region System G&A Expenses to include Region Products Marketing G&A Expenses

Comment 7: Region System G&A and Interest Expense Calculations

Comment 8: U.S. Warranty Expenses

Comment 9: Packing Expenses

[FR Doc. 2015–12250 Filed 5–19–15; 8:45 am]

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DEPARTMENT OF COMMERCE

International Trade Administration

[A-523-808]

Certain Steel Nails From the Sultanate of Oman: Final Determination of Sales at Less Than Fair Value

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: The Department of Commerce (“the Department”) determines that imports of certain steel nails (“nails”) from the Sultanate of Oman (“Oman”) are being sold in the United States at less than fair value (“LTFV”), as provided in section 735 of the Tariff Act of 1930, as amended (the “Act”). The final weighted-average dumping margins of sales at LTFV are listed below in the section entitled “Final Determination Margins.”

DATES: *Effective Date:* May 20, 2015.

FOR FURTHER INFORMATION CONTACT: Lilit Astvatsatrian, 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) 482-6412.

SUPPLEMENTARY INFORMATION:

Background

On December 29, 2014, the Department published in the **Federal Register** the preliminary determination in the LTFV investigation of nails from Oman.¹ In the *Preliminary Determination*, we postponed the final determination until no later than 135 days after the publication of the *Preliminary Determination* in accordance with section 735(a)(2)(A) of the Act and 19 CFR 351.210(b)(2)(ii) and invited parties to comment on our *Preliminary Determination*.

The following events have occurred since the *Preliminary Determination*. Between January 19, 2015 and January 29, 2015, the Department conducted sales and cost verifications of the mandatory respondent, Oman Fasteners, LLC (“Oman Fasteners”). On March 10, 2015, Mid Continent Steel & Wire, Inc. (“Petitioner”), Oman Fasteners, and Overseas International Steel Industry, LLC (“OISI”), an interested party, submitted case briefs. On March 18, 2015, Petitioner, Oman Fasteners, and OISI submitted rebuttal briefs. On April

¹ See *Certain Steel Nails From the Sultanate of Oman: Affirmative Preliminary Determination of Sales at Less Than Fair Value and Postponement of Final Determination*, 79 FR 78034 (December 29, 2014) (“*Preliminary Determination*”).

16, 2015, the Department held a public hearing.

Period of Investigation

The period of investigation (“POI”) is April 1, 2013 through March 31, 2014.

Scope of the Investigation

The product covered by this investigation is certain steel nails from Oman. For a full description of the scope of the investigation, see Appendix I to this notice.

Since the *Preliminary Determination*, several interested parties (*i.e.*, IKEA Supply AG, The Home Depot, Target Corporation, and Petitioner) commented on the scope of these investigations. The Department reviewed these comments and made certain changes. For further discussion, see the Issues and Decision Memorandum.² The scope in Appendix I reflects all modifications to the scope made by the Department for this final determination.

Verification

As provided in section 782(i) of the Act, in January 2015, we verified the sales and cost information submitted by Oman Fasteners for use in our final determination. We used standard verification procedures including an examination of relevant accounting and production records, and original source documents provided by Oman Fasteners.

Analysis of Comments Received

All issues raised in the case and rebuttal briefs by parties in this investigation are addressed in the Issues and Decision Memorandum accompanying this notice, and which is hereby adopted by this notice. A list of the issues raised and to which the Department responded is attached to this notice as Appendix II. 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>. The Issues and Decision memorandum is available to all parties in the Central Records Unit, room 7046 of the main Department of Commerce building. In addition, a

² See Memorandum to Christian Marsh, Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations, from Abdelali Elouaradia, Acting Office Director for Enforcement and Compliance (Office VI), “Certain Steel Nails from the Sultanate of Oman: Issues and Decision Memorandum for the Final Determination of Sales at Less Than Fair Value” (Issues and Decision Memorandum), dated concurrently with this determination and hereby adopted by this notice.

complete version of the Issues and Decision Memorandum can be accessed directly at <http://enforcement.trade.gov>. The signed and electronic versions of the Issues and Decision Memorandum are identical in content.

Changes to the Margin Calculations Since the Preliminary Determination

- We updated Oman Fasteners’ reported sales quantity as a result of minor corrections and findings at the verification.³
- We corrected the misspelled name of a variable in the U.S. sales database which was used in the calculation of the freight revenue cap.⁴
- We excluded a sale with a sale date prior to the beginning of the POI.⁵
- We updated the shipment dates and the U.S. credit expense for certain sales as a result of findings at the verification.⁶
- We adjusted the reported total cost of manufacturing of each control number to reflect the revised per-unit scrap offset identified at the cost verification.⁷

Final Determination Margins

The Department determines that the following weighted-average dumping margins exist for the period April 1, 2013, through March 31, 2014:

Exporter or producer	Weighted-average dumping margin (percent)
Oman Fasteners, LLC	9.10
All Others	9.10

All Others Rate

Section 735(c)(5)(A) of the Act provides that the estimated “all others” rate shall be an amount equal to the

³ See Memorandum to the File from Lilit Astvatsatrian, International Trade Compliance Analyst, “Analysis Memorandum for the Final Determination of the Antidumping Duty Investigation of Certain Steel Nails from the Sultanate of Oman: Oman Fasteners, LLC,” dated concurrently with this determination (“Final Analysis Memorandum”), at pages 1–2 and Attachment 1; see also Verification of the Sales Questionnaire Responses of Oman Fasteners, LLC: Antidumping Duty Investigation of Certain Steel Nails from the Sultanate of Oman, dated February 27, 2015 (“Verification Report”), at page 2 and Exhibit 1.

⁴ See Final Analysis Memorandum, at page 2 and Attachment 1 and IDM, at Comment 3.

⁵ See Final Analysis Memorandum, at page 2 and Attachment 1 and IDM, at Comment 5.

⁶ See Final Analysis Memorandum, at page 2 and Attachment 1; IDM, at Comment 4, and Verification Report, at Exhibits VE–VIII.A–D and VE–VIII.F–G.

⁷ See Memorandum to the File from Robert B. Greger, Verification of Oman Fasteners LLC in the Antidumping Duty Investigation of Certain Steel Nails from the Sultanate of Oman, dated February 18, 2015 at page 2.

weighted average of the estimated weighted-average dumping margins established for exporters and producers individually investigated, excluding any zero or *de minimis* margins, and any margins determined entirely under section 776 of the Act. We based our calculation of the “all others” rate on the margin calculated for Oman Fasteners, the only mandatory respondent in this investigation.

Disclosure

We will disclose to parties in this proceeding the calculations performed for this final determination within five days of the date of public announcement of our final determination, in accordance with 19 CFR 351.224(b).

Continuation of Suspension of Liquidation

Pursuant to section 735(c)(1)(B) of the Act, the Department will instruct U.S. Customs and Border Protection (“CBP”) to continue to suspend liquidation of all entries of certain steel nails from Oman which were entered, or withdrawn from warehouse, for consumption on or after December 29, 2014, the date of publication of the *Preliminary Determination*. We also will instruct CBP to require a cash deposit equal to the weighted-average amount by which normal value exceeds U.S. price, as follows: (1) The cash deposit rate for Oman Fasteners will be equal to the estimated weighted-average dumping margin determined in this final determination; (2) if the exporter is not a firm identified in this investigation but the producer is, the cash deposit rate will be equal to the estimated weighted-average dumping margin established for the producer of the subject merchandise; and (3) the cash deposit rate for all other producers or exporters will be 9.10 percent. These suspension of liquidation instructions will remain in effect until further notice.

International Trade Commission Notification

In accordance with section 735(d) of the Act, we will notify the U.S. International Trade Commission (“ITC”) of our final determination. As our final determination is affirmative, in accordance with section 735(b)(2) of the Act, the ITC will determine within 45 days whether the domestic industry in the United States is materially injured, or threatened with material injury, by reason of imports or sales (or the likelihood of sales) for importation of the subject merchandise. If the ITC determines that such injury exists, the Department will issue an antidumping

duty order directing CBP to assess, upon further instruction by the Department, antidumping duties on all imports of the subject merchandise entered, or withdrawn from warehouse, for consumption on or after the effective date of the suspension of liquidation.

Return or Destruction of Proprietary Information

This notice will serve as a reminder to parties subject to administrative protective order (“APO”) of their responsibility concerning the disposition of proprietary information disclosed under APO in accordance with 19 CFR 351.305(a)(3). Timely written notification of the destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and the terms of an APO is a sanctionable violation.

Notification to Interested Parties

We are issuing and publishing this determination and notice in accordance with sections 735(d) and 777(i) of the Act.

Dated: May 13, 2015.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

Appendix I—Scope of the Investigation

The merchandise covered by this investigation is certain steel nails having a nominal shaft length not exceeding 12 inches.⁸ Certain steel nails include, but are not limited to, nails made from round wire and nails that are cut from flat-rolled steel. Certain steel nails may be of one piece construction or constructed of two or more pieces. Certain steel nails may be produced from any type of steel, and may have any type of surface finish, head type, shank, point type and shaft diameter. Finishes include, but are not limited to, coating in vinyl, zinc (galvanized, including but not limited to electroplating or hot dipping one or more times), phosphate, cement, and paint. Certain steel nails may have one or more surface finishes. Head styles include, but are not limited to, flat, projection, cupped, oval, brad, headless, double, countersunk, and sinker. Shank styles include, but are not limited to, smooth, barbed, screw threaded, ring shank and fluted. Screw-threaded nails subject to this proceeding are driven using direct force and not by turning the nail using a tool that engages with the head. Point styles include, but are not limited to, diamond, needle, chisel and blunt or no point. Certain steel nails may be sold in bulk, or they may be collated in any manner using any material.

Excluded from the scope of this investigation are certain steel nails packaged

⁸The shaft length of certain steel nails with flat heads or parallel shoulders under the head shall be measured from under the head or shoulder to the tip of the point. The shaft length of all other certain steel nails shall be measured overall.

in combination with one or more non-subject articles, if the total number of nails of all types, in aggregate regardless of size, is less than 25. If packaged in combination with one or more non-subject articles, certain steel nails remain subject merchandise if the total number of nails of all types, in aggregate regardless of size, is equal to or greater than 25, unless otherwise excluded based on the other exclusions below.

Also excluded from the scope are certain steel nails with a nominal shaft length of one inch or less that are (a) a component of an unassembled article, (b) the total number of nails is sixty (60) or less, and (c) the imported unassembled article falls into one of the following eight groupings: (1) Builders’ joinery and carpentry of wood that are classifiable as windows, French-windows and their frames; (2) builders’ joinery and carpentry of wood that are classifiable as doors and their frames and thresholds; (3) swivel seats with variable height adjustment; (4) seats that are convertible into beds (with the exception of those classifiable as garden seats or camping equipment); (5) seats of cane, osier, bamboo or similar materials; (6) other seats with wooden frames (with the exception of seats of a kind used for aircraft or motor vehicles); (7) furniture (other than seats) of wood (with the exception of (i) medical, surgical, dental or veterinary furniture; and ii) barbers’ chairs and similar chairs, having rotating as well as both reclining and elevating movements); or (8) furniture (other than seats) of materials other than wood, metal, or plastics (e.g., furniture of cane, osier, bamboo or similar materials). The aforementioned imported unassembled articles are currently classified under the following Harmonized Tariff Schedule of the United States (HTSUS) subheadings: 4418.10, 4418.20, 9401.30, 9401.40, 9401.51, 9401.59, 9401.61, 9401.69, 9403.30, 9403.40, 9403.50, 9403.60, 9403.81 or 9403.89.

Also excluded from the scope of this investigation are steel nails that meet the specifications of Type I, Style 20 nails as identified in Tables 29 through 33 of ASTM Standard F1667 (2013 revision).

Also excluded from the scope of this investigation are nails suitable for use in powder-actuated hand tools, whether or not threaded, which are currently classified under HTSUS subheadings 7317.00.20.00 and 7317.00.30.00.

Also excluded from the scope of this investigation are nails having a case hardness greater than or equal to 50 on the Rockwell Hardness C scale (HRC), a carbon content greater than or equal to 0.5 percent, a round head, a secondary reduced-diameter raised head section, a centered shank, and a smooth symmetrical point, suitable for use in gas-actuated hand tools.

Also excluded from the scope of this investigation are corrugated nails. A corrugated nail is made up of a small strip of corrugated steel with sharp points on one side.

Also excluded from the scope of this investigation are thumb tacks, which are currently classified under HTSUS subheading 7317.00.10.00.

Certain steel nails subject to this investigation are currently classified under

HTSUS subheadings 7317.00.55.02, 7317.00.55.03, 7317.00.55.05, 7317.00.55.07, 7317.00.55.08, 7317.00.55.11, 7317.00.55.18, 7317.00.55.19, 7317.00.55.20, 7317.00.55.30, 7317.00.55.40, 7317.00.55.50, 7317.00.55.60, 7317.00.55.70, 7317.00.55.80, 7317.00.55.90, 7317.00.65.30, 7317.00.65.60 and 7317.00.75.00. Certain steel nails subject to this investigation also may be classified under HTSUS subheading 8206.00.00.00 or other HTSUS subheadings.

While the HTSUS subheadings are provided for convenience and customs purposes, the written description of the scope of this investigation is dispositive.

Appendix II—List of Topics in the Issues and Decision Memorandum

- I. Summary
- II. Background
- III. Scope of the Investigation
- IV. Scope Comments
- V. Discussion of the Issues
- VI. Recommendation

[FR Doc. 2015–12248 Filed 5–19–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

National Institute of Standards and Technology

Proposed Information Collection; Comment Request; Student Information System (SIS)

AGENCY: National Institute of Standards and Technology, Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before July 20, 2015.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at Jjessup@doc.gov).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Kristen Gilbert, Office of Human Resources Management, NIST, 100 Bureau Dr., Mail Stop 1720, Gaithersburg, MD 20899–1080; 301–975–3001; kristen.gilbert@nist.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

The Student Information System (SIS) is designed to collect on-line applications from students for NIST programs such as the Student Volunteer Program (SVP) and Summer High School Intern Program (SHIP). The purpose of the application is to obtain information needed to evaluate applicant qualifications for potential positions.

The Student Information System is an online application which collects basic biographical information about the student. The application contains four sections. The first section collects personal information to include name, address, phone, email, program selection, work availability, and location preferences. The second section collects work and volunteer experience including start and end date, hours worked, name and address of employer, supervisor's contact information, job description, and job-related skills. The third section collects any special training, knowledge, skill, ability, and/or publications that demonstrate the applicant's skill sets to perform a position. The fourth section collects education information to include current enrollment, name and address of the educational institution, grade point average, and expected date of program completion.

II. Method of Collection

The information is collected via NIST's on-line Student Information System.

III. Data

OMB Control Number: 0693–XXXX.

Form Number(s): None.

Type of Review: New collection.

Affected Public: Individuals or households.

Estimated Number of Respondents: 400.

Estimated Time per Response: 45 minutes.

Estimated Total Annual Burden Hours: 300 hours.

Estimated Total Annual Cost to Public: \$0.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the

burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: May 15, 2015.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2015–12175 Filed 5–19–15; 8:45 am]

BILLING CODE 3510–13–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Annual Economic Survey of Federal Gulf and South Atlantic Shrimp Permit Holders

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before July 20, 2015.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at Jjessup@doc.gov).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Christopher Liese, Industry Economist, SEFSC, NMFS, 75 Virginia Beach Drive, Miami FL 33149, (305) 365–4109 or Christopher.Liese@noaa.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for revision and extension of a currently approved information collection.

NOAA Fisheries, Southeast Fisheries Science Center, annually collects

socioeconomic data from commercial fishermen in the Gulf of Mexico and South Atlantic shrimp fisheries who hold one or more permits for harvesting shrimp from federal waters (U.S. Exclusive Economic Zone). Information about revenues, variable and fixed costs, capital investment and other socioeconomic information is collected from a random sample of permit holders. Additionally, we will pilot a short demographic/socioeconomic survey of shrimp vessel crews. Next to nothing is known about the 4–5 thousand individuals crewing federally permitted shrimp vessels. These data are needed to conduct socioeconomic analyses in support of management of the shrimp fishery and to satisfy legal requirements. The data will be used to assess how fishermen will be impacted by and respond to federal regulation likely to be considered by fishery managers.

II. Method of Collection

The information will be collected on paper using a mail survey.

III. Data

OMB Control Number: 0648–0591.
Form Number(s): None.

Type of Review: Regular submission (revision and extension of a currently approved collection).

Affected Public: Business or other for-profit organizations; individuals or households.

Estimated Number of Respondents: 650 (permit holders) and 1,200 (crew).

Estimated Time per Response: 45 minutes (permit holders) and 15 minutes (crew).

Estimated Total Annual Burden Hours: 788.

Estimated Total Annual Cost to Public: \$0 in recordkeeping/reporting costs.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or

included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: May 15, 2015.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2015–12202 Filed 5–19–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Pacific Islands Region Coral Reef Ecosystems Logbook and Reporting

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before July 20, 2015.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at Jjessup@doc.gov).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Walter Ikehara, (808) 725–5175 or Walter.Ikehara@noaa.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

This request is for extension of a current information collection.

National Marine Fisheries Service (NMFS) requires any United States (U.S.) citizen issued a Special Coral Reef Ecosystem Fishing Permit to complete logbooks and submit them to NMFS (50 CFR 665). The Special Coral Reef Ecosystem Fishing Permit is authorized under the Fishery Ecosystem Plans for American Samoa Archipelago, Hawaiian Archipelago, Mariana Archipelago, and Pacific Remote Island Areas. The information in the logbooks is used to obtain fish catch/fishing effort data on

coral reef fishes and invertebrates harvested in designated low-use marine protected areas and on those listed in the regulations as potentially-harvested coral reef taxa in waters of the U.S. exclusive economic zone in the western Pacific region. These data are needed to determine the condition of the stocks, whether the current management measures are having the intended effects, and to evaluate the benefits and costs of changes in management measures. The logbook information includes interactions with protected species, including sea turtles, monk seals, and other marine mammals, which are used to monitor and respond to incidental takes of endangered and threatened marine species.

II. Method of Collection

Reports are submitted to NMFS in the form of paper logbook sheets and paper transshipment forms within 30 days of each landing of coral reef harvest. No electronic forms or web-based reporting is currently available. Notifications are submitted via telephone.

III. Data

OMB Number: 0648–0462.

Form Number: None.

Type of Review: Regular submission (extension of a currently approved information collection).

Affected Public: Business or other for-profit organizations; individuals or households.

Estimated Number of Respondents: 5.

Estimated Time per Response: Pre-trip and pre-landing notifications, 3 minutes; logbook reports, 30 minutes; transshipment reports, 15 minutes.

Estimated Total Annual Burden Hours: 382.

Estimated Total Annual Cost to Public: \$0 (application fees have not been set).

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or

included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: May 15, 2015.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2015-12197 Filed 5-19-15; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

Proposed Information Collection; Comment Request; Alaska Observer Program

AGENCY: National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995.

DATES: Written comments must be submitted on or before July 20, 2015.

ADDRESSES: Direct all written comments to Jennifer Jessup, Departmental Paperwork Clearance Officer, Department of Commerce, Room 6616, 14th and Constitution Avenue NW., Washington, DC 20230 (or via the Internet at Jjessup@doc.gov).

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Patsy Bearden, (907) 586-7008 or patsy.bearden@noaa.gov.

SUPPLEMENTARY INFORMATION:

I. Abstract

The North Pacific Groundfish and Halibut Observer Program (Observer Program) plays a critical role in the conservation and management of Bering Sea, Aleutian Islands, and Gulf of Alaska groundfish and halibut fisheries. Five observer contracting companies provide observer services (see http://www.afsc.noaa.gov/FMA/observer_providers.htm). Observers collect biological samples and fishery-dependent information on total catch and interactions with protected species. Managers use data collected by observers to monitor quotas, manage groundfish and prohibited species

catch, and document and reduce fishery interactions with protected resources. Scientists use observer-collected data for stock assessments and marine ecosystem research.

All sectors of the groundfish fishery, including vessels less than 60 feet length overall and the commercial halibut sector, are now included in the Observer Program. The National Marine Fisheries Service (NMFS) has the flexibility to decide when and where to deploy observers based on a scientifically defensible deployment plan reviewed annually by the North Pacific Fishery Management Council. The Observer Program places all vessels and processors in the groundfish and halibut fisheries off Alaska into one of two observer coverage categories: A full coverage category and a partial coverage category.

II. Method of Collection

This request is for extension of a currently approved information collection.

Electronically submitted landing information submitted by managers of shoreside processors and stationary floating processors (SFPs) is used to assess the observer fee liability for each landing. Managers of shoreside processors and SFPs access reports generated by NMFS' Web-based application for a receipt of the observer fee liability associated with each landing. NMFS makes electronic monitoring available as an alternative tool for fulfilling observer coverage requirements. The electronic monitoring option does not change the funding mechanism or fee amount, but does provide an alternative to carrying a human observer.

III. Data

OMB Control Number: 0648-0318.

Form Number(s): None.

Type of Review: Regular (extension of a current information collection).

Affected Public: Business or other for-profit organizations.

Estimated Number of Respondents: 959.

Estimated Time per Response: 8 hr to review and 1 hr to submit candidate college transcripts and statements, Observer provider; 1 hr for Observer training registration; 7 minutes for Observer briefing registration; 7 minutes for Projected observer assignment; 5 minutes for Physical examination verification; 7 minutes for Observer deployment/logistics report; 30 minutes for Observer debriefing registration; 12 minutes for Certificates of insurance; 30 minutes for Observer provider contracts; 1 hr for Other reports; 30 minutes for

Industry Request for Assistance in Improving Observer Data Quality Issues; 60 hr for Observer provider permit application; 30 minutes for Observer provider invoice copies; 15 minutes each for Update to provider information, Observer declaration and deployment system (ODDs), Observer fee calculation and submittal and Notification of one-time election of observer coverage; 4 hours for Observer appeal; 1 hr for Request for electronic monitoring as exemption for observer coverage.

Estimated Total Annual Burden Hours: 4,130.

Estimated Total Annual Cost to Public: \$3,256.

IV. Request for Comments

Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden (including hours and cost) of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval of this information collection; they also will become a matter of public record.

Dated: May 14, 2015.

Sarah Brabson,

NOAA PRA Clearance Officer.

[FR Doc. 2015-12155 Filed 5-19-15; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XD946

Permits; Foreign Fishing

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

ACTION: Notice of application for permit; request for comments.

SUMMARY: NMFS publishes for public review and comment information regarding a permit application for transshipment of Atlantic herring by Canadian vessels, submitted under

provisions of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). This action is necessary for NMFS to make a determination that the permit application can be approved.

DATES: Written comments must be received by June 3, 2015.

ADDRESSES: Written comments on this action, identified by RIN 0648-XD946, should be sent to Melissa Garcia in the NMFS Office for International Affairs and Seafood Inspection at 1315 East-West Highway, Silver Spring, MD 20910 (phone: (301) 427-8385, fax: (301) 713-2313, email: melissa.garcia@noaa.gov).

FOR FURTHER INFORMATION CONTACT: Melissa Garcia at (301) 427-8385 or by email at melissa.garcia@noaa.gov.

SUPPLEMENTARY INFORMATION:

Background

Section 204(d) of the Magnuson-Stevens Act (16 U.S.C. 1824(d)) authorizes the Secretary of Commerce (Secretary) to issue a transshipment permit authorizing a vessel other than a vessel of the United States to engage in fishing consisting solely of transporting fish or fish products at sea from a point within the United States Exclusive Economic Zone (EEZ) or, with the concurrence of a state, within the boundaries of that state, to a point outside the United States. In addition, Public Law 104-297, section 105(e), directs the Secretary to issue section 204(d) permits for up to 14 Canadian transport vessels to receive Atlantic herring harvested by United States fishermen and to be used in sardine processing. Transshipment must occur from within the boundaries of the State of Maine or within the portion of the EEZ east of the line 69 degrees 30 minutes west and within 12 nautical miles from Maine's seaward boundary.

Section 204(d)(3)(D) of the Magnuson-Stevens Act provides that an application may not be approved until the Secretary determines that "no owner or operator of a vessel of the United States which has adequate capacity to perform the transportation for which the application is submitted has indicated . . . an interest in performing the transportation at fair and reasonable rates." NMFS is publishing this notice as part of its effort to make such a determination with respect to the application described below.

Summary of Application

NMFS received an application requesting authorization for four Canadian transport vessels to receive transfers of herring from United States purse seine vessels, stop seines, and

weirs for the purpose of transporting the herring to Canada for processing. The transshipment operations will occur within the boundaries of the State of Maine or within the portion of the EEZ east of the line 69°30' W. longitude and within 12 nautical miles from Maine's seaward boundary.

Dated: May 13, 2015.

John Henderschedt,

Director, Office for International Affairs and Seafood Inspection, National Marine Fisheries Service.

[FR Doc. 2015-12271 Filed 5-19-15; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XD951

Western Pacific Fishery Management Council; Public Meetings

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

ACTION: Notice of public meetings and hearings.

SUMMARY: The Western Pacific Fishery Management Council (Council) will hold a meeting of its Guam and Commonwealth of the Northern Mariana Islands (CNMI) Mariana Archipelago Fishery Ecosystem Plan (FEP) Advisory Panels (AP) to discuss and make recommendations on fishery management issues in the Western Pacific Region.

DATES: The Guam Mariana Archipelago FEP AP will meet on Friday, June 5, 2015, between 6 p.m. and 7:30 p.m. and the CNMI Mariana Archipelago FEP AP will meet on Friday, June 5, 2015, between 5 p.m. and 7 p.m. All times listed are local island times.

For specific times and agendas, see **SUPPLEMENTARY INFORMATION.**

ADDRESSES: The Guam Mariana Archipelago FEP AP will meet at the Guam Fishermen's Cooperative Association Lanai in Hagatna, Guam, and the CNMI Mariana Archipelago FEP AP will meet at the Division of Fish and Wildlife Conference Room in Tanapag, Saipan, CNMI.

FOR FURTHER INFORMATION CONTACT: Kitty M. Simonds, Executive Director; telephone (808) 522-8220.

SUPPLEMENTARY INFORMATION: Public comment periods will be provided in the agenda. The order in which agenda items are addressed may change. The

meetings will run as late as necessary to complete scheduled business.

Schedule and Agenda for the Guam Mariana Archipelago FEP AP Meeting

6 p.m.–7:30 p.m., Friday, June 5, 2015

1. "Hafa Adai" Welcome and Introductions
2. Review and Approval of the Agenda
3. Issues to be discussed at 163rd Council Meeting
 - A. Upcoming Council Action Items
 - i. Cooperative Research Priorities
 - ii. Five-year Research Priorities
 - B. Mariana Archipelago FEP-Guam Community Activities
4. Mariana Archipelago FEP-Guam Issues
 - A. Report of the Subpanels
 - i. Island Fisheries Subpanel
 - ii. Pelagic Fisheries Subpanel
 - iii. Ecosystems and Habitat Subpanel
 - iv. Indigenous Fishing Rights Subpanel
 - B. Other Issues
5. Public Comment
6. Discussion and Recommendations
7. "At the end of the day" Other Business

Schedule and Agenda for the CNMI Mariana Archipelago FEP AP Meeting

5 p.m.–7 p.m., Friday, June 5, 2015

1. Welcome and Introductions
2. Review and Approval of the Agenda
3. Issues to be discussed at 163rd Council Meeting
 - A. Upcoming Council Action Items
 - i. Cooperative Research Priorities
 - ii. Five-year Research Priorities
 - B. Mariana Archipelago FEP-CNMI Community Activities
4. Mariana Archipelago FEP-CNMI Issues
 - A. Report of the Subpanels
 - i. Island Fisheries Subpanel
 - ii. Pelagic Fisheries Subpanel
 - iii. Ecosystems and Habitat Subpanel
 - iv. Indigenous Fishing Rights Subpanel
 - B. Other Issues
5. Public Comment
6. Discussion and Recommendations
7. Other Business

Special Accommodations

These meetings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Kitty M. Simonds, (808) 522-8220 (voice) or (808) 522-8226 (fax), at least 5 days prior to the meeting date.

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

Dated: May 15, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015-12172 Filed 5-19-15; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XD952

Pacific Fishery Management Council; Public Meeting

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

ACTION: Notice; public meeting.

SUMMARY: The Pacific Fishery Management Council's (Pacific Council) Groundfish Management Team (GMT) will hold a conference call that is open to the public. To attend the GMT teleconference, participants need to dial the following toll-free number 1-888-283-0166 Participant Code: 4432591.

DATES: The GMT meeting will be held Thursday, June 4, 2015 from 1 p.m. until business for the day is completed.

ADDRESSES: The meeting will be held via conference call with a listening station provided at the Pacific Council Office, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220-1384; telephone: (503) 820-2280.

Council address: Pacific Council, 7700 NE Ambassador Place, Suite 101, Portland, OR 97220-1384.

FOR FURTHER INFORMATION CONTACT: Ms. Kelly Ames, Pacific Council; telephone: (503) 820-2426.

SUPPLEMENTARY INFORMATION: The primary purpose of the GMT working meeting is to prepare for the June 2015 Council meeting. Specific agenda topics include a review of the latest West Coast Groundfish Observer Program data; inseason adjustments to groundfish fisheries; salmon Endangered Species Act reconsultation update; and the process for adopting harvest specifications and management measures for the 2017-2018 fisheries. The GMT may also address other assignments relating to groundfish management. No management actions will be decided by the GMT. Public comment will be accommodated if time allows, at the discretion of the GMT Chair. The GMT's task will be to develop recommendations for consideration by the Pacific Council at its June 10-16, 2015 meeting in Spokane, WA.

Although non-emergency issues not contained in the meeting agenda may be discussed, those issues may not be the subject of formal action during this meeting. Action will be restricted to those issues specifically listed in this document and any issues arising after publication of this document that require emergency action under section 305(c) of the Magnuson-Stevens Fishery Conservation and Management Act, provided the public has been notified of the intent to take final action to address the emergency.

Special Accommodations

The meeting is physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Mr. Kris Kleinschmidt at (503) 820-2425 at least 5 days prior to the meeting date.

Dated: May 15, 2015.

Tracey L. Thompson,

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

[FR Doc. 2015-12171 Filed 5-19-15; 8:45 am]

BILLING CODE 3510-22-P

DEPARTMENT OF DEFENSE

Department of the Army

Advisory Committee on Arlington National Cemetery Honor Subcommittee Meeting Notice

AGENCY: Department of the Army, DoD.

ACTION: Notice of open subcommittee meeting.

SUMMARY: The Department of the Army is publishing this notice to announce the following Federal advisory committee meeting of the Honor Subcommittee of the Advisory Committee on Arlington National Cemetery (ACANC). The meeting is open to the public. For more information about the Committee and the Honor Subcommittee, please visit <http://www.arlingtoncemetery.mil/AboutUs/FocusAreas.aspx>.

DATES: The Honor Subcommittee will meet from 11:00 a.m. to 12:00 p.m. on Tuesday, June 23, 2015.

ADDRESSES: Women in Military Service for America Memorial, Conference Room, Arlington National Cemetery, Arlington, VA 22211.

FOR FURTHER INFORMATION CONTACT: Ms. Brenda K. Curfman; Alternate Designated Federal Officer for the committee and the Honor Subcommittee, in writing at Arlington National Cemetery, Arlington, VA 22211, or by email at

brenda.k.curfman.civ@mail.mil, or by phone at 703-614-0998.

SUPPLEMENTARY INFORMATION: This subcommittee meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Sunshine in the Government Act of 1976 (U.S.C. 552b, as amended) and 41 Code of the Federal Regulations (CFR 102-3.150).

Purpose of the Meeting: The Advisory Committee on Arlington National Cemetery is an independent Federal advisory committee chartered to provide the Secretary of the Army independent advice and recommendations on Arlington National Cemetery, including, but not limited to, cemetery administration, the erection of memorials at the cemetery, and master planning for the cemetery. The Secretary of the Army may act on the committee's advice and recommendations. The Honor Subcommittee is directed to provide independent recommendations of methods to address the long-term future of Arlington National Cemetery, including how best to extend the active burials and on what ANC should focus once all available space has been used.

Proposed Agenda: The subcommittee will receive an update from CAA; historic gates update and planning for placement; conduct a review of the current eligibility and honors wait times (specifically for military honors) and impacts.

Public's Accessibility to the Meeting: Pursuant to 5 U.S.C. 552b and 41 CFR 102-3.140 through 102-3.165, and the availability of space, this meeting is open to the public. Seating is on a first-come basis. The Women in Military Service for America is fully handicapped accessible. For additional information about public access procedures, contact Ms. Brenda Curfman, the subcommittee's Alternate Designated Federal Officer, at the email address or telephone number listed in the **FOR FURTHER INFORMATION CONTACT** section.

Written Comments and Statements: Pursuant to 41 CFR 102-3.105(j) and 102-3.140 and section 10(a)(3) of the Federal Advisory Committee Act, the public or interested organizations may submit written comments or statements to the subcommittee, in response to the stated agenda of the open meeting or in regard to the subcommittee's mission in general. Written comments or statements should be submitted to Ms. Brenda Curfman, the subcommittee's Alternate Designated Federal Officer, via electronic mail, the preferred mode

of submission, at the address listed in the **FOR FURTHER INFORMATION CONTACT** section. Each page of the comment or statement must include the author's name, title or affiliation, address, and daytime phone number. Written comments or statements being submitted in response to the agenda set forth in this notice must be received by the Alternate Designated Federal Officer at least seven business days prior to the meeting to be considered by the subcommittee. The Alternate Designated Federal Officer will review all timely submitted written comments or statements with the subcommittee Chairperson, and ensure the comments are provided to all members of the subcommittee before the meeting. Written comments or statements received after this date may not be provided to the subcommittee until its next meeting. Pursuant to 41 CFR 102–3.140d, the Committee is not obligated to allow the public to speak; however, interested persons may submit a written statement or a request to speak for consideration by the subcommittee. After reviewing any written statements or requests submitted, the subcommittee Chairperson and the Alternate Designated Federal Officer may choose to invite certain submitters to present their comments verbally during the open portion of this meeting or at a future meeting. The Alternate Designated Federal Officer in consultation with the subcommittee Chairperson, may allot a specific amount of time for submitters to present their comments verbally.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2015–12120 Filed 5–19–15; 8:45 am]

BILLING CODE 3710–08–P

DEPARTMENT OF DEFENSE

Department of the Army

Advisory Committee on Arlington National Cemetery Explore Subcommittee Meeting Notice

AGENCY: Department of the Army, DoD.

ACTION: Notice of open subcommittee meeting.

SUMMARY: The Department of the Army is publishing this notice to announce the following Federal advisory committee meeting of the Explore Subcommittee of the Advisory Committee on Arlington National Cemetery (ACANC). The meeting is open to the public. For more information about the Committee and the Explore Subcommittee, please visit

<http://www.arlingtoncemetery.mil/AboutUs/FocusAreas.aspx>.

DATES: The Explore Subcommittee will meet from 10:00 a.m. to 11:00 a.m. on Tuesday, June 23, 2015.

ADDRESSES: Women in Military Service for America Memorial, Conference Room, Arlington National Cemetery, Arlington, VA 22211.

FOR FURTHER INFORMATION CONTACT: Ms. Brenda K. Curfman; Alternate Designated Federal Officer for the committee and the Explore Subcommittee, in writing at Arlington National Cemetery, Arlington, VA 22211, or by email at brenda.k.curfman.civ@mail.mil, or by phone at 703–614–0998.

SUPPLEMENTARY INFORMATION: This subcommittee meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Sunshine in the Government Act of 1976 (U.S.C. 552b, as amended) and 41 Code of the Federal Regulations (CFR 102–3.150).

Purpose of the Meeting: The Advisory Committee on Arlington National Cemetery is an independent Federal advisory committee chartered to provide the Secretary of the Army independent advice and recommendations on Arlington National Cemetery, including, but not limited to, cemetery administration, the erection of memorials at the cemetery, and master planning for the cemetery. The Secretary of the Army may act on the committee's advice and recommendations. The Explore Subcommittee is tasked to provide recommendations on Section 60 Mementos study and improving the quality of visitors' experiences, now and for generations to come.

Proposed Agenda: The subcommittee will review the way finding and visitor signage for ANC and long term plan for ADA compliance throughout ANC.

Public's Accessibility to the Meeting: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, and the availability of space, this meeting is open to the public. Seating is on a first-come basis. The Women in Military Service for America is fully handicapped accessible. For additional information about public access procedures, contact Ms. Brenda Curfman, the subcommittee's Alternate Designated Federal Officer, at the email address or telephone number listed in the **FOR FURTHER INFORMATION CONTACT** section.

Written Comments and Statements: Pursuant to 41 CFR 102–3.105(j) and 102–3.140 and section 10(a)(3) of the

Federal Advisory Committee Act, the public or interested organizations may submit written comments or statements to the subcommittee, in response to the stated agenda of the open meeting or in regard to the subcommittee's mission in general. Written comments or statements should be submitted to Ms. Brenda Curfman, the subcommittee's Alternate Designated Federal Officer, via electronic mail, the preferred mode of submission, at the address listed in the **FOR FURTHER INFORMATION CONTACT** section. Each page of the comment or statement must include the author's name, title or affiliation, address, and daytime phone number. Written comments or statements being submitted in response to the agenda set forth in this notice must be received by the Alternate Designated Federal Officer at least seven business days prior to the meeting to be considered by the subcommittee. The Alternate Designated Federal Officer will review all timely submitted written comments or statements with the subcommittee Chairperson, and ensure the comments are provided to all members of the subcommittee before the meeting. Written comments or statements received after this date may not be provided to the subcommittee until its next meeting. Pursuant to 41 CFR 102–3.140d, the Committee is not obligated to allow the public to speak; however, interested persons may submit a written statement or a request to speak for consideration by the subcommittee. After reviewing any written statements or requests submitted, the subcommittee Chairperson and the Alternate Designated Federal Officer may choose to invite certain submitters to present their comments verbally during the open portion of this meeting or at a future meeting. The Alternate Designated Federal Officer in consultation with the subcommittee Chairperson, may allot a specific amount of time for submitters to present their comments verbally.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2015–12129 Filed 5–19–15; 8:45 am]

BILLING CODE 3710–08–P

DEPARTMENT OF DEFENSE

Department of the Army

Advisory Committee on Arlington National Cemetery Remember Subcommittee Meeting Notice

AGENCY: Department of the Army, DoD.

ACTION: Notice of open subcommittee meeting.

SUMMARY: The Department of the Army is publishing this notice to announce the following Federal advisory committee meeting of the Remember Subcommittee of the Advisory Committee on Arlington National Cemetery (ACANC). The meeting is open to the public. For more information about the Committee and the Remember Subcommittee, please visit <http://www.arlingtoncemetery.mil/AboutUs/FocusAreas.aspx>.

DATES: The Remember Subcommittee will meet from 09:00 a.m. to 10:00 a.m. on Tuesday, June 23, 2015.

ADDRESSES: Women in Military Service for America Memorial, Conference Room, Arlington National Cemetery, Arlington, VA 22211.

FOR FURTHER INFORMATION CONTACT: Ms. Brenda K. Curfman; Alternate Designated Federal Officer for the committee and the Remembrance Subcommittee, in writing at Arlington National Cemetery, Arlington VA 22211, or by email at brenda.k.curfman.civ@mail.mil, or by phone at 703-614-0998.

SUPPLEMENTARY INFORMATION: This subcommittee meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Sunshine in the Government Act of 1976 (U.S.C. 552b, as amended) and 41 Code of the Federal Regulations (CFR 102-3.150).

Purpose of the Meeting: The Advisory Committee on Arlington National Cemetery is an independent Federal advisory committee chartered to provide the Secretary of the Army independent advice and recommendations on Arlington National Cemetery, including, but not limited to, cemetery administration, the erection of memorials at the cemetery, and master planning for the cemetery. The Secretary of the Army may act on the committee's advice and recommendations. The primary purpose of the Remember Subcommittee is to review and provide recommendations on preserving and caring for the marble components of the Tomb of the Unknown Soldier (TUS), including addressing the cracks in the large marble sarcophagus, the adjacent marble slabs, and the disposition of the dye block already gifted to the Army.

Proposed Agenda: The subcommittee will receive an update on the status of the entire list of monument and memorial restorations, specifically the TUS, and the process for review of memorial monument requests pending

with the Department of the Army for placement at Arlington National Cemetery.

Public's Accessibility to the Meeting: Pursuant to 5 U.S.C. 552b and 41 CFR 102-3.140 through 102-3.165, and the availability of space, this meeting is open to the public. Seating is on a first-come basis. The Women in Military Service for America is fully handicapped accessible. For additional information about public access procedures, contact Ms. Brenda Curfman, the subcommittee's Alternate Designated Federal Officer, at the email address or telephone number listed in the **FOR FURTHER INFORMATION CONTACT** section.

Written Comments and Statements: Pursuant to 41 CFR 102-3.105(j) and 102-3.140 and section 10(a)(3) of the Federal Advisory Committee Act, the public or interested organizations may submit written comments or statements to the subcommittee, in response to the stated agenda of the open meeting or in regard to the subcommittee's mission in general. Written comments or statements should be submitted to Ms. Brenda Curfman, the subcommittee's Alternate Designated Federal Officer, via electronic mail, the preferred mode of submission, at the address listed in the **FOR FURTHER INFORMATION CONTACT** section. Each page of the comment or statement must include the author's name, title or affiliation, address, and daytime phone number. Written comments or statements being submitted in response to the agenda set forth in this notice must be received by the Alternate Designated Federal Officer at least seven business days prior to the meeting to be considered by the subcommittee. The Alternate Designated Federal Officer will review all timely submitted written comments or statements with the subcommittee Chairperson, and ensure the comments are provided to all members of the subcommittee before the meeting. Written comments or statements received after this date may not be provided to the subcommittee until its next meeting. Pursuant to 41 CFR 102-3.140d, the Committee is not obligated to allow the public to speak; however, interested persons may submit a written statement or a request to speak for consideration by the subcommittee. After reviewing any written statements or requests submitted, the subcommittee Chairperson and the Alternate Designated Federal Officer may choose to invite certain submitters to present their comments verbally during the open portion of this meeting or at a future meeting. The Alternate Designated Federal Officer in

consultation with the subcommittee Chairperson, may allot a specific amount of time for submitters to present their comments verbally.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2015-12156 Filed 5-19-15; 8:45 am]

BILLING CODE 3710-08-P

DEPARTMENT OF DEFENSE

Department of the Army

Notice of Availability of Government-Owned Inventions; Available for Licensing

AGENCY: Department of the Army, DoD.

ACTION: Notice.

SUMMARY: The inventions listed below are assigned to the United States (U.S.) Government as represented by the Secretary of the Army and are available for licensing by the Department of the Army (DoA):

- U.S. Patent Number 7,812,366 entitled "Ultraviolet Light Emitting AlGa_N Composition, and Ultraviolet Light Emitting Device Containing Same", Inventors Sampath *et al.*, Issue date October 12, 2010.
- U.S. Patent Number 8,564,014 entitled "Ultraviolet Light Emitting AlGa_N Composition and Ultraviolet Light Emitting Device Containing Same", Inventors Sampath *et al.*, Issue date October 22, 2013.
- U.S. Patent 7,498,182 entitled "Method of Manufacturing an AlGa_N Composition and Ultraviolet Light Emitting Device Containing Same", Inventors Sampath *et al.*, Issue Date March 3, 2009.

DATES: Request for supplemental information should be made prior to July 1, 2015.

ADDRESSES: Request for supplemental information, including licensing application packages and procedures should be directed to Austin Leach, Ph.D., 406-994-7707, austin.leach@montana.edu, TechLink, 2310 University Way, Building 2-2, Bozeman, MT 59715. TechLink is an authorized Department of Defense Partnership Intermediary per Authority 15 U.S.C. 3715.

FOR FURTHER INFORMATION CONTACT: U.S. Army Research Laboratory Technology Transfer Office, RDRL-DPP/Thomas Mulkern, Building 321, Room 110, Aberdeen Proving Ground, MD 21005-5425. Phone: (410) 278-0889. Email: ORTA@arl.army.mil.

SUPPLEMENTARY INFORMATION: The U.S. Army intends to move expeditiously to

license these inventions. Licensing application packages are available from TechLink and all applications and commercialization plans must be returned to TechLink by August 14, 2015. TechLink will turn over all completed applications to the U.S. Army for evaluation by August 28, 2015, with final negotiations and awards occurring during the months of September and October, 2015. The U.S. Army will consider requests for nonexclusive, partially exclusive, and fully exclusive licenses in the U.S. and may prefer to grant an exclusive license to a company capable of broad commercialization as well as patent maintenance and enforcement within the U.S.

The DoA intends to ensure that its licensed inventions are broadly commercialized throughout the United States.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2015-12158 Filed 5-19-15; 8:45 am]

BILLING CODE 3710-08-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DoD-2012-OS-0014]

Proposed Collection; Comment Request

AGENCY: Defense Logistics Agency, DoD.

ACTION: Notice.

SUMMARY: In compliance with the *Paperwork Reduction Act of 1995*, the Defense Logistics Agency announces a proposed public information collection and seeks public comment on the provisions thereof. Comments are invited on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed information collection; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology.

DATES: Consideration will be given to all comments received by July 20, 2015.

ADDRESSES: You may submit comments, identified by docket number and title, by any of the following methods:

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

- *Mail:* Department of Defense, Office of the Deputy Chief Management Officer, Directorate of Oversight and Compliance, Regulatory and Audit Matters Office, 9010 Defense Pentagon, Washington, DC 20301-9010.

Instructions: All submissions received must include the agency name, docket number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at <http://www.regulations.gov> as they are received without change, including any personal identifiers or contact information.

Any associated form(s) for this collection may be located within this same electronic docket and downloaded for review/testing. Follow the instructions at <http://www.regulations.gov> for submitting comments. Please submit comments on any given form identified by docket number, form number, and title.

FOR FURTHER INFORMATION CONTACT: To request more information on this proposed information collection or to obtain a copy of the proposal and associated collection instruments, please write to the Defense Logistics Agency Headquarters, ATTN: Mr. Robert Bednarcik, J33, 8725 John J. Kingman Rd., Ft. Belvoir, VA 22060-6221; or call (703) 767-1178.

SUPPLEMENTARY INFORMATION:

Title; Associated Form; and OMB Number: End-Use Certificate; DLA Form 1822; OMB No. 0704-0382.

Needs and Uses: The information collection requirement is necessary for all individuals wishing to acquire DOD/Government property identified as U.S. Munitions List Items (MLI) or Commerce Control List Item (CCLI). They must complete this form each time they enter into a transaction. It is used to clear recipients to ensure their eligibility to conduct business with the government. That they are not debarred bidders; Specially Designated Nationals (SDN) or Blocked Persons; have not violated U.S. export laws; will not divert the property to denied/sanctioned countries, unauthorized destinations or sell to debarred/Bidder Experience List firms or individuals. The EUC informs the recipients that when this property is to be exported, they must comply with the International Traffic in Arms Regulation (ITAR), 22 CFR 120 *et seq.*; Export Administration Regulations (EAR), 15 CFR 730 *et seq.*; Office of Foreign Asset Controls (OFAC), 31 CFR 500 *et seq.*; and the United States Customs Service rules and regulations.

Affected Public: Individuals; businesses; contractors; or other for profit; not-for-profit institutions/entities.

Annual Burden Hours: 14,000.
Number of Respondents: 42,000.
Responses per Respondent: 1.
Annual Responses: 42,000.

Average Burden per Response: 20 minutes.

Frequency: Quarterly.

Respondents are individuals/businesses/contractors who receive defense property identified as U.S. Munitions List Items and Commerce Control List Items through: purchase, exchange/trade sale, authorized transfer or donation. They are checked to determine if they are responsible, not debarred bidders, Specially Designated Nationals or Blocked Persons, or have not violated U.S. export laws.

The form is available on the DOD DEMIL/Trade Security Controls Web page, DLA Disposition Services usable property sales Web page, General Services Administration (GSA) auction Web page, and Defense Contract Management Agency offices, FormFlow and ProForm.

Dated: May 15, 2015.

Aaron Siegel,

Alternate OSD Federal Register, Liaison Officer, Department of Defense.

[FR Doc. 2015-12227 Filed 5-19-15; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal Nos. 15-31]

36(b)(1) Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104-164 dated July 21, 1996.

FOR FURTHER INFORMATION CONTACT: Ms. B. English, DSCA/DBO/CFM, (703) 601-3740.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittals 15-31 with attached transmittal, policy justification, and Sensitivity of Technology.

Dated: May 14, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.



DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

MAY 12 2015

The Honorable John A. Boehner
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 15-31, concerning the Department of the Navy's proposed Letter(s) of Offer and Acceptance to Norway for defense articles and services estimated to cost \$345 million. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

J. W. Rixey
Vice Admiral, USN
Director

Enclosures:

1. Transmittal
2. Policy Justification
3. Sensitivity of Technology



Transmittal No. 15-31

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

(i) *Prospective Purchaser:* Government of Norway

(ii) *Total Estimated Value:*

Major Defense Equipment *	\$320 million
Other	\$ 25 million
TOTAL	\$345 million

(iii) *Description and Quantity or Quantities of Articles or Services under*

Consideration for Purchase: Up to 200 AIM-9X Block II Sidewinder Tactical Missiles, 2 AIM-9X Special Air Training Missiles (NATMs), 40 CATM-9X Block II Captive Air Training Missiles (CATMs), 10 AIM-9X Block II Tactical Guidance Units, and 20 AIM-9X Block II CATM Guidance Units, containers, support and test equipment, spare and repair parts, personnel training and training equipment, publications and technical documentation, U.S. Government and

contractor logistics and technical support services, and other related elements of logistics and program support.

- (iv) *Military Department:* Navy (AHV)
- (v) *Prior Related Cases, if any:* None
- (vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None
- (vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex
- (viii) *Date Report Delivered to Congress:* 12 May 15

* as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION

Norway AIM-9X Block II Sidewinder Missiles

The Government of Norway has requested a possible sale of up to 200 AIM-9X Block II Sidewinder Tactical Missiles, 2 AIM-9X Special Air Training Missiles (NATMs), 40 CATM-9X Block II Captive Air Training Missiles (CATMs), 10 AIM-9X Block II Tactical Guidance Units, and 20 AIM-9X Block II CATM Guidance Units, containers, support and test equipment, spare and repair parts, personnel training and training equipment, publications and technical documentation, U.S. Government and contractor logistics and technical support services, and other related elements of logistics and program support. The estimated cost is \$345 million.

This proposed sale will contribute to the foreign policy and national security of the United States by helping to improve the security of a NATO ally which has been, and continues to be, and important force for political stability throughout the world.

Norway requires these capabilities for mutual defense, regional security, force modernization, and U.S. and NATO interoperability. This sale will enhance the Royal Norwegian Air Force's ability to defend Norway against future threats and contribute to current and future NATO operations. Although this is a new capability, Norway will have no difficulty absorbing these missiles into its armed forces.

The proposed sale of this equipment and support will not alter the basic military balance in the region.

The principal contractor will be Raytheon Missile Systems Company in Tucson, Arizona. There are no known offset agreements proposed in connection with this potential sale.

Implementation of this proposed sale may require the assignment of additional U.S. Government or contractor representatives to Government of Norway.

There will be no adverse impact on U.S. defense readiness as a result of this proposed sale.

Transmittal No. 15-31

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The AIM-9X (Block II) Sidewinder Missile represents a substantial increase in missile acquisition and kinematics performance over the AIM-9M and replaces the AIM-9X (Block I) Missile configuration. The missile includes a high off-boresight seeker, enhanced countermeasure rejection capability, low drag/high angle of attack airframe, and the ability to integrate the Helmet Mounted Cueing System. The software algorithms are the most sensitive portion of the AIM-9X missile. A Software Improvement Program (SIP) provides for Software updates. No software source code or algorithms will be released. The missile is classified as Confidential.

2. The AIM-9X (Block II) will result in the transfer of sensitive technology and information. The equipment, hardware, and documentation are classified Confidential. The software and operational performance are classified Secret. The seeker/guidance control section and the target detector are Confidential and contain sensitive state-of-the-art technology. Manuals and technical documentation that are necessary or support operational use and organizational management are classified up to Secret. Performance and operating logic of the counter-countermeasures circuits are classified Secret. The hardware, software, and data identified are classified to protect vulnerabilities, design and performance parameters, and similar critical information.

3. If a technologically advanced adversary were to obtain knowledge of the specific hardware and software elements, the information could be used to develop countermeasures that might reduce weapon system effectiveness or be used in the development of a system with similar advanced capabilities.

4. A determination has been made that the recipient country can provide substantially the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

5. All defense articles and services listed in this transmittal have been authorized for release and export to Norway.

[FR Doc. 2015-12138 Filed 5-19-15; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Intelligence Agency National Intelligence University Board of Visitors; Notice of Federal Advisory Committee Meeting

AGENCY: National Intelligence University, Defense Intelligence Agency, Department of Defense.

ACTION: Notice of closed meeting.

SUMMARY: The Department of Defense is publishing this notice to announce that the following Federal Advisory Committee meeting of the National Intelligence University Board of Visitors has been scheduled. The meeting is closed to the public.

DATES: Tuesday, June 16, 2015 (7:30 a.m. to 5:00 p.m.) and Wednesday, June 17, 2015 (7:30 a.m. to 1:30 p.m.).

ADDRESSES: Intelligence Community Campus—Bethesda, 4600 Sangamore Road, Bethesda, MD 20816.

FOR FURTHER INFORMATION CONTACT: Dr. David R. Ellison, President, DIA National Intelligence University, Washington, DC 20340-5100, Phone: (202) 231-3344.

SUPPLEMENTARY INFORMATION:

Purpose: The Board will discuss several current critical intelligence issues and advise the Director, DIA, as to the successful accomplishment of the mission assigned to the National Intelligence University.

Agenda: The following topics are listed on the National Intelligence University Board of Visitors meeting agenda: Bethesda Campus Tour; Accreditation Requirements; Director's Strategic Guidance; Process Overview; NIU Vision, Mission, and Values; NIU Strategic Goals and Objectives; Resource Requirements; Implementation Strategies; Succession Planning; Honorary Degrees; Executive Session; College of Strategic Intelligence; Concentration Programs and Leadership Certificate; and Research Update/Presentations.

The entire meeting is devoted to the discussion of classified information as defined in 5 U.S.C. 552b(c)(1) and therefore will be closed. Pursuant to 41 CFR 102-3.105(j) and 102-3.140, and section 10(a)(3) of the Federal Advisory Committee Act of 1972, the public or interested organizations may submit written statements to the National Intelligence University Board of Visitors about its mission and functions. Written statements may be submitted at any time or in response to the stated agenda of a planned meeting of the National Intelligence University Board of

Visitors. All written statements shall be submitted to the Designated Federal Officer for the National Intelligence University Board of Visitors, and this individual will ensure that the written statements are provided to the membership for their consideration. Contact information for the Designated Federal Officer can be obtained from the GSA's FACA Database—<http://www.facadatabase.gov/>.

Dated: May 15, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2015-12226 Filed 5-19-15; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Advisory Committee on Military Personnel Testing; Notice of Federal Advisory Committee Meeting

AGENCY: Under Secretary of Defense for Personnel and Readiness, Department of Defense.

ACTION: Meeting notice.

SUMMARY: The Department of Defense is publishing this notice to announce the following Federal Advisory Committee Meeting of the Defense Advisory Committee on Military Personnel Testing. This meeting will be open to the public.

DATES: Thursday, June 25, 2015, from 9:00 a.m. to 4:00 p.m. and Friday, June 26, 2015, from 9:00 a.m. to 12:00 p.m.

ADDRESSES: The Magnolia Hotel, 818 17th Street, Denver, Colorado 80202.

FOR FURTHER INFORMATION CONTACT: Dr. Jane M. Arabian, Assistant Director, Accession Policy, Office of the Under Secretary of Defense for Personnel and Readiness, Room 3D1066, The Pentagon, Washington, DC 20301-4000, telephone (703) 697-9271.

SUPPLEMENTARY INFORMATION:

This meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102-3.150.

Purpose of the Meeting: The purpose of the meeting is to review planned changes and progress in developing computerized tests for military enlistment screening.

Agenda: The agenda includes an overview of current enlistment test development timelines, test development strategies, and planned research for the next 3 years.

Public's Accessibility to the Meeting: Pursuant to 5 U.S.C. 552b and 41 CFR 102-3.140 through 102-3.165, and the availability of space, this meeting is open to the public. Committee's Designated Federal Officer or Point of Contact: Dr. Jane M. Arabian, Assistant Director, Accession Policy, Office of the Under Secretary of Defense for Personnel and Readiness, Room 3D1066, The Pentagon, Washington, DC 20301-4000, telephone (703) 697-9271.

Persons desiring to make oral presentations or submit written statements for consideration at the Committee meeting must contact Dr.

Jane M. Arabian at the address or telephone number in the **FOR FURTHER INFORMATION CONTACT** section no later than June 15, 2015.

Dated: May 15, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2015-12176 Filed 5-19-15; 8:45 am]

BILLING CODE 5001-06-P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Transmittal Nos. 15-34]

36(b)(1) Arms Sales Notification

AGENCY: Defense Security Cooperation Agency, Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing the unclassified text of a section 36(b)(1) arms sales notification. This is published to fulfill the requirements of section 155 of Public Law 104-164 dated July 21, 1996.

FOR FURTHER INFORMATION CONTACT: Ms. B. English, DSCA/DBO/CFM, (703) 601-3740.

The following is a copy of a letter to the Speaker of the House of Representatives, Transmittals 15-34 with attached transmittal, policy justification, and Sensitivity of Technology.

Dated: May 14, 2015.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.




DEFENSE SECURITY COOPERATION AGENCY
201 12TH STREET SOUTH, STE 203
ARLINGTON, VA 22202-5408

MAY 12 2015

The Honorable John A. Boehner
Speaker of the House
U.S. House of Representatives
Washington, DC 20515

Dear Mr. Speaker:

Pursuant to the reporting requirements of Section 36(b)(1) of the Arms Export Control Act, as amended, we are forwarding herewith Transmittal No. 15-34, concerning the Department of the Navy's proposed Letter(s) of Offer and Acceptance to the Government of Japan for defense articles and services estimated to cost \$199 million. After this letter is delivered to your office, we plan to issue a press statement to notify the public of this proposed sale.

Sincerely,

J. W. Rixey
Vice Admiral, USN
Director

- Enclosures:
1. Transmittal
 2. Policy Justification
 3. Sensitivity of Technology



Transmittal No. 15-34
Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act, as amended

- (i) *Prospective Purchaser:* Government of Japan
- (ii) *Total Estimated Value:*
Major Defense Equipment * \$192 million
Other \$7million
TOTAL \$199 million
- (iii) *Description and Quantity or Quantities of Articles or Services under*

Consideration for Purchase: Forty eight (48) UGM-84L Harpoon Block II Missiles, containers, spare and repair parts, support equipment, publications and technical documentation, personnel training and training equipment, U.S. Government and contractor logistics and technical support services, and other related elements of logistics and program support.
(iv) *Military Department:* Navy (ARV)
(v) *Prior Related Cases, if any:*
FMS case SAF-\$2.2B-02May07
FMS case GQY-\$358M-6May11

- (vi) *Sales Commission, Fee, etc., Paid, Offered, or Agreed to be Paid:* None
 - (vii) *Sensitivity of Technology Contained in the Defense Article or Defense Services Proposed to be Sold:* See Attached Annex.
 - (viii) *Date Report Delivered to Congress:* 12 May 15
- * as defined in Section 47(6) of the Arms Export Control Act.

POLICY JUSTIFICATION**Japan—UGM–84L Harpoon Block II Missiles**

The Government of Japan has requested a possible sale of forty eight (48) UGM–84L Harpoon Block II Missiles, containers, spare and repair parts, support equipment, publications and technical documentation, personnel training and training equipment, U.S. Government and contractor logistics and technical support services, and other related elements of logistics and program support. The estimated cost is \$199 million.

This proposed sale will contribute to the foreign policy and national security of the United States. Japan is one of the major political and economic powers in East Asia and the Western Pacific and a key partner of the United States in ensuring peace and stability in that region. It is vital to the U.S. national interest to assist Japan in developing and maintaining a strong and ready self-defense capability. This proposed sale is consistent with U.S. foreign policy and national security objectives and the 1960 Treaty of Mutual Cooperation and Security.

Japan intends to use the Harpoon Block II missiles to supplement its existing Harpoon missile capability. This sale will strengthen the capabilities of the Japan Maritime Self Defense Force and enhance its interoperability with U.S. Naval forces. Japan, which has Harpoon missiles in its inventory, will have no difficulty absorbing these additional missiles into its armed forces.

The proposed sale of this weapon system will not alter the basic military balance in the region.

The principal contractor will be The Boeing Company in St. Louis, Missouri. There are no known offset agreements in connection with this potential sale.

Implementation of this proposed sale will not require any additional U.S. Government or contractor personnel in Japan. However, U.S. Government or contractor personnel in-country visits will be required on a temporary basis in conjunction with program technical and management oversight and support requirements.

There will be no adverse impact on United States defense readiness as a result of this proposed sale.

Transmittal No. 15–34

Notice of Proposed Issuance of Letter of Offer Pursuant to Section 36(b)(1) of the Arms Export Control Act

Annex

Item No. vii

(vii) *Sensitivity of Technology:*

1. The UGM–84L Harpoon Block II missile is a submarine launched Anti-Surface Warfare (ASuW) missile that provides Naval forces with a capability to engage targets in both the “blue water” regions and the littorals of the world. The Harpoon Block II missile, including publications, documentation, operations, supply, maintenance, and training to be conveyed with this proposed sale have the highest classification level of Confidential.

2. The Harpoon Block II missile incorporates components, software, and technical design information that are considered sensitive. The following Harpoon Block II missile components being conveyed by the proposed sale that are considered sensitive and are classified Confidential include:

- The Radar seeker
- The Global Position System/Inertial Navigation System (GPS/INS)
- Operational Flight Program (OFP) Software
- Missile operational characteristics and performance data

These elements are essential to the ability of the Harpoon Block II missile to selectively engage hostile targets under a wide range of operational, tactical and environmental conditions.

3. If a technologically advanced adversary obtained knowledge of the specific hardware or software in the proposed sale, the information could be used to develop countermeasures which might reduce weapons system effectiveness or be used in the development of a system with similar or advanced capabilities.

4. A determination has been made that the recipient country can provide the same degree of protection for the sensitive technology being released as the U.S. Government. This sale is necessary in furtherance of the U.S. foreign policy and national security objectives outlined in the Policy Justification.

5. All defense articles and services listed in this transmittal have been authorized for release and export to the Government of Japan.

[FR Doc. 2015–12153 Filed 5–19–15; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE**Department of the Army, Corps of Engineers****Meeting of the Chief of Engineers Environmental Advisory Board**

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

ACTION: Notice of open Federal advisory committee meeting.

SUMMARY: The Department of the Army is publishing this notice to announce the following Federal advisory committee meeting of the Chief of Engineers, Environmental Advisory Board (EAB). This meeting is open to the public. For additional information about the EAB, please visit the committee’s Web site at <http://www.usace.army.mil/Missions/Environmental/EnvironmentalAdvisoryBoard.aspx>.

DATES: The meeting will be held from 9:00 a.m. to 12:00 p.m. on June 23, 2015. Public registration will begin at 8:30 a.m.

ADDRESSES: The EAB meeting will be conducted at the Embassy Suites Alexandria Old Town; 1900 Diagonal Road; Alexandria, VA 22314 at 703–684–5900.

FOR FURTHER INFORMATION CONTACT: Ms. Mindy M. Simmons, the Designated Federal Officer (DFO) for the committee, in writing at U.S. Army Corps of Engineers, ATTN: CECW–P, 441 G St. NW.; Washington, DC 20314; by telephone at 202–761–4127; and by email at Mindy.M.Simmons@usace.army.mil. Alternatively, contact Ms. Anne Cann, the Alternate Designated Federal Officer (ADFO), in writing at the Institute for Water Resources, U.S. Army Corps of Engineers, ATTN: CEIWR–GW, 7701 Telegraph Road, Casey Building, Alexandria, Virginia 22315–3868; by telephone at 703–428–7166; and by email at Anne.R.Cann@usace.army.mil.

SUPPLEMENTARY INFORMATION: The committee meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

Purpose of the Meeting: The EAB will advise the Chief of Engineers on environmental policy, identification and resolution of environmental issues and missions, and addressing challenges, problems, and opportunities in an environmentally responsible manner. The EAB is interested in written and verbal comments from the public relevant to these purposes.

Proposed Agenda: At this meeting the agenda will include discussions and presentations on ongoing work plan efforts including: Dam removal, project prioritization criteria, federal interest determination, ecosystem goods and services, aging infrastructure and aquatic ecosystem integrity, and

developing effective partnerships with federal, state, tribal, and local stakeholders. The EAB will also review their work plan and discuss a recent products related to Science Technology Engineering and Math (STEM) and environmental flows.

Availability of Materials for the Meeting. A copy of the agenda or any updates to the agenda for the June 23, 2015 meeting will be available at the meeting. The final version will be provided at the meeting. All materials will be posted to the Web site after the meeting.

Public Accessibility to the Meeting: Pursuant to 5 U.S.C. 552b, as amended, and 41 CFR 102–3.140 through 102–3.165, and subject to the availability of space, this meeting is open to the public. Registration of members of the public who wish to attend the meeting will begin at 8:15 a.m. on the day of the meeting. Seating is limited and is on a first-to-arrive basis. Attendees will be asked to provide their name, title, affiliation, and contact information to include email address and daytime telephone number at registration. Any interested person may attend the meeting, file written comments or statements with the committee, or make verbal comments from the floor during the public meeting, at the times, and in the manner, permitted by the committee, as set forth below.

Special Accommodations: The meeting venue is fully handicap accessible, with wheelchair access. Individuals requiring special accommodations to access the public meeting or seeking additional information about public access procedures, should contact Ms. Simmons, the committee DFO, or Ms. Cann, the ADFO, at the email addresses or telephone numbers listed in the **FOR FURTHER INFORMATION CONTACT** section, at least five (5) business days prior to the meeting so that appropriate arrangements can be made.

Written Comments or Statements: Pursuant to 41 CFR 102–3.105(j) and 102–3.140 and section 10(a)(3) of the Federal Advisory Committee Act, the public or interested organizations may submit written comments or statements to the EAB about its mission and/or the topics to be addressed in this public meeting. Written comments or statements should be submitted to Ms. Simmons, the committee DFO, or Ms. Cann, the committee ADFO, via electronic mail, the preferred mode of submission, at the addresses listed in the **FOR FURTHER INFORMATION CONTACT** section. The comment or statement must include the author's name, title, affiliation, address, and daytime

telephone number. Written comments or statements being submitted in response to the agenda set forth in this notice must be received by the committee DFO or ADFO at least five (5) business days prior to the meeting so that they may be made available to the EAB for its consideration prior to the meeting. Written comments or statements received after this date may not be provided to the EAB until its next meeting. Please note that because the EAB operates under the provisions of the Federal Advisory Committee Act, as amended, all written comments will be treated as public documents and will be made available for public inspection.

Verbal Comments: Members of the public will be permitted to make verbal comments during the meeting only at the time and in the manner allowed herein. If a member of the public is interested in making a verbal comment at the open meeting, that individual must submit a request, with a brief statement of the subject matter to be addressed by the comment, at least three (3) business days in advance to the committee DFO or ADFO, via electronic mail, the preferred mode of submission, at the addresses listed in the **FOR FURTHER INFORMATION CONTACT** section. The committee DFO and ADFO will log each request to make a comment, in the order received, and determine whether the subject matter of each comment is relevant to the EAB's mission and/or the topics to be addressed in this public meeting. A 15-minute period near the end of meeting will be available for verbal public comments. Members of the public who have requested to make a verbal comment and whose comments have been deemed relevant under the process described above, will be allotted no more than three (3) minutes during this period, and will be invited to speak in the order in which their requests were received by the DFO and ADFO.

Brenda S. Bowen,

Army Federal Register Liaison Officer.

[FR Doc. 2015–12157 Filed 5–19–15; 8:45 am]

BILLING CODE 3720–58–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Intent To Grant Partially Exclusive Patent License; Equalizer Sight, Inc.

AGENCY: DoD Department of the Navy, DoD.

ACTION: Notice.

SUMMARY: The invention listed below is assigned to the United States

Government as represented by the Secretary of the Navy. The Department of the Navy hereby gives notice of its intent to grant to Equalizer Sight, Inc., a revocable, nonassignable, partially exclusive license to practice in the United States, the Government-owned invention described below: U.S. Patent 7,765,731 (Navy Case 97099); issued August 3, 2010, entitled "QUICK RELEASE GUN SIGHT ADAPTER."

DATES: Anyone wishing to object to the grant of this license has fifteen days from the date of this notice to file written objections along with supporting evidence, if any.

ADDRESSES: Written objections are to be filed with Naval Surface Warfare Center, Crane Div, Code OOL, Bldg 2, 300 Highway 361, Crane, IN 47522–5001.

FOR FURTHER INFORMATION CONTACT: Mr. Christopher Monsey, Naval Surface Warfare Center, Crane Div, Code OOL, Bldg 2, 300 Highway 361, Crane, IN 47522–5001, telephone 812–854–4100.

Authority: 35 U.S.C. 207, 37 CFR part 404.

Dated: May 14, 2015.

N.A. Hagerty-Ford

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2015–12185 Filed 5–19–15; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF DEFENSE

Department of the Navy

Notice of Intent To Grant Partially Exclusive Patent License; 5D Analytics, LLC

AGENCY: Department of the Navy, DoD.
ACTION: Notice.

SUMMARY: The inventions listed below are assigned to the United States Government as represented by the Secretary of the Navy. The Department of the Navy hereby gives notice of its intent to grant to 5D Analytics, LLC, a revocable, nonassignable, partially exclusive license to practice in the United States, the Government-owned inventions described below:

U.S. Patent 8,156,050 (Navy Case 99452); issued April 10, 2012, entitled "Project Management System and Method"//and U.S. Patent Application No. 12/623,374 (Navy Case 100130); published December 2, 2010, entitled "Project Management System and Method."

DATES: Anyone wishing to object to the grant of this license has fifteen days from the date of this notice to file written objections along with supporting evidence, if any.

ADDRESSES: Written objections are to be filed with Naval Surface Warfare Center, Crane Div, Code OOL, Bldg 2, 300 Highway 361, Crane, IN 47522-5001.

FOR FURTHER INFORMATION CONTACT: Mr. Christopher Monsey, Naval Surface Warfare Center, Crane Div, Code OOL, Bldg 2, 300 Highway 361, Crane, IN 47522-5001, telephone 812-854-4100.

Authority: 35 U.S.C. 207, 37 CFR part 404.

Dated: May 14, 2015.

N.A. Hagerty-Ford.

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2015-12184 Filed 5-19-15; 8:45 am]

BILLING CODE 3810-FF-P

DEFENSE NUCLEAR FACILITIES SAFETY BOARD

Sunshine Act Notice

AGENCY: Defense Nuclear Facilities Safety Board.

ACTION: Notice of Closed Meeting.

SUMMARY: Pursuant to the provisions of the Government in the Sunshine Act 5 U.S.C. 552b, and the Defense Nuclear Facilities Safety Board's (Board) regulations implementing the Government in the Sunshine Act, notice is hereby given of the Board's closed meeting described below.

DATES: 3:00 p.m.—4:00 p.m., June 3, 2015.

ADDRESSES: Defense Nuclear Facilities Safety Board, 625 Indiana Avenue NW., Room 352, Washington, DC 20004.

STATUS: Closed. During the closed meeting, the Board Members will discuss issues dealing with potential Recommendations to the Secretary of Energy. The Board is invoking the exemption to close a meeting described in 5 U.S.C. 552b(c)(3) and 10 CFR 1704.4(c). The Board has determined that it is necessary to close the meeting since conducting an open meeting is likely to disclose matters that are specifically exempted from disclosure by statute. In this case, the deliberations will pertain to Board Recommendations which, under 42 U.S.C. 2286d(b) and (h)(3), may not be made publicly available until after they have been received by the Secretary of Energy or the President, respectively.

MATTERS TO BE CONSIDERED: The meeting will proceed in accordance with the closed meeting agenda which is posted on the Board's public Web site at www.dnfsb.gov. Technical staff may present information to the Board. The Board Members are expected to conduct deliberations regarding potential

Recommendations to the Secretary of Energy.

FOR FURTHER INFORMATION CONTACT: Mark Welch, General Manager, Defense Nuclear Facilities Safety Board, 625 Indiana Avenue NW., Suite 700, Washington, DC 20004-2901, (800) 788-4016. This is a toll-free number.

SUPPLEMENTARY INFORMATION: The meeting will be closed to the public. No participation from the public will be considered during the meeting.

Dated: May 18, 2015.

Jessie H. Roberson,
Vice Chairman.

[FR Doc. 2015-12391 Filed 5-18-15; 5:00 pm]

BILLING CODE 3670-01-P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

Proposed Agency Information Collection

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice and Request for OMB Review and Comment.

SUMMARY: The Department of Energy (DOE) has submitted to the Office of Management and Budget (OMB) for clearance, a proposal for collection of information under the provisions of the Paperwork Reduction Act of 1995. The proposed collection will enable DOE to understand the universe of organizations participating in four voluntary programs: Zero Energy Ready Home Program, the Better Buildings Residential Network, the Home Energy Score, and the Home Performance with ENERGY STAR Program (HPwES). The information gathered by DOE in these four programs is necessary for DOE to run the programs effectively.

DATES: Comments regarding this collection must be received on or before June 19, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, please advise the DOE Desk Officer at OMB of your intention to make a submission as soon as possible. The Desk Officer may be telephoned at 202-395-4650.

ADDRESSES: Written comments should be sent to the DOE Desk Officer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10102, 735 17th Street NW., Washington, DC 20503.

And to Mr. Chris Early, U.S. Department of Energy, Building Technologies Program, Mail Stop EE-5B, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585-0121 or by fax at 202-586-4617 or by email at Chris.Early@ee.doe.gov.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to Mr. Chris Early, U.S. Department of Energy, Building Technologies Program, Mail Stop EE-5B, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585-0121. Chris.Early@ee.doe.gov.

SUPPLEMENTARY INFORMATION: This information collection request contains: (1) OMB No. {"New"}; (2) *Information Collection Request Title:* Programs for Improving Energy Efficiency in Residential Buildings (3) *Type of Request:* {New collection.}; (4) *Purpose:* The collected information will help DOE understand the participating partners' activities and progress toward achieving scheduled milestones enabling DOE to make decisions about the best way to run the programs and respond to partners' needs to improve their operations and actions to lower energy consumption. The proposed collection is for the activities of four Department of Energy programs: Zero Energy Ready Home Program, the Better Buildings Residential Network, the Home Energy Score, and the Home Performance with ENERGY STAR Program. Through these programs DOE encourages and assists the people and organizations that volunteer to participate in them to build and renovate new and existing houses to use less energy. The program partners who voluntarily participate in the programs consist of most of the actors in the home building industry including home owners, home builders, home builder tradesman and associations, home design professionals, students in architecture and related building construction industries, home energy raters, home energy auditors, home inspectors, building consultants, manufacturers of building products, professional trainers, utility companies, home building and manufacturing industry associations, consumer and home building industry advocacy organizations, financial institutions, non-profit organizations, educational institutions, nonprofit organizations, energy program administrators and implementers, Home Performance with ENERGY STAR sponsors, state or local

government energy offices or agencies, clean energy non-profits with existing residential energy programs and other organizations who believe peer sharing will help them improve their effectiveness in encouraging homeowners to complete energy upgrades. DOE proposes to collect information about the participants such as their names and addresses, their evaluations of training they received about the programs, descriptions of their qualifications to conduct training for the programs, their plans to get people to participate in the programs, their certifications describing how they can assess homes, estimates of how many homes they can get to participate in the programs, and information about the homes. The DOE published a notice and request for comments related to this current request for OMB clearance to collect information on May 15, 2014 (79 FR 27867) and received no comments. That notice asked for comments for four voluntary programs at DOE, three of which are the same as for this current request for clearance and one is different. The DOE decided not to request clearance to collect information for the Building America Program that was part of that May 15, 2014 request for comments. The DOE, however, added the HPwES program to this current request for clearance. The reason is that operation of part of the HPwES program is to be transferred to the DOE from the Environmental Protection Agency (EPA). The DOE intends to operate HPwES substantially similarly to the way EPA operates the program. The difference in estimates of numbers of responses, number of respondents, burden hours, and costs to respond between the HPwES that was approved by OMB for EPA and the one requested to be approved by DOE are minor. The OMB did give the EPA clearance for collection of information in the HPwES program on August 14, 2014. OMB gave it the ICR Control Number 2060-0586. There are 3 Information Collections associated with that control number.

In place of EPA, DOE wants to collect the information for only one of the three collections associated with Control Number 2060-0586; the one with the Information Collection title "ENERGY STAR Program in the Residential Sector: States and Locals". EPA did not receive any comments in either the 30 or 60 day **Federal Register** Notices for that collection of information; (5) *Annual Estimated Number of Respondents*: 11,585; (6) *Annual Estimated Number of Total Responses*: 46,909; (7) *Annual Estimated Number of Burden Hours*:

22,926; (8) *Annual Estimated Reporting and Recordkeeping Cost Burden*: zero dollars.

Statutory Authority: 42 U.S.C. 16191.

Issued in Washington, DC on May 13, 2015.

Roland J. Risser,

Director, Building Technologies Office, Energy Efficiency and Renewable Energy.

[FR Doc. 2015-12223 Filed 5-19-15; 8:45 am]

BILLING CODE 6450-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER15-1672-000]

Evergreen Wind Power II, 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 Evergreen Wind Power II, LLC 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 June 3, 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(s) are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email FERCOnlineSupport@ferc.gov or call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: May 14, 2015. .

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015-12181 Filed 5-19-15; 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 electric corporate filings:

Docket Numbers: EC15-139-000.

Applicants: Coram California Development, L.P.

Description: Application of Coram California Development, L.P. for Authorization under Section 203 of the Federal Power Act and Requests for Confidential Treatment and Waivers.

Filed Date: 5/13/15.

Accession Number: 20150513-5209.

Comments Due: 5 p.m. ET 6/3/15.

Docket Numbers: EC15-140-000.

Applicants: ALLETE Clean Energy, Inc., MWW Holdings, LLC, CITIBANK, N.A., AS SECURITY AGENT, AES Armenia Mountain Wind, LLC.

Description: Joint Application for Authorization Under Section 203 of the Federal Power Act and Request for Expedited Consideration, Confidential Treatment, and Waivers of ALLETE Clean Energy, Inc., et al.

Filed Date: 5/14/15.

Accession Number: 20150514-5108.

Comments Due: 5 p.m. ET 6/4/15.

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10-1556-007.

Applicants: Longview Power, LLC.

Description: Notice of Change in Status of Longview Power, LLC.

Filed Date: 5/13/15.

Accession Number: 20150513–5211.
Comments Due: 5 p.m. ET 6/3/15.
Docket Numbers: ER15–1701–000.
Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): First Revised Service Agreement No. 1127; Queue Nos. Z1–055 and Z1–056 to be effective 4/13/2015.

Filed Date: 5/13/15.

Accession Number: 20150513–5089.
Comments Due: 5 p.m. ET 6/3/15.

Docket Numbers: ER15–1703–000.
Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): Revisions to OATT Att K-Appx and OA Schedule 1 re FTR Miscellaneous Changes to be effective 7/13/2015.

Filed Date: 5/13/15.

Accession Number: 20150513–5133.
Comments Due: 5 p.m. ET 6/3/15.

Docket Numbers: ER15–1704–000.
Applicants: Public Service Company of Colorado.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): 2015–5–13 NSP-Ada T–L Filing-Non-conforming to be effective 1/1/2015.

Filed Date: 5/13/15.

Accession Number: 20150513–5135.
Comments Due: 5 p.m. ET 6/3/15.

Docket Numbers: ER15–1705–000.
Applicants: Public Service Company of Colorado.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): 20150513 Burlington Wheeling Charges to be effective 10/1/2014.

Filed Date: 5/13/15.

Accession Number: 20150513–5137.
Comments Due: 5 p.m. ET 6/3/15.

Docket Numbers: ER15–1706–000.
Applicants: Newark Energy Center, LLC.

Description: Initial rate filing per 35.12 Application re Reactive Power Tariff to be effective 7/1/2015.

Filed Date: 5/13/15.

Accession Number: 20150513–5149.
Comments Due: 5 p.m. ET 6/3/15.

Docket Numbers: ER15–1707–000.
Applicants: San Diego Gas & Electric Company.

Description: Initial rate filing per 35.12 System Impact Study Agreement, Service Agreement No. 50 to be effective 5/13/2015.

Filed Date: 5/13/15.

Accession Number: 20150513–5156.
Comments Due: 5 p.m. ET 6/3/15.

Docket Numbers: ER15–1708–000.
Applicants: L'Anse Warden Electric Company.

Description: Compliance filing per 35: Amendment to be effective 4/7/2015.

Filed Date: 5/13/15.

Accession Number: 20150513–5184.
Comments Due: 5 p.m. ET 6/3/15.

Docket Numbers: ER15–1709–000.

Applicants: New York Independent System Operator, Inc., Niagara Mohawk Power Corporation.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): IA (SA No. 2211) between National Grid and the Village of Skaneateles to be effective 3/31/2015.

Filed Date: 5/14/15.

Accession Number: 20150514–5009.
Comments Due: 5 p.m. ET 6/4/15.

Docket Numbers: ER15–1710–000.

Applicants: ISO New England Inc.
Description: ISO New England Inc. submits First Quarter 2015 Capital Budget Report.

Filed Date: 5/13/15.

Accession Number: 20150513–5199.
Comments Due: 5 p.m. ET 6/3/15.

Docket Numbers: ER15–1711–000.

Applicants: Tampa Electric Company.
Description: § 205(d) rate filing per 35.13(a)(2)(iii): OATT Order 676–H Ministerial Filing to be effective 5/16/2015.

Filed Date: 5/14/15.

Accession Number: 20150514–5067.
Comments Due: 5 p.m. ET 6/4/15.

Docket Numbers: ER15–1712–000.

Applicants: Duke Energy Florida, Inc., Duke Energy Carolinas, LLC.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): OATT Schedule 10–A Amendment to be effective 1/1/2014.

Filed Date: 5/14/15.

Accession Number: 20150514–5070.
Comments Due: 5 p.m. ET 6/4/15.

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: May 14, 2015.

Nathaniel J. Davis, Sr.,
Deputy Secretary.

[FR Doc. 2015–12179 Filed 5–19–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: RP15–284–000.

Applicants: Columbia Gas Transmission, LLC.

Description: Compliance filing per 154.501: Environmental Report.

Filed Date: 5/1/15.

Accession Number: 20150501–5186.

Comments Due: 5 p.m. ET 5/13/15.

Docket Numbers: RP15–941–000.

Applicants: Discovery Gas Transmission LLC.

Description: Tariff Withdrawal per 154.205(a): Withdrawal of 2015 System Map Update.

Filed Date: 5/6/15.

Accession Number: 20150506–5115.

Comments Due: 5 p.m. ET 5/18/15.

Docket Numbers: RP15–972–000.

Applicants: Enable Mississippi River Transmission, L.

Description: § 4(d) rate filing per 154.204: Negotiated Rate Filing to Amend LER 5680's Attachment A 5–06–15 to be effective 5/6/2015.

Filed Date: 5/6/15.

Accession Number: 20150506–5184.

Comments Due: 5 p.m. ET 5/18/15.

Docket Numbers: RP15–973–000.

Applicants: Kern River Gas Transmission Company.

Description: § 4(d) rate filing per 154.204: 2015 Mcf to Dth to be effective 6/15/2015.

Filed Date: 5/6/15.

Accession Number: 20150506–5190.

Comments Due: 5 p.m. ET 5/18/15.

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: May 7, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015-12206 Filed 5-19-15; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #2

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10-1484-011

Applicants: Shell Energy North America (U.S.), L.P.

Description: Supplement to March 3, 2015 Notice of Non-Material Change in Status of Shell Energy North America (U.S.), L.P.

Filed Date: 5/13/15.

Accession Number: 20150513-5207.

Comments Due: 5 p.m. ET 6/3/15.

Docket Numbers: ER14-2882-001.

Applicants: The Empire District Electric Company.

Description: Compliance filing per 35: Compliance Filing Revising Formula Rate Protocols to be effective 4/1/2015.

Filed Date: 5/14/15.

Accession Number: 20150514-5150.

Comments Due: 5 p.m. ET 6/4/15.

Docket Numbers: ER15-1713-000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): 2015-05-14 SA 2786 ITC Midwest-IPL GIA (J233) to be effective 5/15/2015.

Filed Date: 5/14/15.

Accession Number: 20150514-5113.

Comments Due: 5 p.m. ET 6/4/15.

Docket Numbers: ER15-1714-000.

Applicants: Targray Americas Inc.
Description: Initial rate filing per 35.12 New Filing to be effective 7/1/2015.

Filed Date: 5/14/15.

Accession Number: 20150514-5120.

Comments Due: 5 p.m. ET 6/4/15.

Docket Numbers: ER15-1715-000.

Applicants: PJM Interconnection, L.L.C.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): PJM and NCEMC submit Revised Service Agreement No. 3347 to be effective 5/1/2015.

Filed Date: 5/14/15.

Accession Number: 20150514-5133.

Comments Due: 5 p.m. ET 6/4/15.

Docket Numbers: ER15-1716-000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): 2015-05-14 Revs to App F (Bylaws) to be effective 7/14/2015.

Filed Date: 5/14/15.

Accession Number: 20150514-5136.

Comments Due: 5 p.m. ET 6/4/15.

Docket Numbers: ER15-1717-000.

Applicants: Midcontinent Independent System Operator, Inc., International Transmission Company.

Description: § 205(d) rate filing per 35.13(a)(2)(iii): 2015-05-14 SA 2788 ITC-Wyandotte Interconnection Facilities Agreement to be effective 5/15/2015.

Filed Date: 5/14/15.

Accession Number: 20150514-5140.

Comments Due: 5 p.m. ET 6/4/15.

Take notice that the Commission received the following qualifying facility filings:

Docket Numbers: QF15-701-000.

Applicants: Lockhart BioEnergy, LLC.
Description: Refund Report of Lockhart BioEnergy, LLC.

Filed Date: 5/14/15.

Accession Number: 20150514-5116.

Comments Due: 5 p.m. ET 5/14/15.

Take notice that the Commission received the following electric reliability filings:

Docket Numbers: RR14-6-002.

Applicants: North American Electric Reliability Corp.

Description: Request of the North American Electric Reliability Corporation for Approval of an Expenditure Greater Than \$500,000 from Operating Reserves.

Filed Date: 5/14/15.

Accession Number: 20150514-5119.

Comments Due: 5 p.m. ET 5/21/15.

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: May 14, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015-12180 Filed 5-19-15; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. IC15-8-000]

Commission Information Collection Activities (FERC-576); Comment Request; Extension

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of information collection and request for comments.

SUMMARY: In compliance with the requirements of the Paperwork Reduction Act of 1995, 44 U.S.C. 3506(c)(2)(A), the Federal Energy Regulatory Commission (Commission or FERC) is soliciting public comment on the currently approved information collection, FERC-576, Report of Service Interruptions.

DATES: Comments on the collection of information are due July 20, 2015.

ADDRESSES: You may submit comments (identified by Docket No. IC15-8-000) by either of the following methods:

- eFiling at Commission's Web site: <http://www.ferc.gov/docs-filing/efiling.asp>.

- Mail/Hand Delivery/Courier: Federal Energy Regulatory Commission, Secretary of the Commission, 888 First Street NE., Washington, DC 20426.

Instructions: All submissions must be formatted and filed in accordance with submission guidelines at: <http://www.ferc.gov/help/submission-guide.asp>. For user assistance contact FERC Online Support by email at ferconlinesupport@ferc.gov, or by phone at: (866) 208-3676 (toll-free), or (202) 502-8659 for TTY.

Docket: Users interested in receiving automatic notification of activity in this docket or in viewing/downloading comments and issuances in this docket may do so at <http://www.ferc.gov/docs-filing/docs-filing.asp>.

FOR FURTHER INFORMATION CONTACT:

Ellen Brown may be reached by email at DataClearance@FERC.gov, telephone at (202) 502-8663, and fax at (202) 273-0873.

SUPPLEMENTARY INFORMATION:

Title: FERC-576, Report of Service Interruptions.

OMB Control No.: 1902-0004.

Type of Request: Three-year extension of the FERC-576 information collection

requirements with no changes to the current reporting requirements.

Abstract: A natural gas company must obtain Commission authorization to engage in the transportation, sale, or exchange of natural gas in interstate commerce under the Natural Gas Act (NGA).¹ The NGA also empowers the Commission to oversee continuity of service in the transportation of natural gas in interstate commerce. The information collected under FERC-576 notifies the Commission of: (1) Damage to jurisdictional natural gas facilities as a result of a hurricane, earthquake, or other natural disaster, or terrorist activity, (2) serious interruptions to service, and (3) damage to jurisdictional natural gas facilities due to natural disaster or terrorist activity, that creates the potential for serious delivery problems on the pipeline's own system or the pipeline grid.

Filings (in accordance with the provisions of section 4(d) of the NGA)² must contain information necessary to advise the Commission when a change in service has occurred. Section 7(d) of the NGA³ authorizes the Commission to issue a temporary certificate in cases of emergency to assure maintenance of

adequate service or to serve particular customers, without notice or hearing.

Respondents to the FERC-576 are encouraged to submit the reports by email to *pipelineoutage@ferc.gov* but also have the option of faxing the reports to the Director of the Division of Pipeline Certificates. 18 CFR 260.9(b) requires that a report of service interruption or damage to natural gas facilities state: (1) The location of the service interruption or damage to natural gas pipeline or storage facilities; (2) The nature of any damage to pipeline or storage facilities; (3) Specific identification of the facilities damaged; (4) The time the service interruption or damage to the facilities occurred; (5) The customers affected by the service interruption or damage to the facilities; (6) Emergency actions taken to maintain service; and (7) Company contact and telephone number. The Commission may contact pipelines reporting damage or other pipelines to determine availability of supply, and if necessary, authorize transportation or construction of facilities to alleviate constraints in response to these reports.

A report required by 18 CFR 260.9(a)(1)(i) of damage to natural gas facilities resulting in loss of pipeline

throughput or storage deliverability shall be reported to the Director of the Commission's Division of Pipeline Certificates at the earliest feasible time when pipeline throughput or storage deliverability has been restored.

In any instance in which an incident or damage report involving jurisdictional natural gas facilities is required by Department of Transportation (DOT) reporting requirements under the Natural Gas Pipeline Safety Act of 1968, a copy of such report shall be submitted to the Director of the Commission's Division of Pipeline Certificates, within 30 days of the reportable incident⁴.

If the Commission failed to collect these data, it would lose the ability to monitor and evaluate transactions, operations, and reliability of interstate pipelines and perform its regulatory functions. These reports are kept by the Commission Staff as non-public information and are not made part of the public record.

Type of Respondents: Natural gas companies

*Estimate of Annual Burden*⁵: The Commission estimates the annual public reporting burden for the information collection as:

FERC-576: REPORT OF SERVICE INTERRUPTIONS

	Number of respondents (1)	Annual number of responses per respondent (2)	Total number of responses (1) * (2) = (3)	Average burden and cost per response ⁶ (4)	Total annual burden hours and total annual cost (3) * (4) = (5)	Cost per respondent (\$) (5) ÷ (1)
Submittal of Original Email/Fax	22	2	44	1 \$72	44 \$3,168	\$72
Submittal of Damage Report	22	2	44	0.25 \$18	11 \$198	18
Submittal of DOT Incident Report	22	1	22	0.25 \$18	5.5 \$99	18
Total	60.5 \$3,465	108

¹ Public Law 75 688; 15 U.S.C. 717 & 717w.

² (15 U.S.C. 717c).

³ (15 U.S.C. 717f).

⁴ 18 CFR 260.9(d).

⁵ The Commission defines burden as the total time, effort, or financial resources expended by

persons to generate, maintain, retain, or disclose or provide information to or for a Federal agency. For further explanation of what is included in the information collection burden, reference 5 Code of Federal Regulations 1320.3.

⁶ The estimates for cost per response are derived using the following formula: Average Burden Hours

per Response * \$72.00 per Hour = Average Cost per Response. The hourly cost figure comes from the FERC average salary (\$149,489/year). Commission staff believes the FERC average salary to be representative wage for industry respondents.

Comments: Comments are invited on: (1) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information will have practical utility; (2) the accuracy of the agency's estimate of the burden and cost of the collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the burden of the collection of information on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Dated: May 14, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015-12216 Filed 5-19-15; 8:45 am]

BILLING CODE 6717-01P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. RM93-11-000]

Revisions to Oil Pipeline Regulations Pursuant to the Energy Policy Act of 1992; Notice of Annual Change in the Producer Price Index for Finished Goods

The Commission's regulations include a methodology for oil pipelines to change their rates through use of an index system that establishes ceiling levels for such rates. The Commission bases the index system, found at 18 CFR 342.3, on the annual change in the Producer Price Index for Finished Goods (PPI-FG), plus two point six five percent (PPI-FG + 2.65). The Commission determined in an *Order Establishing Index For Oil Price Change Ceiling Levels*,¹ issued December 16, 2010, that PPI-FG + 2.65 is the appropriate oil pricing index factor for pipelines to use for the five-year period commencing July 1, 2011.

The regulations provide that the Commission will publish annually, an index figure reflecting the final change in the PPI-FG, after the Bureau of Labor Statistics publishes the final PPI-FG in May of each calendar year. The annual average PPI-FG index figures were 196.6 for 2013 and 200.4 for 2014.²

¹ 133 FERC ¶ 61,228 at P 1 (2010).

² Bureau of Labor Statistics (BLS) publishes the final figure in mid-May of each year. This figure is publicly available from the Division of Industrial Prices and Price Indexes of the BLS, at 202-691-7705, and in print in August in Table 1 of the annual data supplement to the BLS publication *Producer Price Indexes* via the Internet at <http://www.bls.gov/ppi/home.htm>. To obtain the BLS data, scroll down to "PPI Databases" and click on "Top Picks" of the Commodity Data including "headline" FD-ID indexes (Producer Price Index—PPI). At the next screen, under the heading "Producer Price Index Commodity Data," select the box, "Finished goods—WPUSOP3000," then scroll to the bottom of this screen and click on Retrieve data.

Thus, the percent change (expressed as a decimal) in the annual average PPI-FG from 2013 to 2014, plus 2.65 percent, is positive 0.045829.³ Oil pipelines must multiply their July 1, 2014, through June 30, 2015, index ceiling levels by positive 1.045829⁴ to compute their index ceiling levels for July 1, 2015, through June 30, 2016, in accordance with 18 CFR 342.3(d). For guidance in calculating the ceiling levels for each 12 month period beginning January 1, 1995,⁵ see *Explorer Pipeline Company*, 71 FERC ¶ 61,416 at n.6 (1995).

In addition to publishing the full text of this Notice in the **Federal Register**, the Commission provides all interested persons an opportunity to view and/or print this Notice via the Internet through FERC's Home Page (<http://www.ferc.gov>) and in FERC's Public Reference Room during normal business hours (8:30 a.m. to 5:00 p.m. Eastern time) at 888 First Street, NE., Room 2A, Washington, DC 20426. The full text of this Notice is available on FERC's Home Page at the eLibrary link. To access this document in eLibrary, type the docket number excluding the last three digits of this document in the docket number field and follow other directions on the search page.

User assistance is available for eLibrary and other aspects of FERC's Web site during normal business hours. For assistance, please contact the Commission's Online Support at 1-866-208-3676 (toll free) or 202-502-6652 (email at FERCOnlineSupport@ferc.gov), or the Public Reference Room at 202-502-8371, TTY 202-502-8659. E-mail the Public Reference Room at public.reference.room@ferc.gov.

Dated: May 14, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015-12182 Filed 5-19-15; 8:45 am]

BILLING CODE 6717-01-P

³ $[200.4 - 196.6] / 196.6 = 0.019329 + 0.0265 = 0.045829$

⁴ $1 + 0.045829 = 1.045829$.

⁵ For a listing of all prior multipliers issued by the Commission, see the Commission's Web site, <http://www.ferc.gov/industries/oil/gen-info/pipeline-index.asp>.

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP15-482-000]

Sabine Pass Liquefaction, LLC; Sabine Pass LNG, L.P.; Notice of Application

Take notice that on May 5, 2015, Sabine Pass Liquefaction, LLC and Sabine Pass LNG, L.P. (collectively, Sabine), 700 Milam Street, Suite 1900, Houston, Texas 77002, filed in Docket No. CP15-482-000 an application pursuant to section 3(a) of the Natural Gas Act (NGA) for a limited amendment to construct approximately 5,000 feet of 36-inch diameter pipeline and appurtenances in Cameron Parish, Louisiana (EMP Project). Sabine states that the EMP Project will connect to Transcontinental Gas Pipe Line Company, LLC's proposed Gulf Trace Expansion Project in Docket No. CP15-29-000, all as more fully set forth in the application which is on file with the Commission and open to public inspection. The filing is available for review at the Commission in the Public Reference Room or may be viewed on the Commission's Web site web at <http://www.ferc.gov> using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, contact FERC at FERCOnlineSupport@ferc.gov or call toll-free, (886) 208-3676 or TTY, (202) 502-8659.

Any questions concerning these applications may be directed to Lisa M. Toney, Norton Rose Fulbright US LLP, 666 Fifth Avenue, New York, New York 10103 by telephone at (212) 318-3009 or by email at lisa.toney@nortonrosefulbright.com.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice, the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of

the date of issuance of the Commission staff's EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit seven copies of filings made in the proceeding with the Commission and must mail a copy to the applicant and to every other party. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the "eFiling" link at <http://www.ferc.gov>. Persons unable to file electronically should submit an original and 7 copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

Comment Date: June 4, 2015.

Dated: May 14, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015-12215 Filed 5-19-15; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings

Take notice that the Commission has received the following Natural Gas Pipeline Rate and Refund Report filings:

Filings Instituting Proceedings

Docket Numbers: PR15-35-000.

Applicants: Southcross Alabama Pipeline LLC.

Description: Submits tariff filing per 284.123(b)(2) + (g); Southcross Alabama Section 311 Rate Petition (5-1-15) to be effective 5/1/2015; Filing Type: 1310.

Filed Date: 5/1/15.

Accession Number: 20150501-5283.

Comments Due: 5 p.m. ET 5/11/15

284.123(g) Protests Due: 5 p.m. ET 6/19/15.

Docket Numbers: PR14-36-000.

Applicants: Mid Louisiana Gas Transmission, LLC.

Description: Submits tariff filing per 284.224: Application for a Blanket Certificate to be effective 9/1/2015; Filing Type: 1340.

Filed Date: 5/6/15.

Accession Number: 20150506-5119.

Comments/Protests Due: 5 p.m. ET 5/27/15.

Docket Numbers: RP15-974-000.

Applicants: Midwestern Gas Transmission Company.

Description: § 4(d) rate filing per 154.204: Revisions to Pro Forma Service Agreements to be effective 6/8/2015.

Filed Date: 5/7/15.

Accession Number: 20150507-5146.

Comments Due: 5 p.m. ET 5/19/15.

Docket Numbers: RP15-975-000.

Applicants: Transcontinental Gas Pipe Line Company.

Description: § 4(d) rate filing per 154.204: Rockaway Delivery Lateral Initial Rate Filing to be effective 5/14/2015.

Filed Date: 5/7/15.

Accession Number: 20150507-5195.

Comments Due: 5 p.m. ET 5/19/15.

Docket Numbers: RP15-976-000.

Applicants: Texas Eastern

Transmission, LP.

Description: § 4(d) rate filing per 154.204: Duke Energy Indiana, Inc 712322—Negotiated Rate Agreement to be effective 6/1/2015.

Filed Date: 5/7/15.

Accession Number: 20150507-5216.

Comments Due: 5 p.m. ET 5/19/15.

Docket Numbers: RP15-977-000.

Applicants: Freebird Gas Storage, L.L.C.

Description: Compliance filing per 154.203: Freebird Gas Storage, L.L.C., FERC Order 801 (Correction to Filing ID 80) to be effective 6/4/2015.

Filed Date: 5/7/15.

Accession Number: 20150507-5218.

Comments Due: 5 p.m. ET 5/19/15.

Docket Numbers: RP15-978-000.

Applicants: Equitrans, L.P.

Description: § 4(d) rate filing per 154.204: Equitrans' Tariff Clean-Up Filing—May 2015 to be effective 6/8/2015.

Filed Date: 5/8/15.

Accession Number: 20150508-5063.

Comments Due: 5 p.m. ET 5/20/15.

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 date(s). Protests may be considered, but intervention is necessary to become a party to the proceeding.

Filings in Existing Proceedings

Docket Numbers: RP15-670-002.

Applicants: Enable Gas Transmission, LLC.

Description: Compliance filing per 154.203: Fuel Tracker Compliance Filing to be effective 5/1/2015.

Filed Date: 5/8/15.

Accession Number: 20150508-5170.

Comments Due: 5 p.m. ET 5/20/15.

Any person desiring to protest in any of the above proceedings must file in accordance with Rule 211 of the Commission's Regulations (18 CFR 385.211) on or before 5:00 p.m. Eastern time on the specified comment date.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: <http://www.ferc.gov/>

docs-filing/efiling/filing-req.pdf. For other information, call (866) 208-3676 (toll free). For TTY, call (202) 502-8659.

Dated: May 11, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015-12207 Filed 5-19-15; 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 electric rate filings:

Docket Numbers: ER10-3254-002.

Applicants: Cooperative Energy Incorporated (An Electric Membership Corporation).

Description: Updated Market Power Analysis of Cooperative Energy Incorporated (An Electric Membership Corporation).

Filed Date: 5/12/15.

Accession Number: 20150512-5209.

Comments Due: 5 p.m. ET 7/13/15.

Docket Numbers: ER13-913-005.

Applicants: Ohio Valley Electric Corporation.

Description: Compliance filing per 35: Order 1000 Regional Compliance Filing for Transmission Process to be effective 6/1/2015.

Filed Date: 5/13/15.

Accession Number: 20150513-5078.

Comments Due: 5 p.m. ET 6/3/15.

Docket Numbers: ER14-2866-001.

Applicants: Louisville Gas and Electric Company.

Description: Compliance filing per 35: Att O Formula Rate Protocols Compliance Filing to be effective 1/1/2015.

Filed Date: 5/12/15.

Accession Number: 20150512-5156.

Comments Due: 5 p.m. ET 6/2/15.

Docket Numbers: ER15-1130-001.

Applicants: Midcontinent Independent System Operator, Inc., Ameren Illinois Company.

Description: Tariff Amendment per 35.17(b): 2015-05-12_SA 2752 Deficiency Response Ameren-Bishop Hill FSA to be effective 1/28/2015.

Filed Date: 5/12/15.

Accession Number: 20150512-5170.

Comments Due: 5 p.m. ET 6/2/15.

Docket Numbers: ER15-1700-000.

Applicants: Cooperative Energy Incorporated (An Electric Membership Corporation).

Description: Compliance filing per 35: Cooperative Energy Inc Revised Electric Tariff Filing to be effective 5/13/2015.

Filed Date: 5/12/15.

Accession Number: 20150512-5204.

Comments Due: 5 p.m. ET 6/2/15.

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: May 13, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015-12178 Filed 5-19-15; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP15-150-000]

Columbia Gas Transmission, LLC; Notice of Intent To Prepare an Environmental Assessment for the Proposed Line WB2VA Integrity Project, and 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 Line WB2VA Integrity Project (project) involving abandonment, construction, and operation of facilities by Columbia Gas Transmission, LLC (Columbia) in Hardy County, West Virginia, and Shenandoah, Page, Rockingham, and Greene Counties, Virginia. The Commission will use this EA in its decision-making process to determine whether the project is in the public convenience and necessity.

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 June 15, 2015.

If you sent comments on this project to the Commission before the opening of this docket on April 2, 2015, you will need to file those comments in Docket No. CP15-150-000 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.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The company would seek to negotiate a mutually acceptable agreement. However, if the Commission approves the project, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings where compensation would be determined in accordance with state law.

Columbia 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).

Public Participation

For your convenience, there are three methods available 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. 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) 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) 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 (CP15-150-000) 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

Columbia proposes replacement and modification of existing equipment at numerous sites along the Line WB2VA pipeline, and at Lost River and Bickers Compressor Stations in Hardy County, West Virginia, and Shenandoah, Page, Rockingham, and Greene Counties, Virginia. The project would include the installation of pig launchers,¹ receivers, mainline valves and other appurtenant facilities. Also, Columbia would replace the two 20-inch-diameter pipelines beneath the South Fork of the Shenandoah River with a new 24-inch-diameter pipeline. To maintain service during the proposed pipeline replacement activities, Columbia would install temporary fittings and temporary bypass piping. Once the installation of the new segment of pipeline is complete and tied-in to the existing WB2VA pipeline, the temporary bypass piping would be removed.

This project is part of Columbia's multi-year modernization program developed to address its aging infrastructure. The existing mainline valves do not permit the use of smart pigs as an inspection tool, and the two existing 20-inch-diameter pipelines crossing the South Fork of Shenandoah River create a similar barrier. The project modifications would create a continuous, 24-inch-diameter pipeline between Columbia's existing Lost River and Bickers Compressor Stations that would allow for smart pig inspections.

¹A "pig" is a tool that the pipeline company inserts into and pushes through the pipeline for cleaning the pipeline, conducting internal inspections, or other purposes."

The general location of the project facilities is shown in appendix 1.²

Land Requirements for Construction

Construction of the proposed facilities would disturb about 37.9 acres of land. Following construction, Columbia would maintain about 26.0 acres for permanent operation of the project's facilities; which is 1.0 acre more than it is currently using. 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 a Certificate of Public Convenience and Necessity. NEPA also requires us³ 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 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*. Depending on the comments

²The appendices referenced in this notice will not appear in the *Federal Register*. Copies of appendices were sent to all those receiving this notice in the mail and are available at www.ferc.gov using the link called "eLibrary" or from the Commission's Public Reference Room, 888 First Street NE., Washington, DC 20426, or call (202) 502-8371. For instructions on connecting to *eLibrary*, refer to the last page of this notice.

³"We," "us," and "our" refer to the environmental staff of the Commission's Office of Energy Projects.

received during the scoping process, we may 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.⁴ 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 Offices (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.⁵ We will define the project-specific Area of Potential Effects (APE) in consultation with the SHPOs 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.

Currently Identified Environmental Issues

We have already identified several issues that we think deserve attention based on a preliminary review of the proposed facilities and the environmental information provided by Columbia. This preliminary list of

⁴The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Part 1501.6.

⁵The 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.

issues may be changed based on your comments and our analysis.

- Endangered Species
- Groundwater
- Karst Topography

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.

If 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. Intervenor 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 in the User's Guide under the "e-filing" link on the Commission's Web site.

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 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.*, CP15-150). Be sure you have selected an appropriate date range. For

assistance, please contact FERC Online Support at 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 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.

Finally, public meetings or site visits will be posted on the Commission's calendar located at www.ferc.gov/EventCalendar/EventsList.aspx along with other related information.

Dated: May 14, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015-12213 Filed 5-19-15; 8:45 am]

BILLING CODE 6717-01-P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP15-161-000]

Roadrunner Gas Transmission, LLC; Notice of Intent To Prepare an Environmental Assessment for the Proposed Roadrunner Border 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 Roadrunner Border Crossing Project involving construction and operation of facilities for the export of natural gas by Roadrunner Gas Transmission, LLC (Roadrunner) 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 June 13, 2015.

If you sent comments on this project to the Commission before the opening of this docket on April 9, 2015, you will need to file those comments in Docket No. CP15-161-000 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.

If you are a landowner receiving this notice, a pipeline company representative may contact you about the acquisition of an easement to construct, operate, and maintain the proposed facilities. The company would seek to negotiate a mutually acceptable agreement. However, if the Commission approves the project, that approval conveys with it the right of eminent domain. Therefore, if easement negotiations fail to produce an agreement, the pipeline company could initiate condemnation proceedings where compensation would be determined in accordance with state law.

Roadrunner 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).

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. 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) 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) 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 (CP15-161-000) 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

Roadrunner proposes to construct a new border crossing at the international boundary between the United States and Mexico in El Paso County, Texas. The Roadrunner Border Crossing Project would consist of the construction of approximately 900 feet of FERC-jurisdictional 30-inch-diameter pipeline, installed beneath the Rio Grande River near San Elizario in El Paso County, Texas. The new pipeline would have a maximum daily export capacity of 875,000 million cubic feet per day, designed to transport natural gas to a new delivery interconnect with Tarahumara Pipeline S. de C.V. (Tarahumara Pipeline) at the United States/Mexico border for electric generation and industrial market needs in Mexico.

The Roadrunner Border Crossing Project would interconnect with Roadrunner's new intrastate pipeline facilities, including 205 miles of 30-inch-diameter pipeline, metering stations, and a new natural gas compressor station in Pecos County, Texas. The intrastate facilities would be subject to the jurisdiction of the Texas Railroad Commission and would be non-jurisdictional to the FERC. Roadrunner would concurrently construct the non-jurisdictional facilities in two phases between 2015 and 2016.

The general location of the project facilities is shown in appendix 1.¹

¹ The appendices referenced in this notice will not appear in the **Federal Register**. Copies of appendices were sent to all those receiving this notice in the mail and are available at www.ferc.gov using the link called "eLibrary" or from the Commission's Public Reference Room, 888 First Street NE., Washington, DC 20426, or call (202) 502-8371. For instructions on connecting to eLibrary, refer to the last page of this notice.

Land Requirements for Construction

Construction of the Roadrunner Cross Border Pipeline Project pipeline would affect a total of 23.4 acres of land in the United States including 3.1 acres of additional temporary workspace for HDD construction and hydrostatic testing of the pipeline, 18.7 acres of temporary access roads, and 1.6 acres of operational right-of-way that would overlap between the FERC jurisdictional and non-jurisdictional pipeline facilities.

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 us² 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 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. Depending on the comments received during the scoping process, we may 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,

² "We," "us," and "our" refer to the environmental staff of the Commission's Office of Energy Projects.

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.³ 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.

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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.⁴ 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

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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 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.*, CP15–161). Be sure you have selected an appropriate date range. For assistance, please contact FERC Online Support at 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.

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Finally, public meetings or site visits will be posted on the Commission’s

calendar located at www.ferc.gov/EventCalendar/EventsList.aspx along with other related information.

Dated: May 14, 2015.

Kimberly D. Bose,

Secretary.

[FR Doc. 2015–12214 Filed 5–19–15; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL 9927–99–Region 5]

Request for Nominations of Experts to the Science and Information Subcommittee of the Great Lakes Advisory Board

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) announces the formation of a new Science and Information Subcommittee (SIS) of the Great Lakes Advisory Board (the Board) and requests nominations of experts to be considered for appointment to the SIS. The SIS will assist the Board in providing ongoing advice on Great Lakes “adaptive management,” the process of learning from past decisions to make more effective future Great Lakes Restoration Initiative (GLRI) decisions. The SIS may provide other recommendations, as requested by the federal Great Lakes Interagency Task Force (IATF) and for the benefit of the IATF. Sources in addition to this **Federal Register** Notice may be used in the solicitation of nominees.

DATES: Nominations should be submitted within June 19, 2015 per instructions below.

ADDRESSES: Submit nominations electronically with the subject line “SIS Nomination 2014” to cestaric.rita@epa.gov. You may also submit nominations by mail to: Rita Cestaric, Designated Federal Officer (DFO), U.S. Environmental Protection Agency, Great Lakes National Program Office, 77 W. Jackson Boulevard, Chicago, Illinois 60604.

FOR FURTHER INFORMATION CONTACT: Rita Cestaric, Designated Federal Officer, U.S. Environmental Protection Agency, 77 W. Jackson, Chicago, IL 60604; email address: cestaric.rita@epa.gov; telephone number: (312) 886–6815. General information concerning Great Lakes restoration and protection and the Advisory Board can be found at <http://www.glri.us>.

SUPPLEMENTARY INFORMATION:

Background: The Board is a federal advisory committee chartered under the Federal Advisory Committee Act (FACA), Public Law 92–463. EPA established the Board in 2013 to provide independent advice to the EPA Administrator in her capacity as Chair of the IATF. The Board conducts business in accordance with FACA and related regulations. The Board consists of eighteen experts representing a broad range of Great Lakes interests.

The SIS is being formed to provide expert advice on matters related to Board work. Specifically, the SIS may provide advice on the technical aspects of Great Lakes restoration and protection including refinement and implementation of an Adaptive Management Framework under the GLRI. It may provide other advice as requested, such as domestic implementation of the Great Lakes Water Quality Agreement (Science) Annex 10, the identification of significant gaps in Great Lakes scientific knowledge, the development and use of information systems to assist in adaptive management and other matters as requested by the federal agencies regarding Great Lakes protection and restoration.

The SIS will as needed, but it is anticipated to meet in person or by teleconference at least two times a year. The anticipated workload for members will be approximately 100–150 hours per year. SIS members may be invited to participate in meetings of the Board, in addition to participation on the SIS.

The SIS is anticipated to be composed of ten to fifteen members. Federal agency representatives may serve as advisors to the SIS. EPA will work directly with federal agencies to solicit qualified federal participants. This solicitation is focused exclusively on non-Federal candidates for membership.

Request for Nominations: Nominees should be regionally, nationally or internationally recognized experts in one or more of the following disciplines: Ecology, environmental chemistry, environmental engineering, geology, fisheries and wildlife management, public health, social sciences, behavioral sciences, economics, and/or information management, including technological platforms (*e.g.*, dashboards) for information delivery. It is helpful, but not necessary, to have demonstrated experience with Great Lakes-specific issues.

How To Submit Nominations: Any interested person or organization may nominate qualified individuals for appointment to the SIS. Individuals may self-nominate. Nominations can be submitted in electronic format

(preferred) or in hard copy format (see **ADDRESSES** section above). To be considered, nominations should include a cover letter and curriculum vitae. The cover letter should include why the nominee wishes to be considered and a short biographical sketch (no more than two paragraphs). The CV should contain contact information for the person making the nomination; contact information for the nominee; the disciplinary and specific areas of expertise of the nominee; sources of recent grant and/or contract support; current position, educational background, research activities, and recent service on other national advisory committees or national professional organizations.

The SIS will include members who possess the necessary domains of knowledge and the collective breadth of experience to adequately address the charge. Selection criteria to be used for SIS membership include: (a) Scientific and/or technical expertise, knowledge and experience; (b) availability and willingness to serve; (c) skills working in committees, subcommittees and advisory panels; and, (d) diversity of expertise and viewpoints. EPA values and welcomes diversity and encourages nominations of women and men of all racial and ethnic groups. A SIS that includes geographically diverse membership will also be a consideration by EPA in selecting nominees.

Individuals having questions about the nomination procedures should contact Rita Cestaric, DFO, as indicated above in this notice. The EPA will acknowledge the receipt of all nominations. To help the Agency in evaluating the effectiveness of its outreach efforts, please tell us how you learned of this opportunity.

Dated: May 12, 2015.

Stan Meiburg,

Acting Deputy Administrator.

[FR Doc. 2015-12259 Filed 5-19-15; 8:45 am]

BILLING CODE 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

Federal Advisory Committee Act; Communications Security, Reliability, and Interoperability Council

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) Communications Security, Reliability, and Interoperability Council (CSRIC) V will hold its first meeting.

DATES: June 24, 2015.

ADDRESSES: Federal Communications Commission, Room TW-C305 (Commission Meeting Room), 445 12th Street SW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT:

Jeffery Goldthorp, Designated Federal Officer, (202) 418-1096 (voice) or jeffery.goldthorp@fcc.gov (email); or Lauren Kravetz, Deputy Designated Federal Officer, (202) 418-7944 (voice) or lauren.kravetz@fcc.gov (email).

SUPPLEMENTARY INFORMATION: The meeting will be held on June 24, 2015, from 1:00 p.m. to 5:00 p.m. in the Commission Meeting Room of the Federal Communications Commission, Room TW-C305, 445 12th Street SW., Washington, DC 20554.

The CSRIC is a Federal Advisory Committee that will provide recommendations to the FCC regarding best practices and actions the FCC can take to ensure the security, reliability, and interoperability of communications systems. On March 19, 2015, the FCC, pursuant to the Federal Advisory Committee Act, renewed the charter for the CSRIC for a period of two years through March 18, 2017. The meeting on June 24, 2015, will be the first meeting of the CSRIC under the current charter. 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://www.fcc.gov/live>. The public may submit written comments before the meeting to Jeffery Goldthorp, CSRIC Designated Federal Officer, by email to jeffery.goldthorp@fcc.gov or U.S. Postal Service Mail to Jeffery Goldthorp, Associate Bureau Chief, Public Safety and Homeland Security Bureau, Federal Communications Commission, 445 12th Street SW., Room 7-A325, 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 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 requests will be accepted, but may be impossible to fill.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 2015-12116 Filed 5-19-15; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL COMMUNICATIONS COMMISSION

[OMB 3060-1158]

Information Collection Being Reviewed by the Federal Communications Commission

AGENCY: Federal Communications Commission.

ACTION: Notice and request for comments.

SUMMARY: As part of its continuing effort to reduce paperwork burdens, and as required by the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501-3520), the Federal Communications Commission (FCC or Commission) invites the general public and other Federal agencies to take this opportunity to comment on the following information collections. Comments are requested concerning: Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; the accuracy of the Commission's burden estimate; ways to enhance the quality, utility, and clarity of the information collected; ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology; and ways to further reduce the information collection burden on small business concerns with fewer than 25 employees. The FCC may not conduct or sponsor a collection of information unless it displays a currently valid OMB control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the PRA that does not display a valid OMB control number.

DATES: Written PRA comments should be submitted on or before July 20, 2015. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all PRA comments to Cathy Williams, FCC, via email PRA@fcc.gov and to Cathy.Williams@fcc.gov.

FOR FURTHER INFORMATION CONTACT: For additional information about the information collection, contact Cathy Williams at (202) 418-2918.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060-1158.

Title: Disclosure of Network Management Practices, Preserving the Open Internet and Broadband Industry Practices, Report and Order, GN Docket No. 14-28.

Form Number: N/A.

Type of Review: Revision of a currently approved collection.

Respondents: Businesses or other for-profit entities; Not-for profit entities; State, local or tribal governments.

Number of Respondents and Responses: 3,188 respondents; 3,188 responses.

Estimated Time per Response: 28.9 hours (average).

Frequency of Response: On occasion reporting requirement; Third party disclosure requirement.

Obligation to Respond: Mandatory. The statutory authority for the information collection requirements are contained in sections 1, 2, 3, 4, 10, 201, 202, 301, 303, 316, 332, 403, 501, 503 of the Communications Act of 1934, as amended, and section 706 of the Telecommunications Act of 1996, as amended, and 47 U.S.C. Sections 151, 152, 153, 154, 160, 201, 202, 301, 303, 316, 332, 403, 501, 503, and 1302.

Total Annual Burden: 92,133 hours.

Total Annual Cost: \$640,000.

Nature and Extent of Confidentiality: An assurance of confidentiality is not offered because this information collection does not require the collection of personally identifiable information from individuals.

Privacy Impact Assessment: No impacts(s).

Needs and Uses: The rules adopted in the Protecting and Promoting the Open Internet Report and Order on Remand, Declaratory Ruling, and Order, GN Docket No. 14-28, FCC 15-24, require all providers of broadband Internet access service to publicly disclose accurate information regarding the network management practices, performance, and commercial terms of their broadband Internet access services sufficient for consumers to make informed choices regarding use of such services and for content, application, service, and device providers to develop, market, and maintain Internet offerings. The rules ensure transparency and continued Internet openness, while making clear that broadband providers

can manage their networks effectively. The Commission anticipates that small entities may have less of a burden, and larger entities may have more of a burden than the average compliance burden. This is because larger entities serve more customers, are more likely to serve multiple geographic regions, and are not eligible to avail themselves of the temporary exemption from the enhancements granted to smaller providers.

Federal Communications Commission.

Marlene H. Dortch,

Secretary, Office of the Secretary, Office of the Managing Director.

[FR Doc. 2015-12133 Filed 5-19-15; 8:45 am]

BILLING CODE 6712-01-P

FEDERAL DEPOSIT INSURANCE CORPORATION

Agency Information Collection Activities: Proposed Collection Renewal; Comment Request (3064-0135)

AGENCY: Federal Deposit Insurance Corporation (FDIC).

ACTION: Notice and request for comment.

SUMMARY: The FDIC, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on the renewal of the above-captioned information collection, as required by the Paperwork Reduction Act of 1995. Currently, the FDIC is soliciting comment on renewal of the information collection described below.

DATES: Comments must be submitted on or before June 19, 2015.

ADDRESSES: Interested parties are invited to submit written comments to the FDIC by any of the following methods:

- <http://www.FDIC.gov/regulations/laws/federal/>.
- *Email:* comments@fdic.gov. Include the name of the collection in the subject line of the message.
- *Mail:* Gary A. Kuiper, Counsel, (202.898.3877), MB-3074, or John Popeo, Counsel, (202.898.6923), MB-3007, Federal Deposit Insurance Corporation, 550 17th Street NW., Washington, DC 20429.
- *Hand Delivery:* Comments may be hand-delivered to the guard station at the rear of the 17th Street Building (located on F Street), on business days between 7:00 a.m. and 5:00 p.m.

All comments should refer to the relevant OMB control number. A copy of the comments may also be submitted

to: OMB desk officer for the FDIC: Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Gary A. Kuiper or John Popeo, at the FDIC address above.

SUPPLEMENTARY INFORMATION: Proposal to renew the following currently-approved collection of information:
Title: Asset Purchaser Eligibility Certification.

OMB Control Number: 3064-0135.

Form Number: FDIC 7300/06, "Purchaser Eligibility Certification;" 7300/07 "Pre-Qualification Request;" and 7300/08, "Contact Information Form."

Affected Public: Business or other financial institutions.

Frequency of Response: On occasion.

Estimated Number of Respondents: 600.

Estimated Time per Response: 1.0 hour (Purchaser Eligibility Certification, 30 minutes; Pre-Qualification Request, 20 minutes; and Contact Information Form, 10 minutes).

Total Annual Burden: 600 hours.

General Description of Collection: The FDIC uses the Purchaser Eligibility Certification form, FDIC Form No. 7300/06, to identify prospective bidders who are not eligible to purchase assets of failed institutions from the FDIC. Specifically, section 11(p) of the Federal Deposit Insurance Act prohibits the sale of assets of failed institutions to certain individuals or entities that profited or engaged in wrongdoing at the expense of those failed institutions, or seriously mismanaged failed institutions. The Pre-Qualification Request form, FDIC Form No. 7300/07, is designed to determine which prospective bidders are qualified to bid on particular types of assets.

Request for Comment

Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the FDIC's functions, including whether the information has practical utility; (b) the accuracy of the estimates of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the information collection on respondents, including through the use of automated collection techniques or other forms of information technology. All comments will become a matter of public record.

Dated at Washington, DC, this 15th day of May 2015.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2015-12169 Filed 5-19-15; 8:45 am]

BILLING CODE 6714-01-P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice to All Interested Parties of the Termination of the Receivership of 10066, First National Bank of Anthony, Anthony, KS

NOTICE IS HEREBY GIVEN that the Federal Deposit Insurance Corporation ("FDIC") as Receiver for First National Bank of Anthony, Anthony, KS ("the Receiver") intends to terminate its receivership for said institution. The FDIC was appointed receiver of First National Bank of Anthony on June 19, 2009. The liquidation of the receivership assets has been completed. To the extent permitted by available funds and in accordance with law, the Receiver will be making a final dividend payment to proven creditors.

Based upon the foregoing, the Receiver has determined that the continued existence of the receivership will serve no useful purpose. Consequently, notice is given that the receivership shall be terminated, to be effective no sooner than thirty days after the date of this Notice. If any person wishes to comment concerning the termination of the receivership, such comment must be made in writing and sent within thirty days of the date of this Notice to: Federal Deposit Insurance Corporation, Division of Resolutions and Receiverships, Attention: Receivership Oversight Department 32.1, 1601 Bryan Street, Dallas, TX 75201.

No comments concerning the termination of this receivership will be considered which are not sent within this time frame.

Dated: May 15, 2015.

Federal Deposit Insurance Corporation.

Robert E. Feldman,

Executive Secretary.

[FR Doc. 2015-12168 Filed 5-19-15; 8:45 am]

BILLING CODE 6714-01-P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreements under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission,

Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (www.fmc.gov) or by contacting the Office of Agreements at (202) 523-5793 or tradeanalysis@fmc.gov.

Agreement No.: 011876-001.

Title: Seafreight/Crowley Space Charter Agreement.

Parties: Seafreight Line, Ltd. and Crowley Caribbean Services, LLC.
Filing Party: Wayne R. Rohde, Esq.; Cozen O'Connor; 1627 I Street NW., Suite 1100; Washington, DC 20006-4007.

Synopsis: The amendment adds the trade between Jacksonville, provides for reciprocal space chartering, and changes the name of the Crowley entity that is party to the agreement.

Agreement No.: 012091-001.

Title: HLAG/HSDG Slot Charter Agreement.

Parties: Hapag-Lloyd Aktiengesellschaft and Hamburg Sudamerikanische Dampfschiffahrts-Gesellschaft KG.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Connor; 1627 I Street NW., Suite 1100; Washington, DC 20006-4007.

Synopsis: The amendment would increase the amount of space being chartered under the agreement.

Agreement No.: 012208-002.

Title: Hoegh/Grimaldi Space Charter Agreement.

Parties: Hoegh Autoliners AS; Grimaldi Deep Sea S.p.A.; and Grimaldi Euromed S.p.A. (acting as a single party).

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Connor; 1627 I Street NW.; Suite 1100; Washington, DC 20006.

Synopsis: The Amendment adds Grimaldi Euromed S.p.A. as a party to the agreement.

Agreement No.: 012312-002.

Title: Grimaldi Deep Sea S.p.A./ Mitsui O.S.K Lines Ltd. Space Charter Agreement.

Parties: Grimaldi Deep Sea S.p.A. and Grimaldi Euromed S.p.A.; Mitsui O.S.K. Lines Ltd.

Filing Party: Eric. C. Jeffrey, Esq.; Nixon Peabody LLP; 401 9th Street NW., Suite 900; Washington, DC 20004.

Synopsis: The amendment adds Grimaldi Euromed S.p.A. as a party to the agreement, and corrects the spelling of party Mitsui O.S.K. Lines Ltd.

Agreement No.: 012330.

Title: Liberty Global Logistics LLC/ Bahri General Cargo Cooperative Working Agreement.

Parties: Liberty Global Logistics LLC and Bahri General Cargo.

Filing Parties: Brenda Shapiro, Esq; Winston & Strawn LLP; 200 Park Avenue; New York, NY; 10166.

Synopsis: The agreement would authorize the parties to purchase space on the vessels operated by one another in the trade between the U.S. East and Gulf Coasts on the one hand, and ports along the Mediterranean Sea, Red Sea, Gulf of Aden, Arabian Sea, Gulf of Oman, and Persian Gulf on the other hand.

Agreement No.: 012331.

Title: Crowley/APL Space Charter Agreement

Parties: APL Co. Pte Ltd and American President Lines, Ltd. (collectively "APL"); and Crowley Latin America Services, LLC.

Filing Party: Eric. C. Jeffrey, Esq.; Nixon Peabody LLP; 401 9th Street NW., Suite 900; Washington, DC 20004.

Synopsis: The agreement authorizes Crowley to charter space to APL in the trade from the U.S. East Coast to Panama.

Agreement No.: 012332.

Title: CMA CGM/HJS Slot Exchange Agreement.

Parties: CMA CGM, S.A.; and Hanjin Shipping Co., Ltd.

Filing Party: Draughn B. Arbona, Esq; CMA CGM (America) LLC; 5701 Lake Wright Drive; Norfolk, VA 23502

Synopsis: The Agreement authorizes the parties to exchange slots in the trade between Vietnam, China, Hong Kong, and Korea, on the one hand, and the U.S. West Coast, on the other hand.

Agreement No.: 012333.

Title: APL/CMA CGM USEC—Middle East Slot Charter Agreement

Parties: American President Lines, Ltd.; and CMA CGM S.A.

Filing Party: Eric. C. Jeffrey, Esq.; Nixon Peabody LLP; 401 9th Street NW., Suite 900; Washington, DC 20004.

Synopsis: The agreement authorizes APL to charter space to CMA CGM in the trade between the U.S. East Coast, on the one hand, and Egypt and the United Arab Emirates, on the other hand.

Agreement No.: 201162-011.

Title: NYSA-ILA Assessment Agreement.

Parties: International Longshoremen's Association and New York Shipping Association.

Filing Parties: Donato Caruso, Esq.; The Lambos Firm, LLP; 303 South Broadway, Suite 410; Tarrytown, NY 10591 and Andre Mazzola, Esq.; Marrinan & Mazzola Mardon, P.C.; 26 Broadway, 17th Floor; New York, NY 10004.

Synopsis: The amendment adds an assessment on loaded waste containers effective March 1, 2015.

By Order of the Federal Maritime Commission.

Dated: May 15, 2015.

Karen V. Gregory,
Secretary.

[FR Doc. 2015-12235 Filed 5-19-15; 8:45 am]

BILLING CODE 6731-AA-P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than June 13, 2015.

A. Federal Reserve Bank of Boston (Richard Walker, Community Affairs Officer) 600 Atlantic Avenue, Boston, Massachusetts 02210-2204:

1. *Wessagussett Mutual Holding Company, its mid-tier subsidiary Wessagussett Bancorp, Inc. and its subsidiary bank, Weymouth Bank*; all of East Weymouth, Massachusetts to acquire Equitable Bancorp, MHC, its mid-tier subsidiary Equitable Bancorp, Inc. and its subsidiary bank, Equitable Co-operative Bank, all of Lynn, Massachusetts.

Board of Governors of the Federal Reserve System, May 14, 2015.

Michael J. Lewandowski,
Associate Secretary of the Board.

[FR Doc. 2015-12136 Filed 5-19-15; 8:45 am]

BILLING CODE 6210-01-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 June 3, 2015.

A. Federal Reserve Bank of Kansas City (Dennis Denney, Assistant Vice President) 1 Memorial Drive, Kansas City, Missouri 64198-0001:

1. *Justine Hurry, Glenbrook, Nevada*; to acquire control of PB Financial Group, Inc., and thereby acquire control of Premier Bank, both in Denver, Colorado.

Board of Governors of the Federal Reserve System, May 14, 2015.

Michael J. Lewandowski,
Associate Secretary of the Board.

[FR Doc. 2015-12137 Filed 5-19-15; 8:45 am]

BILLING CODE 6210-01-P

GENERAL SERVICES ADMINISTRATION

[Notice-MG-2015-03; Docket No. 2015-0002; Sequence No. 14]

Office of Federal High-Performance Green Buildings; Green Building Advisory Committee; Notification of Upcoming Conference Calls

AGENCY: Office of Government-wide Policy, General Services Administration (GSA).

ACTION: Meeting notice.

SUMMARY: Notice of these conference calls is being provided according to the requirements of the Federal Advisory

Committee Act, 5 U.S.C. App. 10(a)(2). This notice provides the schedule for a series of conference calls, supplemented by Web meetings, for two task groups of the Committee. The conference calls are open for the public to listen in.

Interested individuals must register to attend as instructed below under

SUPPLEMENTARY INFORMATION.

DATES: *Task group conference call dates:* The conference calls will be held according to the following schedule:

The *Portfolio Prioritization* task group will hold conference calls on Mondays as needed from June 8, 2015 to September 28, 2015 from 11:00 a.m. to 12:00 p.m., Eastern Daylight time.

The *Energy Use Index* task group will hold conference calls on Mondays as needed from June 8, 2015 to September 28, 2015 from 3:00 p.m. to 4:00 p.m., Eastern Daylight time.

FOR FURTHER INFORMATION CONTACT: Mr. Ken Sandler, Designated Federal Officer, Office of Federal High-Performance Green Buildings, Office of Government-wide Policy, General Services Administration, 1800 F Street NW., Washington, DC 20405, telephone 202-219-1121 (Note: This is not a toll-free number). Additional information about the Committee, including meeting materials and updates on the task groups and their schedules, will be available on-line at <http://www.gsa.gov/gbac>.

SUPPLEMENTARY INFORMATION:

Procedures for Attendance

Contact Mr. Ken Sandler at ken.sandler@gsa.gov to register to listen in to any or all of these conference calls. To attend the conference calls, submit your full name, organization, email address, and phone number. Requests to listen in to the calls must be received by 5:00 p.m. Eastern Daylight time on Thursday, June 4, 2015. (GSA will be unable to provide technical assistance to any listener experiencing technical difficulties. Testing access to the Web meeting site in advance of calls is recommended.)

Background

The Administrator of the U.S. General Services Administration established the Committee on June 20, 2011 (**Federal Register**/Vol. 76, No. 118) pursuant to Section 494 of the Energy Independence and Security Act of 2007 (EISA, 42 U.S.C. 17123). Under this authority, the Committee advises GSA on the rapid transformation of the Federal building portfolio to sustainable technologies and practices. The Committee reviews strategic plans, products and activities of the Office of Federal High-

Performance Green Buildings and provides advice regarding how the Office can accomplish its mission most effectively.

The *Portfolio Prioritization* task group is pursuing the motion of two committee members to “propose a process for Federal agencies to consistently incorporate green building and resilience requirements into their capital investment criteria and strategies.” The *Energy Use Index* task group is pursuing the motion of a committee member to “develop guidelines for creating a new energy intensity metric [to reflect impacts of] densified facilities, centrally located workplace sites . . . and expansion of telework and hoteling.”

Both groups have met previously and had their work endorsed by the full Committee at its April 23, 2015 meeting. The conference calls will focus on how the task groups can further refine these motions into final consensus recommendations of each group to the full Committee, which will in turn decide whether to proceed with formal advice to GSA based upon these recommendations. Additional background information and updates will be posted on GSA’s Web site at <http://www.gsa.gov/gbac>.

Dated: May 14, 2015.

Kevin Kampschroer,

Federal Director, Office of Federal High-Performance Green Buildings, General Services Administration.

[FR Doc. 2015–12210 Filed 5–19–15; 8:45 am]

BILLING CODE 6820–14–P

GOVERNMENT ACCOUNTABILITY OFFICE

Appointment to the Methodology Committee of the Patient-Centered Outcomes Research Institute (PCORI)

AGENCY: Government Accountability Office (GAO).

ACTION: Notice of appointment.

SUMMARY: The Methodology Committee assists PCORI in developing and updating methodological standards and guidance for comparative clinical effectiveness research. The Patient Protection and Affordable Care Act directs the Comptroller General to appoint up to 15 members to PCORI’s Methodology Committee. This notice announces the appointment of a new member, Adam Wilcox, Ph.D., Director of Medical Informatics at Intermountain Healthcare in Salt Lake City, Utah.

DATES: The appointment is effective May 2015.

ADDRESSES: GAO: 441 G Street NW., Washington, DC 20548.

PCORI: 1828 L Street NW., Suite 900, Washington, DC 20036.

FOR MORE INFORMATION CONTACT: GAO: Office of Public Affairs, (202) 512–4800. PCORI: Joe Selby, MD, MPH, (202) 827–7700.

[Sec. 6301, Pub. L. 111–148].

Gene L. Dodaro,

Comptroller General of the United States.

[FR Doc. 2015–11955 Filed 5–19–15; 8:45 am]

BILLING CODE 1610–02–M

GOVERNMENT ACCOUNTABILITY OFFICE

Appointments to the Health Information Technology (HIT) Policy Committee

AGENCY: Government Accountability Office (GAO).

ACTION: Notice of appointments.

SUMMARY: The American Recovery and Reinvestment Act requires the Comptroller General of the United States to appoint 13 of 20 members to the HIT Policy Committee. As of April 2015, new appointees to the HIT Policy Committee are Kathleen Blake, MD, MPH, an expert in health care quality measurement and reporting; Donna Cryer, JD, an advocate for patients or consumers; and Brent Snyder, Esq., a representative of health care providers. **DATES:** Appointments are effective as of April 2015.

ADDRESSES: GAO: 441 G Street NW., Washington, DC 20548.

FOR MORE INFORMATION CONTACT: GAO: Office of Public Affairs, (202) 512–4800.

SUPPLEMENTARY INFORMATION:

More information about the new appointees is provided below. Kathleen Blake, MD, MPH, is Vice President for Performance Improvement at the American Medical Association (AMA) and resides in Chicago, Illinois, and Santa Fe, New Mexico. She was appointed to fill the health care quality measurement and reporting opening.

Donna Cryer, JD, is Founder and President of the Global Liver Institute in Washington, DC, which facilitates collaboration among patient advocates, policymakers, regulators, health systems, and payers to solve challenges to advancing liver health and treating liver diseases. She was appointed to fill the patients or consumers advocate opening.

Brent Snyder, Esq. is Chief Information Officer at Adventist Health System (AHS) and lives in Springfield, Tennessee. He was appointed to fill the

representative of health care providers opening.

42 U.S.C. 300jj-12.

Gene L. Dodaro,

Comptroller General of the United States.

[FR Doc. 2015–11957 Filed 5–19–15; 8:45 am]

BILLING CODE 1610–02–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed changes to the currently approved information collection project: “*Medical Expenditure Panel Survey (MEPS) Household Component and the MEPS Medical Provider Component.*” In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by July 20, 2015.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at doris.lefkowitz@AHRQ.hhs.gov.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT:

Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at doris.lefkowitz@AHRQ.hhs.gov.

SUPPLEMENTARY INFORMATION:

Proposed Project

Medical Expenditure Panel Survey (MEPS) Household Component (HC)

For over thirty years, results from the MEPS and its predecessor surveys (the 1977 National Medical Care Expenditure Survey, the 1980 National Medical Care Utilization and Expenditure Survey and the 1987 National Medical Expenditure Survey) have been used by OMB, DHHS, Congress and a wide number of health services researchers to analyze health care use, expenses and health policy.

Major changes continue to take place in the health care delivery system. The MEPS is needed to provide information about the current state of the health care system as well as to track changes over time. The MEPS permits annual estimates of use of health care and expenditures and sources of payment for that health care. It also permits tracking individual change in employment, income, health insurance and health status over two years. The use of the National Health Interview Survey (NHIS) as a sampling frame expands the MEPS analytic capacity by providing another data point for comparisons over time.

Households selected for participation in the MEPS–HC are interviewed five times in person. These rounds of interviewing are spaced about 5 months apart. The interview will take place with a family respondent who will report for him or herself and for other family members.

The goal of MEPS–HC is to provide nationally representative estimates for the U.S. civilian noninstitutionalized population for health care use, expenditures, sources of payment and health insurance coverage

Medical Expenditure Panel Survey (MEPS) Medical Provider Component (MPC)

The MEPS–MPC will contact medical providers (hospitals, physicians, home health agencies and institutions) identified by household respondents in the MEPS–HC as sources of medical care for the time period covered by the interview, and all pharmacies providing prescription drugs to household members during the covered time period. The MEPS–MPC is not designed to yield national estimates as a stand-alone survey. The sample is designed to target the types of individuals and providers for whom household reported expenditure data was expected to be insufficient. For example, Medicaid enrollees are targeted for inclusion in the MEPS–MPC because this group is expected to have limited information about payments for their medical care.

There is one addition to the MEPS–MPC being implemented in this renewal request, the MEPS MPC Medical Organizations Survey (MOS). The MEPS MOS will expand current MPC data collection activities to include information on the organization of the practices of office-based care providers identified as a usual source of care in the MEPS MPC. This additional data collection will be for a subset of office-based care providers already included in the MEPS MPC sample. In the MEPS MPC sample, for a nationally

representative sample of adults, primary location for individual's office-based usual sources of care will be identified. The MEPS MPC will contact these places where medical care is provided, determine the appropriate respondent and administer a MEPS MOS. The design of the survey will be multimodal including some telephone contact. Additional data collection methods may include phone, fax, mail, self-administration, electronic transmission, and the Web. The data collection method chosen for a provider shall be the method that results in the most complete and accurate data with least burden to the provider.

The MEPS–MPC collects event level data about medical care received by sampled persons during the relevant time period. The data collected from medical providers include:

- Dates on which medical encounters during the reference period occurred
- Data on the medical content of each encounter, including ICD–9 (or ICD–10) and CPT–4 codes
- Data on the charges associated with each encounter, the sources paying for the medical care, including the patient/family, public sources, and private insurance, and amounts paid by each source

Data collected from pharmacies include:

- Date of prescription fill.
- National drug code (NDC) or prescription name, strength and form.
- Quantity.
- Payments, by source.

The MEPS–MPC has the following goal:

- To serve as an imputation source for and to supplement/replace household reported expenditure and source of payment information. This data will supplement, replace and verify information provided by household respondents about the charges, payments, and sources of payment associated with specific health care encounters.

This study is being conducted by AHRQ through its contractors, Westat and RTI International, pursuant to AHRQ's statutory authority to conduct and support research on healthcare and on systems for the delivery of such care, including activities with respect to the cost and use of health care services and with respect to health statistics and surveys. 42 U.S.C. 299a(a)(3) and (8); 42 U.S.C. 299b–2.

Method of Collection

To achieve the goals of the MEPS–HC the following data collections are implemented:

1. Household Component Core Instrument. The core instrument collects data about persons in sample households. Topical areas asked in each round of interviewing include condition enumeration, health status, health care utilization including prescribed medicines, expense and payment, employment, and health insurance. Other topical areas that are asked only once a year include access to care, income, assets, satisfaction with health plans and providers, children's health, and adult preventive care. While many of the questions are asked about the entire reporting unit (RU), which is typically a family, only one person normally provides this information. All sections of the current core instrument are available on the AHRQ Web site at http://meps.ahrq.gov/mepsweb/survey_comp/survey_questionnaires.jsp.

2. Adult Self-Administered Questionnaire. A brief self-administered questionnaire will be used to collect self-reported (rather than through household proxy) information on health status, health opinions and satisfaction with health care for adults 18 and older (see http://meps.ahrq.gov/mepsweb/survey_comp/survey.jsp#supplemental). The satisfaction with health care items are a subset of items from the Consumer Assessment of Healthcare Providers and Systems (CAHPS®). The health status items are from the Short Form 12 Version 2 (SF–12 version 2), which has been widely used as a measure of self-reported health status in the United States, the Kessler Index (K6) of non-specific psychological distress, and the Patient Health Questionnaire (PHQ–2). This questionnaire is unchanged from the previous OMB clearance.

3. Diabetes Care Self Administered Questionnaire. A brief self-administered paper-and-pencil questionnaire on the quality of diabetes care is administered once a year (during round 3 and 5) to persons identified as having diabetes. Included are questions about the number of times the respondent reported having a hemoglobin A1c blood test, whether the respondent reported having his or her feet checked for sores or irritations, whether the respondent reported having an eye exam in which the pupils were dilated, the last time the respondent had his or her blood cholesterol checked and whether the diabetes has caused kidney or eye problems. Respondents are also asked if their diabetes is being treated with diet, oral medications or insulin. This questionnaire is unchanged from the previous OMB clearance. See http://meps.ahrq.gov/mepsweb/survey_comp/survey.jsp#supplemental.

4. Authorization forms for the MEPS–MPC Provider and Pharmacy Survey. As in previous panels of the MEPS, we will ask respondents for authorization to obtain supplemental information from their medical providers (hospitals, physicians, home health agencies and institutions) and pharmacies. See http://meps.ahrq.gov/mepsweb/survey_comp/survey.jsp#MPC_AF for the pharmacy and provider authorization forms.

5. MEPS Validation Interview. Each interviewer is required to have at least 15 percent of his/her caseload validated to insure that computer-assisted personal interview (CAPI) questionnaire content was asked appropriately and procedures followed, for example the use of show cards. Validation flags are set programmatically for cases pre-selected by data processing staff before each round of interviewing. Home office and field management may also request that other cases be validated throughout the field period. When an interviewer fails a validation all their work is subject to 100 percent validation. Additionally, any case completed in less than 30 minutes is validated. A validation abstract form containing selected data collected in the CAPI interview is generated and used by the validator to guide the validation interview.

To achieve the goal of the MEPS–MPC the following data collections are implemented:

1. MPC Contact Guide/Screening Call. An initial screening call is placed to determine the type of facility, whether the practice or facility is in scope for the MEPS–MPC, the appropriate MEPS–MPC respondent and some details about the organization and availability of medical records and billing at the practice/facility. All hospitals, physician offices, home health agencies, institutions and pharmacies are screened by telephone. A unique screening instrument is used for each of these seven provider types in the MEPS–MPC, except for the two home care provider types which use the same screening form; see [http://meps.ahrq.gov/mepsweb/survey_comp/survey.jsp#MPC CG](http://meps.ahrq.gov/mepsweb/survey_comp/survey.jsp#MPC	CG).

2. Home Care Provider Questionnaire for Health Care Providers. This questionnaire is used to collect data from home health care agencies which provide medical care services to household respondents. Information collected includes type of personnel providing care, hours or visits provided per month, and the charges and payments for services received. See http://meps.ahrq.gov/mepsweb/survey_comp/survey.jsp#MPC.

3. Home Care Provider Questionnaire for Non-Health Care Providers. This questionnaire is used to collect information about services provided in the home by non-health care workers to household respondents because of a medical condition; for example, cleaning or yard work, transportation, shopping, or child care. See http://meps.ahrq.gov/mepsweb/survey_comp/survey.jsp#MPC.

4. Medical Event Questionnaire for Office-Based Providers. This questionnaire is for office-based physicians, including doctors of medicine (MDs) and osteopathy (DOs), as well as providers practicing under the direction or supervision of an MD or DO (e.g., physician assistants and nurse practitioners working in clinics). Providers of care in private offices as well as staff model HMOs are included. See http://meps.ahrq.gov/mepsweb/survey_comp/survey.jsp#MPC.

5. Medical Event Questionnaire for Separately Billing Doctors. This questionnaire collects information from physicians identified by hospitals (during the Hospital Event data collection) as providing care to sampled persons during the course of inpatient, outpatient department or emergency room care, but who bill separately from the hospital. See http://meps.ahrq.gov/mepsweb/survey_comp/survey.jsp#MPC.

6. Hospital Event Questionnaire. This questionnaire is used to collect information about hospital events, including inpatient stays, outpatient department, and emergency room visits. Hospital data are collected not only from the billing department, but from medical records and administrative records departments as well. Medical records departments are contacted to determine the names of all the doctors who treated the patient during a stay or visit. In many cases, the hospital administrative office also has to be contacted to determine whether the doctors identified by medical records billed separately from the hospital itself; the doctors that do bill separately from the hospital will be contacted as part of the Medical Event Questionnaire for Separately Billing Doctors. HMOs are included in this provider type. See http://meps.ahrq.gov/mepsweb/survey_comp/survey.jsp#MPC.

7. Institutions Event Questionnaire. This questionnaire is used to collect information about institution events, including nursing homes, rehabilitation facilities and skilled nursing facilities. Institution data are collected not only from the billing department, but from medical records and administrative records departments as well. Medical

records departments are contacted to determine the names of all the doctors who treated the patient during a stay. In many cases, the institution administrative office also has to be contacted to determine whether the doctors identified by medical records billed separately from the institution itself. See http://meps.ahrq.gov/mepsweb/survey_comp/survey.jsp#MPC.

8. Pharmacy Data Collection Questionnaire. This questionnaire requests the national drug code (NDC) and when that is not available the prescription name, date prescription was filled, payments by source, prescription strength and form (when the NDC is not available), quantity, and person for whom the prescription was filled. When the NDC is available, we do not ask for prescription name, strength or form because that information is embedded in the NDC; this reduces burden on the respondent. Most pharmacies have the requested information available in electronic format and respond by providing a computer generated printout of the patient's prescription information. If the computerized form is unavailable, the pharmacy can report their data to a telephone interviewer. Pharmacies are also able to provide a CD-ROM with the requested information if that is preferred. HMOs are included in this provider type. See http://meps.ahrq.gov/mepsweb/survey_comp/survey.jsp#MPC.

9. Medical Organizations Survey Questionnaire. This questionnaire will collect essential information on important features of the staffing, organization, policies, and financing for identified usual source of office based care providers. This additional data collection will be a subset of office based care providers already included in the MEPS MPC sample and will be a nationally representative sample of adults' primary location for individuals office based usual sources of care.

Dentists, optometrists, psychologists, podiatrists, chiropractors, and others not providing care under the supervision of a MD or DO are considered out of scope for the MEPS–MPC.

The MEPS is a multi-purpose survey. In addition to collecting data to yield annual estimates for a variety of measures related to health care use and expenditures, MEPS also provides estimates of measures related to health status, consumer assessment of health care, health insurance coverage, demographic characteristics, employment and access to health care indicators. Estimates can be provided

for individuals, families and population subgroups of interest. Data obtained in this study are used to provide, among others, the following national estimates:

- Annual estimates of health care use and expenditures for persons and families.
- Annual estimates of sources of payment for health care utilizations, including public programs such as Medicare and Medicaid, private insurance, and out of pocket payments.
- Annual estimates of health care use, expenditures and sources of payment of persons and families by type of utilization including inpatient stay, ambulatory care, home health, dental care and prescribed medications.
- The number and characteristics of the population eligible for public programs including the use of services and expenditures of the population(s) eligible for benefits under Medicare and Medicaid.
- The number, characteristics, and use of services and expenditures of persons and families with various forms of insurance.
- Annual estimates of consumer satisfaction with health care, and indicators of health care quality for key conditions.
- Annual estimates to track disparities in health care use and access.

In addition to national estimates, data collected in this ongoing, longitudinal study are used to study the determinants of the use of services and expenditures, and changes in the access to and the provision of health care in relation to:

- Socio-economic and demographic factors such as employment or income.
 - The health status and satisfaction with health care of individuals and families.
 - The health needs and circumstances of specific subpopulation groups such as the elderly and children.
- To meet the need for national data on health care use, access, cost and quality, MEPS-HC collects information on:
- Access to care and barriers to receiving needed care.
 - Satisfaction with usual providers.
 - Health status and limitations in activities.
 - Medical conditions for which health care was used.
 - Use, expense and payment (as well as insurance status of person receiving care) for health services.

Given the twin problems of nonresponse and response error of some household reported data, information is collected directly from medical

providers in the MEPS-MPC to improve the accuracy of expenditure estimates derived from the MEPS-HC. Because of their greater level of precision and detail, we also use MEPS-MPC data as the main source of imputations of missing expenditure data. Thus, the MEPS-MPC is designed to satisfy the following analytical objectives:

- Serve as source data for household reported events with missing expenditure information.
- Serve as an imputation source to reduce the level of bias in survey estimates of medical expenditures due to item nonresponse and less complete and less accurate household data.
- Serve as the primary data source for expenditure estimates of medical care provided by separately billing doctors in hospitals, emergency rooms, and outpatient departments, Medicaid recipients and expenditure estimates for pharmacies.
- Allow for an examination of the level of agreement in reported expenditures from household respondents and medical providers.

Data from the MEPS, both the HC and MPC components, are intended for a number of annual reports produced by AHRQ, including the National Healthcare Quality and Disparities Report.

The MEPS MPC MOS data will be used to create a database that will be unique in providing an internally consistent source of information both on individuals' characteristics and health care utilization and expenditures, and on the characteristics of the providers they use. The following areas will be addressed in the MOS as they potentially affect individuals' access to, use of and affordability of health care services:

- Organizational characteristics, *e.g.*, size, specialties covered, practice rules and procedures, patient mix and scope of care provided, membership in an ACO, certification as a primary care medical home.
- Use of health information technology.
- Policies and practices related to the ACA.
- Financial arrangements, *e.g.*, reimbursement methods, number and types of insurance contracts, compensation arrangements within the practice.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents' time to participate in the

MEPS-HC and the MEPS-MPC. The MEPS-HC Core Interview will be completed by 15,093 * (see note below Exhibit 1) "family level" respondents, also referred to as RU respondents. Since the MEPS-HC consists of 5 rounds of interviewing covering a full two years of data, the annual average number of responses per respondent is 2.5 responses per year. The MEPS-HC core requires an average response time of 92 minutes to administer. The Adult SAQ will be completed once a year by each person in the RU that is 18 years old and older, an estimated 28,254 persons. The Adult SAQ requires an average of 7 minutes to complete. The Diabetes care SAQ will be completed once a year by each person in the RU identified as having diabetes, an estimated 2,345 persons, and takes about 3 minutes to complete. The authorization form for the MEPS-MPC Provider Survey will be completed once for each medical provider seen by any RU member. The 14,489 RUs in the MEPS-HC will complete an average of 5.4 forms, which require about 3 minutes each to complete. The authorization form for the MEPS-MPC Pharmacy Survey will be completed once for each pharmacy for any RU member who has obtained a prescription medication. RUs will complete an average of 3.1 forms, which take about 3 minutes to complete. About one third of all interviewed RUs will complete a validation interview as part of the MEPS-HC quality control, which takes an average of 5 minutes to complete. The total annual burden hours for the MEPS-HC are estimated to be 67,826 hours.

All medical providers and pharmacies included in the MEPS-MPC will receive a screening call and the MEPS-MPC uses 7 different questionnaires; 6 for medical providers and 1 for pharmacies. Each questionnaire is relatively short and requires 2 to 19 minutes to complete. The total annual burden hours for the MEPS-MPC are estimated to be 18,876 hours. The total annual burden for the MEPS-HC and MPC is estimated to be 86,702 hours.

Exhibit 2 shows the estimated annual cost burden associated with the respondents' time to participate in this information collection. The annual cost burden for the MEPS-HC is estimated to be \$1,680,727; the annual cost burden for the MEPS-MPC is estimated to be \$299,477. The total annual cost burden for the MEPS-HC and MPC is estimated to be \$1,980,204.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
MEPS-HC				
MEPS-HC Core Interview	* 15,093	2.5	92/60	57,857
Adult SAQ	28,254	1	7/60	3,296
Diabetes care SAQ	2,345	1	3/60	117
Authorization form for the MEPS-MPC Provider Survey	14,489	5.4	3/60	3,912
Authorization form for the MEPS-MPC Pharmacy Survey	14,489	3.1	3/60	2,246
MEPS-HC Validation Interview	4,781	1	5/60	398
Subtotal for the MEPS-HC	79,451	Na	na	67,826
MEPS-MPC/MOS				
MPC Contact Guide/Screening Call **	35,222	1	2/60	1,174
Home care for health care providers questionnaire	532	1.49	9/60	119
Home care for non-health care providers questionnaire	25	1	11/60	5
Office-based providers questionnaire	11,785	1.44	10/60	2,828
Separately billing doctors questionnaire	12,693	3.43	13/60	9,433
Hospitals questionnaire	5,077	3.51	9/60	2,673
Institutions (non-hospital) questionnaire	117	2.03	9/60	36
Pharmacies questionnaire	4,993	4.44	3/60	1,108
Medical Organizations Survey questionnaire	6,000	1	15/60	1,500
Subtotal for the MEPS-MPC	76,444	na	na	18,876
Grand Total	155,895	na	na	86,702

* While the expected number of responding units for the annual estimates is 14,489, it is necessary to adjust for survey attrition of initial respondents by a factor of 0.96 (15,093 = 14,489/0.96).

** There are 6 different contact guides; one for office based, separately billing doctor, hospital, institution, and pharmacy provider types, and the two home care provider types use the same contact guide.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate	Total cost burden
MEPS-HC				
MEPS-HC Core Interview	15,093	57,857	* \$24.78	1,433,696
Adult SAQ	28,254	3,296	24.78	81,675
Diabetes care SAQ	2,345	117	24.78	2,899
Authorization forms for the MEPS-MPC Provider Survey	14,489	3,912	24.78	96,939
Authorization form for the MEPS-MPC Pharmacy Survey	14,489	2,246	24.78	55,656
MEPS-HC Validation Interview	4,781	398	24.78	9,862
Subtotal for the MEPS-HC	79,451	67,826	Na	\$1,680,727
MEPS-MPC/MOS				
MPC Contact Guide/Screening Call	35,222	1,174	** \$15.93	18,702
Home care for health care providers questionnaire	532	119	** \$15.93	1,896
Home care for non-health care providers questionnaire	25	5	** \$15.93	\$80
Office-based providers questionnaire	11,785	2,828	** \$15.93	\$45,050
Separately billing doctors questionnaire	12,693	9,433	** \$15.93	\$150,268
Hospitals questionnaire	5,077	2,673	** \$15.93	\$42,581
Institutions (non-hospital) questionnaire	117	36	** 15.93	\$573
Pharmacies questionnaire	4,993	1,108	** 14.83*	\$16,432
Medical Organizations Survey questionnaire	6,000	1,500	** 15.93	\$23,895
Subtotal for the MEPS-MPC	76,444	18,876	na	\$299,477
Grand Total	155,895	86,073	na	\$1,980,204

* Mean hourly wage for All Occupations (00-0000).

** Mean hourly wage for Medical Secretaries (43-6013).

*** Mean hourly wage for Pharmacy Technicians (29-2052).

Occupational Employment Statistics,
 May 2013 National Occupational
 Employment and Wage Estimates
 United States, U.S. Department of Labor,
 Bureau of Labor Statistics. http://www.bls.gov/oes/current/oes_nat.htm#b29-0000.

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper

performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to

enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Sharon B. Arnold,
Deputy Director.

[FR Doc. 2015-12229 Filed 5-19-15; 8:45 am]

BILLING CODE 4160-90-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2015-0016]

Proposed Revised Vaccine Information Materials for Seasonal Influenza Vaccines

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: Under the National Childhood Vaccine Injury Act (NCVIA) (42 U.S.C. 300aa-26), the Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) develops vaccine information materials that all health care providers are required to give to patients/parents prior to administration of specific vaccines. HHS/CDC seeks written comment on the proposed updated vaccine information statements for inactivated and live attenuated influenza vaccines.

DATES: Written comments must be received on or before July 20, 2015.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2015-0016, by any of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the instructions for submitting comments.
- *Mail:* Written comments should be addressed to Suzanne Johnson-DeLeon (msj1@cdc.gov), National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop A-19, 1600 Clifton Road NE., Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and docket number. All relevant comments

received will be posted without change to <http://regulations.gov>, including any personal information provided. For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Skip Wolfe (crw4@cdc.gov), National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop A-19, 1600 Clifton Road NE., Atlanta, Georgia 30329.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act of 1986 (Pub. L. 99-660), as amended by section 708 of Public Law 103-183, added section 2126 to the Public Health Service Act. Section 2126, codified at 42 U.S.C. 300aa-26, requires the Secretary of Health and Human Services to develop and disseminate vaccine information materials for distribution by all health care providers in the United States to any patient (or to the parent or legal representative in the case of a child) receiving vaccines covered under the National Vaccine Injury Compensation Program (VICP).

Development and revision of the vaccine information materials, also known as Vaccine Information Statements (VIS), have been delegated by the Secretary to the Centers for Disease Control and Prevention (CDC). Section 2126 requires that the materials be developed, or revised, after notice to the public, with a 60-day comment period, and in consultation with the Advisory Commission on Childhood Vaccines, appropriate health care provider and parent organizations, and the Food and Drug Administration. The law also requires that the information contained in the materials be based on available data and information, be presented in understandable terms, and include:

- (1) A concise description of the benefits of the vaccine,
- (2) A concise description of the risks associated with the vaccine,
- (3) A statement of the availability of the National Vaccine Injury Compensation Program, and
- (4) Such other relevant information as may be determined by the Secretary.

The vaccines initially covered under the National Vaccine Injury Compensation Program were diphtheria, tetanus, pertussis, measles, mumps, rubella and poliomyelitis vaccines. Since April 15, 1992, any health care provider in the United States who intends to administer one of these covered vaccines is required to provide copies of the relevant vaccine information materials prior to

administration of any of these vaccines. Since then, the following vaccines have been added to the National Vaccine Injury Compensation Program, requiring use of vaccine information materials for them as well: Hepatitis B, *Haemophilus influenzae* type b (Hib), varicella (chickenpox), pneumococcal conjugate, rotavirus, hepatitis A, meningococcal, human papillomavirus (HPV), and seasonal influenza vaccines. Instructions for use of the vaccine information materials are found on the CDC Web site at: <http://www.cdc.gov/vaccines/hcp/vis/index.html>.

HHS/CDC is proposing updated versions of the inactivated and live attenuated seasonal influenza vaccine information statements.

The vaccine information materials referenced in this notice are being developed in consultation with the Advisory Commission on Childhood Vaccines, the Food and Drug Administration, and parent and health care provider groups.

We invite written comment on the proposed vaccine information materials entitled "Influenza (Flu) Vaccine (Inactivated or Recombinant): What you need to know" and "Influenza (Flu) Vaccine (Live, Intranasal): What you need to know." Copies of the proposed vaccine information materials are available at <http://www.regulations.gov> (see Docket Number CDC-2015-0016). Comments submitted will be considered in finalizing these materials. When the final materials are published in the **Federal Register**, the notice will include an effective date for their mandatory use.

Dated: May 14, 2015.

Ron A. Otten,

Acting Deputy Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2015-12240 Filed 5-19-15; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[Docket No. CDC-2015-0014]

Proposed Revised Vaccine Information Materials for Pneumococcal Conjugate Vaccine (PCV13)

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: Under the National Childhood Vaccine Injury Act (NCVIA) (42 U.S.C. 300aa-26), the Centers for

Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) develops vaccine information materials that all health care providers are required to give to patients/parents prior to administration of specific vaccines. HHS/CDC seeks written comment on the proposed updated vaccine information statement for pneumococcal conjugate vaccine (PCV13).

DATES: Written comments must be received on or before July 20, 2015.

ADDRESSES: You may submit comments, identified by Docket No. CDC-2015-0014, by any of the following methods:

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

- *Mail:* Written comments should be addressed to Suzanne Johnson-DeLeon (msj1@cdc.gov), National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop A-19, 1600 Clifton Road NE., Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and docket number. All relevant comments received will be posted without change to <http://regulations.gov>, including any personal information provided. For access to the docket to read background documents or comments received, go to <http://www.regulations.gov>.

FOR FURTHER INFORMATION CONTACT: Skip Wolfe (crw4@cdc.gov), National Center for Immunization and Respiratory Diseases, Centers for Disease Control and Prevention, Mailstop A-19, 1600 Clifton Road NE., Atlanta, Georgia 30329.

SUPPLEMENTARY INFORMATION: The National Childhood Vaccine Injury Act of 1986 (Pub. L. 99-660), as amended by section 708 of Public Law 103-183, added section 2126 to the Public Health Service Act. Section 2126, codified at 42 U.S.C. 300aa-26, requires the Secretary of Health and Human Services to develop and disseminate vaccine information materials for distribution by all health care providers in the United States to any patient (or to the parent or legal representative in the case of a child) receiving vaccines covered under the National Vaccine Injury Compensation Program (VICP).

Development and revision of the vaccine information materials, also known as Vaccine Information Statements (VIS), have been delegated by the Secretary to the Centers for Disease Control and Prevention (CDC). Section 2126 requires that the materials be developed, or revised, after notice to the public, with a 60-day comment period, and in consultation with the

Advisory Commission on Childhood Vaccines, appropriate health care provider and parent organizations, and the Food and Drug Administration. The law also requires that the information contained in the materials be based on available data and information, be presented in understandable terms, and include:

- (1) A concise description of the benefits of the vaccine,
- (2) A concise description of the risks associated with the vaccine,
- (3) A statement of the availability of the National Vaccine Injury Compensation Program, and
- (4) Such other relevant information as may be determined by the Secretary.

The vaccines initially covered under the National Vaccine Injury Compensation Program were diphtheria, tetanus, pertussis, measles, mumps, rubella and poliomyelitis vaccines. Since April 15, 1992, any health care provider in the United States who intends to administer one of these covered vaccines is required to provide copies of the relevant vaccine information materials prior to administration of any of these vaccines. Since then, the following vaccines have been added to the National Vaccine Injury Compensation Program, requiring use of vaccine information materials for them as well: Hepatitis B, *Haemophilus influenzae* type b (Hib), varicella (chickenpox), pneumococcal conjugate, rotavirus, hepatitis A, meningococcal, human papillomavirus (HPV), and seasonal influenza vaccines. Instructions for use of the vaccine information materials are found on the CDC Web site at: <http://www.cdc.gov/vaccines/hcp/vis/index.html>.

HHS/CDC is proposing an updated version of the pneumococcal conjugate vaccine (PCV13) vaccine information statement.

The vaccine information materials referenced in this notice are being developed in consultation with the Advisory Commission on Childhood Vaccines, the Food and Drug Administration, and parent and health care provider groups.

We invite written comment on the proposed vaccine information materials entitled "Pneumococcal Conjugate Vaccine (PCV13): What You Need to Know." A copy of the proposed vaccine information materials is available at <http://www.regulations.gov> (see Docket Number CDC-2015-0014). Comments submitted will be considered in finalizing these materials. When the final materials are published in the **Federal Register**, the notice will include an effective date for their mandatory use.

Dated: May 15, 2015.

Ron A. Otten,

Acting Deputy Associate Director for Science, Centers for Disease Control and Prevention.

[FR Doc. 2015-12239 Filed 5-19-15; 8:45 am]

BILLING CODE 4163-18-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2012-N-0247]

Agency Information Collection Activities; Proposed Collection; Comment Request; Guidance for Industry on Formal Meetings With Sponsors and Applicants for Prescription Drug User Fee Act Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the 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 in response to the notice. This notice solicits comments on the information collection contained in the guidance for industry on formal meetings with sponsors and applicants for Prescription Drug User Fee Act (PDUFA) products.

DATES: Submit either electronic or written comments on the collection of information by July 20, 2015.

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd., COLE-14526, Silver Spring, MD 20993-0002, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA, (44 U.S.C. 3501-3520), Federal

Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to 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, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Guidance for Industry on Formal Meetings With Sponsors and Applicants for PDUFA Products OMB Control Number 0910-0429—Extension

This information collection approval request is for FDA guidance on the procedures for formal meetings between FDA and sponsors or applicants regarding the development and review of PDUFA products. The guidance describes procedures for requesting, scheduling, conducting, and documenting such formal meetings. The guidance provides information on how the Agency will interpret and apply section 119(a) of the Food and Drug Administration Modernization Act (FDAMA), specific PDUFA goals for the management of meetings associated with the review of human drug applications for PDUFA products, and provisions of existing regulations describing certain meetings (§§ 312.47 and 312.82 (21 CFR 312.47 and 312.82)).

The guidance describes two collections of information: The

submission of a meeting request containing certain information and the submission of an information package in advance of the formal meeting. Agency regulations at §§ 312.47(b)(1)(ii), (b)(1)(iv), and (b)(2) describe information that should be submitted in support of a request for an end-of-phase 2 meeting and a pre-NDA meeting. The information collection provisions of § 312.47 have been approved by OMB control number 0910-0014. However, the guidance provides additional recommendations for submitting information to FDA in support of a meeting request. As a result, FDA is submitting additional estimates for OMB approval.

I. Request for a Meeting

Under the guidance, a sponsor or applicant interested in meeting with the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER) should submit a meeting request to the appropriate FDA component as an amendment to the underlying application. FDA regulations (§§ 312.23, 314.50, and 601.2 (21 CFR 312.23, 314.50, and 601.2)) state that information provided to the Agency as part of an investigational new drug application (IND), new drug application (NDA), or biological license application (BLA) must be submitted with an appropriate cover form. Form FDA 1571 must accompany submissions under INDs and Form FDA 356h must accompany submissions under NDAs and BLAs. Both forms have valid OMB control numbers as follows: Form FDA 1571—OMB control number 0910-0014 and Form FDA 356h—OMB control number 0910-0338.

In the guidance document, CDER and CBER ask that a request for a formal meeting be submitted as an amendment to the application for the underlying product under the requirements of §§ 312.23, 314.50, and 601.2; therefore, requests should be submitted to the Agency with the appropriate form attached, either Form FDA 1571 or Form FDA 356h. The Agency recommends that a request be submitted in this manner for two reasons: (1) To ensure that each request is kept in the administrative file with the entire underlying application, and (2) to ensure that pertinent information about the request is entered into the appropriate tracking databases. Use of the information in the Agency's tracking databases enables the Agency to monitor progress on the activities attendant to scheduling and holding a formal meeting and to ensure that appropriate steps will be taken in a timely manner.

Under the guidance, the Agency requests that sponsors and applicants include in meeting requests certain information about the proposed meeting. Such information includes:

- Information identifying and describing the product;
- The type of meeting being requested;
- A brief statement of the purpose of the meeting;
- A list of objectives and expected outcomes from the meeting;
- A preliminary proposed agenda;
- A draft list of questions to be raised at the meeting;
- A list of individuals who will represent the sponsor or applicant at the meeting;
- A list of Agency staff requested to be in attendance;
- The approximate date that the information package will be sent to the Agency; and
- Suggested dates and times for the meeting.

This information will be used by the Agency to determine the utility of the meeting, to identify Agency staff necessary to discuss proposed agenda items, and to schedule the meeting.

II. Information Package

A sponsor or applicant submitting an information package to the Agency in advance of a formal meeting should provide summary information relevant to the product and supplementary information pertaining to any issue raised by the sponsor, applicant, or Agency. The Agency recommends that information packages generally include:

- Identifying information about the underlying product;
- A brief statement of the purpose of the meeting;
- A list of objectives and expected outcomes of the meeting;
- A proposed agenda for the meeting;
- A list of specific questions to be addressed at the meeting;
- A summary of clinical data that will be discussed (as appropriate);
- A summary of preclinical data that will be discussed (as appropriate); and
- Chemistry, manufacturing, and controls information that may be discussed (as appropriate).

The purpose of the information package is to provide Agency staff the opportunity to adequately prepare for the meeting, including the review of relevant data concerning the product. Although FDA reviews similar information in the meeting request, the information package should provide updated data that reflect the most current and accurate information available to the sponsor or applicant.

The Agency finds that reviewing such information is critical to achieving a productive meeting.

The collection of information described in the guidance reflects the current and past practice of sponsors and applicants to submit meeting requests as amendments to INDs, NDAs, and BLAs and to submit background information prior to a scheduled meeting. Agency regulations currently permit such requests and recommend the submission of an information package before an end-of-phase 2 meeting (§§ 312.47(b)(1)(ii) and (b)(1)(iv)) and a pre-NDA meeting (§ 312.47(b)(2)).

Description of Respondents: A sponsor or applicant for a drug or biological product who requests a formal meeting with the Agency regarding the development and review of a PDUFA product.

Burden Estimate: Provided in this document is an estimate of the annual reporting burden for the submission of meeting requests and information packages under the guidance.

III. Request for a Formal Meeting

Based on data collected from the review divisions and offices within CDER and CBER, FDA estimates that approximately 1,099 sponsors and

applicants (respondents) request approximately 2,366 formal meetings with CDER annually and approximately 175 respondents request approximately 264 formal meetings with CBER annually regarding the development and review of a PDUFA product. The hours per response, which is the estimated number of hours that a respondent would spend preparing the information to be submitted with a meeting request in accordance with the guidance, is estimated to be approximately 10 hours. Based on FDA’s experience, the Agency expects it will take respondents this amount of time to gather and copy brief statements about the product and a description of the purpose and details of the meeting.

IV. Information Package

Based on data collected from the review divisions and offices within CDER and CBER, FDA estimates that approximately 959 respondents submitted approximately 1,901 information packages to CDER annually and approximately 142 respondents submitted approximately 193 information packages to CBER annually prior to a formal meeting regarding the development and review of a PDUFA product. The hours per response, which

is the estimated number of hours that a respondent would spend preparing the information package in accordance with the guidance, is estimated to be approximately 18 hours. Based on FDA’s experience, the Agency expects it will take respondents this amount of time to gather and copy brief statements about the product, a description of the details for the anticipated meeting, and data and information that generally would already have been compiled for submission to the Agency.

As stated earlier, the guidance provides information on how the Agency will interpret and apply section 119(a) of the FDAMA, specific PDUFA goals for the management of meetings associated with the review of human drug applications for PDUFA products, and provisions of existing regulations describing certain meetings (§§ 312.47 and 312.82). The information collection provisions in § 312.47 concerning end-of-phase 2 meetings and pre-NDA meetings have been approved by OMB control number 0910–0014. However, the guidance provides additional recommendations for submitting information to FDA in support of a meeting request. As a result, FDA is submitting for OMB approval these additional estimates.

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

Meeting requests and information packages	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Meeting Requests:					
CDER	1,099	2.15	2,366	10	23,660
CBER	175	1.51	264	10	2,640
Total					26,300
Information Packages:					
CDER	959	1.99	1,901	18	34,218
CBER	142	1.36	193	18	3,474
Total					37,692
Grand Total					63,992

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: May 14, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–12170 Filed 5–19–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0397]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; State Enforcement Notifications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by June 19, 2015.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs,

OMB, Attn: FDA Desk Officer, FAX: 202-395-7285, or emailed to oir_submission@omb.eop.gov. All comments should be identified with the OMB control number 0910-0275. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, 8455 Colesville Rd.; COLE-14526, Silver Spring, MD 20993-0002 PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA

has submitted the following proposed collection of information to OMB for review and clearance.

State Enforcement Notifications—21 CFR 100.2(d)

OMB Control Number 0910-0275—Extension

Section 310(b) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 337(b)) authorizes a State to enforce certain sections of the FD&C Act in their own name and within their own jurisdiction. However, before doing so, a State must provide notice to FDA according to 21 CFR 100.2. The information required in a letter of

notification under § 100.2(d) enables us to identify the food against which a State intends to take action and to advise that State whether Federal enforcement action against the food has been taken or is in process. With certain narrow exceptions, Federal enforcement action precludes State action under the FD&C Act.

In the **Federal Register** of March 13, 2015 (80 FR 13392), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

21 CFR section	Number of respondents	Number of responses per respondents	Total annual responses	Average burden per response	Total hours
100.2(d)	1	1	1	10	10

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

The estimated reporting burden for § 100.2(d) is minimal because enforcement notifications are seldom used by States. During the last 3 years, we have not received any new enforcement notifications; therefore, we estimate that one or fewer notifications will be submitted annually. Although we have not received any new enforcement notifications in the last 3 years, we believe these information collection provisions should be extended to provide for the potential future need of a State government to submit enforcement notifications informing us when it intends to take enforcement action under the FD&C Act against a particular food located in the State.

Dated: May 15, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-12236 Filed 5-19-15; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the

provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke, Initial Review Group, Neurological Sciences and Disorders B.

Date: June 25–26, 2015.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Wyndam Grand Chicago Riverfront Hotel, 71 E. Wacker Drive, Chicago, IL 60601.

Contact Person: Birgit Neuhuber, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Boulevard, Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-3562, neuhuber@ninds.nih.gov.

Name of Committee: Neurological Sciences Training Initial Review Group, NST-2 Subcommittee.

Date: June 29–30, 2015.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: The Fairmont Washington, DC, 2401 M Street NW., Washington, DC 20037.

Contact Person: Elizabeth A. Webber, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Research, NINDS/NIH/DHHS/Neuroscience Center, 6001 Executive Boulevard, Suite 3208, MSC 9529, Bethesda, MD 20892-9529, 301-496-1917, webbere@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: May 14, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-12125 Filed 5-19-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; 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: Oncology 2—Translational Clinical Integrated Review

Group; Radiation Therapeutics and Biology Study Section.

Date: June 15–16, 2015.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Bo Hong, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6194, MSC 7804, Bethesda, MD 20892, 301–996–6208, hongb@csr.nih.gov.

Name of Committee: Biobehavioral and Behavioral Processes Integrated Review Group; Motor Function, Speech and Rehabilitation Study Section.

Date: June 15, 2015.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: St. Gregory Hotel, 2033 M Street NW., Washington, DC 20036.

Contact Person: Biao Tian, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3166, MSC 7848, Bethesda, MD 20892, 301–402–4411, tianbi@csr.nih.gov.

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Cancer Biomarkers Study Section.

Date: June 17, 2015.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites at the Chevy Chase Pavilion, 4300 Military Road NW., Washington, DC 20015.

Contact Person: Lawrence Ka-Yun Ng, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6152, MSC 7804, Bethesda, MD 20892, 301–357–9318, ngkl@csr.nih.gov.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Cellular Aspects of Diabetes and Obesity Study Section.

Date: June 18, 2015.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Doubletree Hotel Bethesda (Formerly Holiday Inn Select), 8120 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Alexander D Politis, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3210, MSC 7808, Bethesda, MD 20892, (301) 435–1150, politisa@csr.nih.gov.

Name of Committee: Endocrinology, Metabolism, Nutrition and Reproductive Sciences Integrated Review Group; Molecular and Cellular Endocrinology Study Section.

Date: June 18, 2015.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: John Bleasdale, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6170, MSC 7892, Bethesda, MD 20892, 301–435–4514, bleasdaleje@csr.nih.gov.

Name of Committee: Molecular, Cellular and Developmental Neuroscience Integrated Review Group; Synapses, Cytoskeleton and Trafficking Study Section.

Date: June 18–19, 2015.

Time: 8:30 a.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Hotel Monaco Alexandria, 480 King Street, Alexandria, VA 22314.

Contact Person: Christine A Piggee, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4186, MSC 7850, Bethesda, MD 20892, 301–435–0657, christine.piggee@nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel, Traumatic Brain Injury and Cerebrovascular Disorders.

Date: June 19, 2015.

Time: 1:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Alexander Yakovlev, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5206, MSC 7846, Bethesda, MD 20892–7846, 301–435–1254, yakovleva@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 15, 2015.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–12242 Filed 5–19–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Inventions; Availability for Licensing

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The inventions listed below are owned by an agency of the U.S. Government and are available for licensing in the U.S. in accordance with 35 U.S.C. 209 and 37 CFR part 404 to achieve expeditious commercialization of results of federally-funded research and development. Foreign patent applications are filed on selected inventions to extend market coverage

for companies and may also be available for licensing.

FOR FURTHER INFORMATION CONTACT: Licensing information and copies of the U.S. patent applications listed below may be obtained by writing to the indicated licensing contact at the Office of Technology Transfer, National Institutes of Health, 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852–3804; telephone: 301–496–7057; fax: 301–402–0220. A signed Confidential Disclosure Agreement will be required to receive copies of the patent applications.

SUPPLEMENTARY INFORMATION: Technology descriptions follow.

A Novel Therapeutic Vector for Hemoglobin Disorders

Description of Technology:

Investigators at the National Heart, Lung, and Blood Institute have designed a novel lentiviral vector as a potential gene therapy for sickle cell anemia and beta-thalassemia. The novel lentiviral vector encodes the beta-globin gene in a forward orientation and can produce 5–10 fold higher viral titer and 4–10 fold higher gene transfer efficiency to hematopoietic stem cells than reverse-oriented lentiviral vectors. In vivo studies conducted in rhesus macaques show beta-globin production after transplantation with this novel lentiviral vector. This technology could provide an alternative therapy for patients suffering from blood disorders associated with beta-globin gene mutations.

Potential Commercial Applications: Gene therapy.

Competitive Advantages:

- Increased viral titers
- Increased transduction efficiency
- Large scale vector production

Development Stage:

- Early-stage
- In vitro data available
- In vivo data available (animal)

Inventors: Naoya Uchida and John F. Tisdale (NHLBI).

Intellectual Property: HHS Reference No. E–165–2014/0—U.S. Provisional Application No. 62/048,881 filed September 11, 2014.

Licensing Contact: Cristina Thalhammer-Reyero, Ph.D.; 301–495–4507; thalhamc@mail.nih.gov.

Collaborative Research Opportunity: The National Heart, Lung and Blood Institute is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate or commercialize this technology. For collaboration opportunities, please contact Denise Crooks at crooksd@mail.nih.gov.

X-Clometer: Optimizing Portable Radiography

Description of Technology: The technology offered for licensing and commercial development relates to a method and apparatus that can significantly improve the diagnostic performance of portable chest (CXR) and abdominal x-rays. This device quantifies angulation of a patient to provide for a better comparison of day-to-day improvement.

The portable CXR is one of the most commonly requested diagnostic medical tests around the world. They are performed nearly daily on some of the sickest patients in hospitals. Paradoxically, it is well documented that portable radiography of the chest is inconsistent and often inadequate.

An upright projection best evaluates effusions, rules out free air, or detects air-fluid levels. Optimally, the images are obtained at similar angles each day, even if not erect, to allow accurate comparisons and assessment of change. It is well documented that portable radiography of the chest is inconsistent and often inadequate. To achieve optimal quality of the exam the technologist attempts the most upright projection; balanced with patient condition and ability to achieve this often impossible task.

Potential Commercial Applications: Portable chest and abdominal x-rays performed at patient's hospital bedside.

Competitive Advantages:

- Currently, there is no quantitative marker to indicate degree of the upright position. Prior markers with small ball bearings sinking to a small circle only indicate if the patient is supine or not. This technology introduces a simple dynamic marker that can quantify the angle at a glance for the radiologist to best compare patient condition over time. This device objectively quantifies cassette angle with a ball bearing in a cylindrical tube with markers to indicate upright position in degrees.

- The technology improves performance of CXR, allowing reliable comparisons of patient condition over time. Thus, better therapies can be planned and unnecessary CT (Computerized Tomography) can be prevented.

- The technology improves care for Intensive Care Unit patients, as developing effusion and the need for immediate drainage (as one of many examples) can be more effectively assessed with the present apparatus. A widespread use of the device will save lives through improved diagnosis and comparison of effusions.

Development Stage:

- A performance of a visual prototype was demonstrated. The visual prototype was imaged at 5 selected angles with a chest phantom. Initial in-vitro results demonstrate that angles can be quantified to within 30 degrees.

- Improved prototypes with more accuracy are currently being manufactured for to patient use. *In-vivo* studies will soon be underway to validate clinical utility.

Inventors: Les R. Folio (CC) and Lucas S. Folio

Publications:

1. Wandtke JC. Bedside chest radiography. *Radiology*. 1994; 190:1–10. [PMID 8043058]
2. Pneumatikos I, Bouros D. Pleural effusions in critically ill patients. *Respiration*. 2008; 76(3):241–248. [PMID 18824883]
3. Mattison LE, et al. Pleural effusions in the medical ICU: Prevalence, causes, and clinical implications. *Chest*. 1997 Apr;111(4):1018–1023. [PMID 9106583]
4. Fartoukh M, et al. Clinically documented pleural effusions in medical ICU patients: How useful is routine thoracentesis? *Chest*. 2002 Jan;121(1):178–184. [PMID 11796448]
5. Bekemeyer WB, et al. Efficacy of chest radiography in a respiratory intensive care unit. A prospective study. *Chest*. 1985 Nov; 88(5): 691–696. [PMID: 4053711]
6. Tocino I. Chest imaging in intensive care unit. *Eur J Radiol* 1996 Aug;23(1):46–57. [PMID 8872073]

Patent Status: HHS Reference No. E–036–2011/0—U.S. Patent Application No. 14/005,024 filed September 13, 2013.

Licensing Contact: Tedd Fenn; 424–297–0336; tedd.fenn@nih.gov

Collaborative Research Opportunity: The NIH Clinical Center, Radiology and Imaging Sciences, is seeking statements of capability or interest from parties interested in collaborative research to further develop, evaluate, or commercialize X-Clometer. Please contact Ken Rose, Ph.D. at 240–276–5509 or rosek@mail.nih.gov for more information.

Dated: May 14, 2015.

Richard U. Rodriguez,

Acting Director, Office of Technology Transfer, National Institutes of Health.

[FR Doc. 2015–12124 Filed 5–19–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review 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: Infectious Diseases and Microbiology Integrated Review Group; Virology—A Study Section.

Date: June 8–9, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Long Beach Hotel, 111 East Ocean Blvd., Long Beach, CA 90802.

Contact Person: Kenneth M. Izumi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3204, MSC 7808, Bethesda, MD 20892, 301–496–6980, izumikm@csr.nih.gov.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Skeletal Muscle and Exercise Physiology Study Section.

Date: June 10–11, 2015.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Historic Inns of Annapolis, 58 State Circle, Annapolis, MD 21401.

Contact Person: Richard Ingraham, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4116, MSC 7814, Bethesda, MD 20892, 301–496–8551, ingrahamrh@mail.nih.gov.

Name of Committee: Oncology 1–Basic Translational Integrated Review Group; Cancer Etiology Study Section.

Date: June 11–12, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Gaithersburg Marriott Washingtonian Center, 9751 Washingtonian Boulevard, Gaithersburg, MD 20878.

Contact Person: Svetlana Kotliarova, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, Bethesda, MD 20892, 301–594–7945, kotliars@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: Palliative care and survivorship.

Date: June 11, 2015.

Time: 6:00 p.m. to 8:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Long Beach Hotel, 111 East Ocean Blvd., Long Beach, CA 90802.

Contact Person: Martha L. Hare, Ph.D., RN, Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3154, MSC 7770, Bethesda, MD 20892, (301) 451-8504, harem@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Molecular Neurodegeneration.

Date: June 15, 2015.

Time: 4:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance Washington DC, Dupont Circle, 1143 New Hampshire Avenue NW., Washington, DC 20037.

Contact Person: Peter B. Guthrie, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4142, MSC 7850, Bethesda, MD 20892, (301) 435-1239, guthriep@csr.nih.gov.

Name of Committee: Oncology 1—Basic Translational Integrated Review Group; Tumor Progression and Metastasis Study Section.

Date: June 17–18, 2015.

Time: 8:00 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Wardman Park Washington DC Hotel, 2660 Woodley Road, NW., Washington, DC 20008.

Contact Person: Rolf Jakobi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6187, MSC 7806, Bethesda, MD 20892, 301-495-1718, jakobir@mail.nih.gov.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Musculoskeletal, Oral and Skin Sciences AREA review.

Date: June 17, 2015.

Time: 8:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Yanming Bi, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301-451-0996, ybi@csr.nih.gov.

Name of Committee: Genes, Genomes, and Genetics Integrated Review Group; Prokaryotic Cell and Molecular Biology Study Section.

Date: June 17–18, 2015.

Time: 8:30 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Renaissance M Street Hotel, 1143 New Hampshire Avenue NW., Washington, DC 20037.

Contact Person: Dominique Lorang-Leins, Ph.D., Scientific Review Officer, National Institutes of Health, Center for Scientific Review, 6701 Rockledge Drive, Room 5108, MSC 7766, Bethesda, MD 20892, 301.326.9721, Lorangd@mail.nih.gov.

Name of Committee: Oncology 2—Translational Clinical Integrated Review Group; Cancer Immunopathology and Immunotherapy Study Section.

Date: June 18–19, 2015.

Time: 8:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Embassy Suites Alexandria, 1900 Diagonal Road, Alexandria, VA 22314.

Contact Person: Denise R Shaw, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6158, MSC 7804, Bethesda, MD 20892, 301-435-0198, shawdeni@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 14, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-12126 Filed 5-19-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Program Project: A Predictive Understanding of Cell Motility.

Date: May 28–29, 2015.

Time: 8:30 a.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892, (Virtual Meeting).

Contact Person: Sergei Ruvinov, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4158, MSC 7806, Bethesda, MD 20892, 301-435-1180, ruvinser@csr.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.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393–93.396, 93.837–93.844, 93.846–93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: May 15, 2015.

Anna Snouffer,

Deputy Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-12241 Filed 5-19-15; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

[1651-0019]

Agency Information Collection Activities: Vessel Entrance or Clearance Statement

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security.

ACTION: 30-Day notice and request for comments; Extension of an existing collection of information.

SUMMARY: U.S. Customs and Border Protection (CBP) of the Department of Homeland Security will be submitting the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act: Vessel of Entrance or Clearance Statement (CBP Form 1300). This is a proposed extension of an information collection that was previously approved. CBP is proposing that this information collection be extended with no change to the burden hours or to the information collected. This document is published to obtain comments from the public and affected agencies.

DATES: Written comments should be received on or before June 19, 2015 to be assured of consideration.

ADDRESSES: Interested persons are invited to submit written comments on this proposed information collection to the Office of Information and Regulatory Affairs, Office of Management and Budget. Comments should be addressed to the OMB Desk Officer for Customs and Border Protection, Department of Homeland Security, and sent via electronic mail to oir_submission@omb.eop.gov or faxed to (202) 395-5806.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to Tracey Denning, U.S. Customs and Border Protection, Regulations and Rulings, Office of

International Trade, 90 K Street NE., 10th Floor, Washington, DC 20229-1177, at 202-325-0265.

SUPPLEMENTARY INFORMATION: This proposed information collection was previously published in the **Federal Register** (80 FR 12829) on March 11, 2015, allowing for a 60-day comment period. This notice allows for an additional 30 days for public comments. This process is conducted in accordance with 5 CFR 1320.10. CBP invites the general public and other Federal agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13; 44 U.S.C. 3507). The comments should address: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimates of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden, including the use of automated collection techniques or the use of other forms of information technology; and (e) the annual costs to respondents or record keepers from the collection of information (total capital/startup costs and operations and maintenance costs). The comments that are submitted will be summarized and included in the CBP request for OMB approval. All comments will become a matter of public record. In this document, CBP is soliciting comments concerning the following information collection:

Title: Vessel Entrance or Clearance Statement.

OMB Number: 1651-0019.

Form Number: CBP Form 1300.

Abstract: CBP Form 1300, *Vessel Entrance or Clearance Statement*, is used to collect essential commercial vessel data at time of formal entrance and clearance in U.S. ports. The form allows the master to attest to the truthfulness of all CBP forms associated with the manifest package, and collects information about the vessel, cargo, purpose of entrance, certificate numbers, and expiration for various certificates. It also serves as a record of fees and tonnage tax payments in order to prevent overpayments. CBP Form 1300 was developed through agreement by the United Nations Intergovernmental Maritime Consultative Organization (IMCO) in conjunction with the United States and various other countries. This form is authorized by 19 U.S.C. 1431, 1433, and

1434, and provided for by 19 CFR 4.7-4.9, and accessible at <http://www.cbp.gov/newsroom/publications/forms?title=1300>.

Current Actions: CBP proposes to extend the expiration date of this information collection with no change to the burden hours or to the information being collected.

Type of Review: Extension (without change).

Affected Public: Businesses.

Estimated Number of Respondents: 12,000.

Estimated Number of Responses per Respondent: 22.

Estimated Total Annual Responses: 264,000.

Estimated Time per Response: 30 minutes.

Estimated Total Annual Burden Hours: 132,000.

Dated: May 13, 2015,

Tracey Denning,

Agency Clearance Officer, U.S. Customs and Border Protection.

[FR Doc. 2015-12107 Filed 5-19-15; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR-5835-N-07]

60-Day Notice of Proposed Information Collection: Personal Financial and Credit Statement

AGENCY: Office of the Assistant Secretary for Housing- Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* July 20, 2015.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street, SW., Room 4176, Washington, DC 20410-5000; telephone 202-402-3400 (this is not a toll-free number) or email at Colette.Pollard@hud.gov for a copy of

the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877-8339.

FOR FURTHER INFORMATION CONTACT:

Theodore K. Toon, Director, Office of Multifamily Production, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410, email: Theodore.K.Toon@hud.gov, telephone (202) 402-8386 (this is not a toll free number) for copies of the proposed forms and other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877-8339.

Copies of available documents submitted to OMB may be obtained from Ms. Colette Pollard, email: Colette.Pollard@hud.gov, telephone (202) 402-3400.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Personal Financial and Credit Statement.

OMB Approval Number: 2502-0001.

Type of Request: Extension of currently approved collection.

Form Number: HUD-92417.

Description of the need for the information and proposed use: The information collection is legally required to collect information to evaluate the character, ability, and capital or the sponsor, mortgagor, and general contractor for mortgage insurance.

Respondents: Business, non-profit.

Estimated Number of Respondents: 1,555.

Estimated Number of Responses: 1,555.

Frequency of Response: Occasion.

Average Hours per Response: 8.

Total Estimated Burdens: 12,440.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: May 13, 2015.

Laura M. Marin,

Associate General Deputy Assistant Secretary for Housing-Associate Deputy Federal Housing Commissioner.

[FR Doc. 2015-12273 Filed 5-19-15; 8:45 am]

BILLING CODE 4210-67-P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS-R4-ES-2015-N086; 40120-1112-0000-F2]

Receipt of Applications for Endangered Species Permits

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered species. With some exceptions, the Endangered Species Act (ESA) prohibits activities with listed species unless a Federal permit is issued that allows such activities. The ESA requires that we invite public comment before issuing these permits.

DATES: We must receive written data or comments on the applications at the address given below by *June 19, 2015*.

ADDRESSES: Documents and other information submitted with the applications are available for review, subject to the requirements of the Privacy Act and Freedom of Information Act, by any party who submits a written request for a copy of such documents to the following office within 30 days of the date of publication of this notice: U.S. Fish and Wildlife Service, 1875 Century Boulevard, Suite 200, Atlanta, GA 30345 (Attn: Karen Marlowe, Permit Coordinator).

FOR FURTHER INFORMATION CONTACT: Karen Marlowe, 10(a)(1)(A) Permit Coordinator, telephone 205-726-2667; facsimile 205-726-2479.

SUPPLEMENTARY INFORMATION: The public is invited to comment on the following applications for permits to conduct certain activities with endangered and threatened species under section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), and our regulations in the Code of Federal Regulations (CFR) at 50 CFR 17. This notice is provided under section 10(c) of the Act.

If you wish to comment, you may submit comments by any one of the following methods. You may mail comments to the Fish and Wildlife Service's Regional Office (see **ADDRESSES** section) or send them via electronic mail (email) to *permitsR4ES@fws.gov*. Please include your name and return address in your email message. If you do not receive a confirmation from the Fish and Wildlife Service that we have received your email message, contact us directly at the telephone number listed above (see **FOR FURTHER INFORMATION CONTACT**). Finally, you may hand-deliver comments to the Fish and Wildlife Service office listed above (see **ADDRESSES**).

Before including your address, telephone number, email address, or other personal identifying information in your comments, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comments to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Permit Applications

Permit Application Number: TE 100070-2

Applicant: J. Alison Cochran, U.S. Forest Service, Double Springs, Alabama

The applicant requests renewal of her permit to take (enter hibernacula and maternity roosts, capture via mist-net or harp trap, band, radio-tag, collect hair and fecal samples, wing-punch, light-tag, and salvage) Indiana bats (*Myotis sodalis*) and gray bats (*Myotis grisescens*) and to add authorization to conduct the same activities with the northern long-eared bat (*Myotis septentrionalis*) on U.S. Forest Service lands in the State of Alabama.

Permit Application Number: TE 64232B-0

Applicant: Joshua R. Young, Lexington, Kentucky

The applicant requests a permit to take (capture, handle, identify, tag, and release) the gray bat (*Myotis grisescens*), Indiana bat (*Myotis sodalis*), northern long-eared bat (*Myotis septentrionalis*), Virginia big-eared bat (*Corynorhinus (=plecotus) townsendii virginianus*) and 29 species of freshwater mussels for purposes of conducting presence/absence surveys and habitat and population monitoring in Kentucky.

Permit Application Number: TE 171516-4

Applicant: Mark Gumbert, Copperhead Consulting, Paint Lick, Kentucky

The applicant requests an amendment of his current permit to add authorization to conduct surveys for the rayed bean (*Villosa fabalis*) and to expand the geographic area of permitted activities to include the State of West Virginia.

Permit Application Number: TE 206741-1

Applicant: Veronica Mullen, Metro Water Services, Nashville, Tennessee

The applicant requests renewal of her current permit to take (capture, identify, measure, sex, release) Nashville crayfish (*Orconectes shoupi*) for the purposes of conducting presence/absence studies and population surveys in Davidson County, Tennessee.

Permit Application Number: TE 62778B-0

Applicant: Chanston Osborne, Apogee Environmental, Richmond, Kentucky

The applicant requests authorization to take (enter hibernacula, capture with mist nets or harp traps, handle, identify, band, radio-tag) Indiana bats (*Myotis sodalis*) and northern long-eared bats (*Myotis septentrionalis*) for the purpose of conducting presence/absence surveys throughout the species' respective ranges.

Permit Application Number: TE 65346A-1

Applicant: Matthew Roberts, Apogee Environmental, Berea, Kentucky

The applicant requests renewal and amendment of his current permit to take (enter hibernacula, capture with mist nets or harp traps, handle, identify, band, radio-tag) Indiana bats (*Myotis sodalis*), gray bats (*Myotis grisescens*), and northern long-eared bats (*Myotis septentrionalis*) for the purpose of conducting presence/absence surveys

throughout the species' respective ranges.

Permit Application Number: TE 65002A-1

Applicant: Robert Oney, Apogee Environmental, Winchester, Kentucky

The applicant requests renewal and amendment of his current permit to take (enter hibernacula, capture with mist nets or harp traps, handle, identify, band, radio-tag) Indiana bats (*Myotis sodalis*), gray bats (*Myotis grisescens*), and northern long-eared bats (*Myotis septentrionalis*) for the purpose of conducting presence/absence surveys throughout the species' respective ranges.

Permit Application Number: TE 007748-3

Applicant: Jason Nolde, USDA Forest Service, Pineville, Louisiana

The applicant requests renewal of the current permit to take (capture, band, translocate, install artificial nest cavities and restrictors, monitor nest cavities) red-cockaded woodpeckers (*Picoides borealis*), primarily for population monitoring and management in Louisiana and, secondarily, to assist in recovery activities throughout the species' range in Kentucky, Mississippi, South Carolina, Florida, Georgia, Arkansas, North Carolina, Tennessee, and Alabama.

Permit Application Number: TE 63355B-0

Applicant: David Heil, T.H.E. Engineers, Lexington, Kentucky

The applicant requests authorization to take (capture with mist nets or harp traps, handle, identify, band, and radio-tag) Indiana bats (*Myotis sodalis*), gray bats (*Myotis grisescens*), northern long-eared bats (*Myotis septentrionalis*), and Virginia big-eared bats (*Corynorhinus townsendii ingens*) for the purpose of conducting presence/absence surveys in Kentucky.

Permit Application Number: TE 63357B-0

Applicant: Timothy Estep, Worcester, Massachusetts

The applicant requests authorization to sell in interstate commerce artificially propagated green pitcher plants (*Sarracenia oreophila*), Alabama canebrake pitcher plants (*Sarracenia rubra* ssp. *alabamensis*), mountain sweet pitcher-plants (*Sarracenia rubra* ssp. *jonesii*), and hairy rattleweeds (*Baptisia arachnifera*) throughout the United States.

Permit Application Number: TE 056217-4

Applicant: Jeanette Wyneken, Florida Atlantic University, Boca Raton, Florida

The applicant requests renewal of her current permit to take (survey, collect hatchlings, hold in captivity, examine, and release) leatherback (*Dermochelys coriacea*), green (*Chelonia mydas*), and loggerhead (*Caretta caretta*) sea turtles for the purposes of inventory, monitoring, and research activities.

Dated: May 11, 2015.

Leopoldo Miranda,

Assistant Regional Director—Ecological Services, Southeast Region.

[FR Doc. 2015-12188 Filed 5-19-15; 8:45 am]

BILLING CODE 4310-55-P

National Environmental Policy Act (NEPA), and the Framework Agreement for Early Restoration Addressing Injuries Resulting from the *Deepwater Horizon* Oil Spill, the Federal and State natural resource trustee agencies (Trustees) have prepared a Draft Phase IV Early Restoration Plan and Environmental Assessments (Draft Phase IV ERP/EA) describing and proposing a suite of early restoration projects intended to continue the process of restoring natural resources and services injured or lost as a result of the *Deepwater Horizon* oil spill, which occurred on or about April 20, 2010, in the Gulf of Mexico. The Draft Phase IV ERP/EA proposes 10 early restoration projects that are consistent with the early restoration program alternatives selected in the Final Phase III Early Restoration Plan/Programmatic Environmental Impact Statement (Phase III ERP/PEIS). The Draft Phase IV ERP/EA also includes a notice of change and supporting analysis for one Phase III Early Restoration Project, "Enhancement of Franklin County Parks and Boat Ramps—Eastpoint Fishing Pier Improvements." The purpose of this notice is to inform the public of the availability of the Draft Phase IV ERP/EA and to seek public comments on the 10 proposed early restoration projects and supporting analysis.

DATES: Comments Due Date: We will consider public comments received on or before June 19, 2015.

Public Meetings: The Trustees have scheduled a series of public meetings to facilitate public review and comment on the Draft Phase IV ERP/EA. Both written and verbal comments will be taken at each public meeting. The Trustees will hold an open house for each meeting followed by a formal meeting. Each public meeting will include a presentation of the Draft Phase IV ERP/EA. The public meeting schedule is as follows:

DEPARTMENT OF THE INTERIOR

[FWS-R4-FHC-2015-N088: FVHC98210408710-XXX-FF04G01000]

Deepwater Horizon Oil Spill; Draft Phase IV Early Restoration Plan and Environmental Assessments

AGENCY: Interior.

ACTION: Notice of availability; request for comments.

SUMMARY: In accordance with the Oil Pollution Act of 1990 (OPA), the

Date	Time	Location
Tuesday, June 2, 2015	6:00 p.m. Open House 6:30 p.m. Public Meeting	Crowne Plaza Pensacola Grand Hotel, 200 East Pensacola Street, Pensacola, FL.
Wednesday, June 3, 2015	6:00 p.m. Open House 6:30 p.m. Public Meeting	Renaissance Mobile Riverview Plaza Hotel, 64 South Water Street, Mobile, AL.
Thursday, June 4, 2015	6:00 p.m. Open House 6:30 p.m. Public Meeting	University of Southern Mississippi, FEC Auditorium, 730 East Beach Boulevard, Long Beach, MS.
Monday, June 8, 2015	6:00 p.m. Open House 6:30 p.m. Public Meeting	Belle Chasse Auditorium, 8398 Louisiana 23, Belle Chasse, LA 70037.
Wednesday, June 10, 2015	6:00 p.m. Open House 6:30 p.m. Public Meeting	Texas A&M University at Galveston, Seawolf Parkway on Pelican Island, Auditorium, Galveston, TX.
Thursday, June 11, 2015	6:00 p.m. Open House 6:30 p.m. Public Meeting	Harte Research Institute for Gulf of Mexico Studies, Texas A&M University at Corpus Christi, 6300 Ocean Drive, Corpus Christi, TX.

ADDRESSES:

Obtaining Documents: You may download the Draft Phase IV ERP/EA at: <http://www.gulfspillrestoration.noaa.gov> or <http://www.doi.gov/deepwaterhorizon>. Alternatively, you may request a CD of the Draft Phase IV ERP/EA (see **FOR FURTHER INFORMATION CONTACT**). You may also view the document at any of the public facilities listed at <http://www.gulfspillrestoration.noaa.gov>.

Submitting Comments: You may submit comments on the Draft Phase IV ERP/EA by one of following methods:

- Via the Web: <http://www.gulfspillrestoration.noaa.gov>.

- Via U.S. Mail: U.S. Fish and Wildlife Service, P.O. Box 49567, Atlanta, GA 30345.

FOR FURTHER INFORMATION CONTACT:

Nanciann Regalado, at nanciann_regalado@fws.gov.

SUPPLEMENTARY INFORMATION:**Introduction**

On or about April 20, 2010, the mobile offshore drilling unit *Deepwater Horizon*, which was being used to drill a well for BP Exploration and Production, Inc. (BP), in the Macondo prospect (Mississippi Canyon 252—MC252), experienced a significant explosion, fire, and subsequent sinking in the Gulf of Mexico, resulting in an unprecedented volume of oil and other discharges from the rig and from the wellhead on the seabed. The *Deepwater Horizon* oil spill is the largest oil spill in U.S. history, discharging millions of barrels of oil over a period of 87 days. In addition, well over 1 million gallons of dispersants were applied to the waters of the spill area in an attempt to disperse the spilled oil. An undetermined amount of natural gas was also released into the environment as a result of the spill.

The Trustees are conducting the natural resource damage assessment for the *Deepwater Horizon* oil spill under the Oil Pollution Act 1990 (OPA; 33 U.S.C. 2701 *et seq.*). Pursuant to OPA, Federal and State agencies act as trustees on behalf of the public to assess natural resource injuries and losses, and to determine the actions required to compensate the public for those injuries and losses. OPA further instructs the designated trustees to develop and implement a plan for the restoration, rehabilitation, replacement, or acquisition of the equivalent of the injured natural resources under their trusteeship, including the loss of use and services from those resources from the time of injury until the time of restoration to baseline (the resource

quality and conditions that would exist if the spill had not occurred) is complete. Pursuant to the process articulated in the Framework for Early Restoration Addressing Injuries Resulting from the *Deepwater Horizon* Oil Spill (Framework Agreement), the Trustees previously selected, and BP agreed to fund, a total of 54 early restoration projects, expected to cost a total of approximately \$700 million, through the Phase I Early Restoration Plan/Environmental Assessment (Phase I ERP/EA), Phase II Early Restoration Plan/Environmental Review (Phase II ERP/ER), and the Programmatic and Phase III Early Restoration Plan and Early Restoration Programmatic Environmental Impact Statement (Phase III ERP/PEIS). These plans are available at: <http://www.gulfspillrestoration.noaa.gov/restoration/early-restoration/>.

The Trustees are:

- U.S. Department of the Interior (DOI), as represented by the National Park Service, U.S. Fish and Wildlife Service, and Bureau of Land Management;
- National Oceanic and Atmospheric Administration (NOAA), on behalf of the U.S. Department of Commerce;
- U.S. Department of Agriculture (USDA);
- U.S. Department of Defense (DOD);¹
- U.S. Environmental Protection Agency (USEPA);
- State of Louisiana Coastal Protection and Restoration Authority, Oil Spill Coordinator's Office, Department of Environmental Quality, Department of Wildlife and Fisheries, and Department of Natural Resources;
- State of Mississippi Department of Environmental Quality;
- State of Alabama Department of Conservation and Natural Resources and Geological Survey of Alabama;
- State of Florida Department of Environmental Protection and Fish and Wildlife Conservation Commission;
- For the State of Texas: Texas Parks and Wildlife Department, Texas General Land Office, and Texas Commission on Environmental Quality.

Background

On April 20, 2011, BP agreed to provide up to \$1 billion toward early restoration projects in the Gulf of Mexico to address injuries to natural resources caused by the *Deepwater Horizon* oil spill. The Framework

¹ Although a trustee under OPA by virtue of the proximity of its facilities to the *Deepwater Horizon* oil spill, DOD is not a member of the Trustee Council and does not currently participate in Trustee decision making.

Agreement represents a preliminary step toward the restoration of injured natural resources and is intended to expedite the start of restoration in the Gulf in advance of the completion of the injury assessment process. The Framework Agreement provides a mechanism through which the Trustees and BP can work together “to commence implementation of early restoration projects that will provide meaningful benefits to accelerate restoration in the Gulf as quickly as practicable” prior to the resolution of the Trustees’ natural resource damages claim. Early restoration is not intended to and does not fully address all injuries caused by the *Deepwater Horizon* oil spill. Restoration beyond early restoration projects will be required to fully compensate the public for natural resource losses, including recreational use losses, from the *Deepwater Horizon* oil spill.

The Trustees actively solicited public input on restoration project ideas through a variety of mechanisms, including public meetings, electronic communication, and creation of a Trustee-wide public Web site and database to share information and receive public project submissions. Their key objective in pursuing early restoration is to secure tangible recovery of natural resources and natural resource services for the public’s benefit while the longer term process of fully assessing injury and damages is under way. The Trustees released the Phase I ERP/EA in April 2012 and the Phase II ERP/ER in December 2012 after public review of drafts of those documents. After public review, the Trustees released the Phase III ERP/PEIS on June 26, 2014. Subsequently, the Trustees approved the Phase III ERP/PEIS in a Record of Decision on October 31, 2014.

The Trustees are proposing 10 additional early restoration projects in Phase IV to address injuries from the *Deepwater Horizon* oil spill. The 10 projects proposed in this Draft Phase IV ERP/EA are consistent with the Programmatic ERP and PEIS included in the Final Phase III ERP/PEIS previously developed by the Trustees. The Trustees are proposing these projects at this time while continuing to work with BP to develop additional early restoration projects in accordance with the Framework Agreement. The Draft Phase IV ERP/EA is not intended to and does not fully address all injuries caused by the spill or provide the extent of restoration needed to make the public and the environment whole.

Overview of the Draft Phase IV ERP/EA

The Draft Phase IV ERP/EA is being released in accordance with the Oil Pollution Act (OPA), the Natural Resources Damage Assessment (NRDA) regulations found in the Code of Federal Regulations (CFR) at 15 CFR 990, the National Environmental Policy Act (42 U.S.C. 4321 *et seq.*), and the Framework for Early Restoration Addressing Injuries Resulting from the *Deepwater Horizon* Oil Spill.

The Trustees are considering 10 projects in the Draft Phase IV ERP/EA. The total estimated cost for proposed Phase IV projects is approximately \$134 million. Details on the proposed projects are provided in the Draft Phase IV ERP/EA. The Draft Phase IV ERP/EA also includes a notice of change and supporting analysis for one Phase III Early Restoration Project, "Enhancement of Franklin County Parks and Boat Ramps—Eastpoint Fishing Pier Improvements."

The proposed restoration projects are intended to continue the process of using early restoration funding to restore natural resources, ecological services, and recreational use services injured or lost as a result of the *Deepwater Horizon* oil spill. The Trustees considered hundreds of projects leading to the identification of these 10 projects and considered both ecological and recreational use restoration projects to restore injuries caused by the *Deepwater Horizon* oil spill, addressing both the physical and biological environment, as well as the relationship people have with the environment.

Early restoration actions are not intended to provide the full extent of restoration needed to make the public and the environment whole. The Trustees anticipate that additional early restoration projects will be proposed in the future as the early restoration process continues.

Next Steps

As described above, public meetings are scheduled to facilitate the public review and comment process. After the public comment period ends, the Trustees will consider and address the comments received before issuing a Final Phase IV Early Restoration Plan and Environmental Assessments (Final Phase IV ERP/EA). After issuing a Final Phase IV ERP/EA, the Trustees will file negotiated stipulations for approved projects with the court. Approved projects will then proceed to implementation, pending compliance with all applicable State and Federal laws.

Invitation to Comment

The Trustees seek public review and comment on the 10 proposed early restoration project and supporting analysis included in the Draft Phase IV ERP/EA. 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.

Administrative Record

The documents comprising the Administrative Record can be viewed electronically at the following location: <http://www.doi.gov/deepwaterhorizon>.

Authority

The authority of this action is the Oil Pollution Act of 1990 (33 U.S.C. 2701 *et seq.*) and the implementing Natural Resource Damage Assessment regulations found at 15 CFR 990.

Cynthia K. Dohner,
DOI Authorized Official.

[FR Doc. 2015-11945 Filed 5-19-15; 8:45 am]

BILLING CODE 4310-55-P

DEPARTMENT OF THE INTERIOR**Bureau of Land Management**

[LLORE00000.L63500000.DR0000.
LXSS021H0000.15XL1116AF HAG 15-0077]

Notice of Availability of the Record of Decision for the West Eugene Wetlands in Oregon and Approved Resource Management Plan

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability.

SUMMARY: The Bureau of Land Management (BLM) announces the availability of the Record of Decision (ROD) for the Approved Resource Management Plan (RMP) for the West Eugene Wetlands planning area located in western Oregon. The Oregon/Washington State Director signed the ROD on April 17, 2015, which constitutes the final decision of the BLM and makes the Approved RMP effective immediately.

ADDRESSES: Copies of the ROD/Approved RMP are available upon request from the Eugene District Manager, Bureau of Land Management, 3106 Pierce Parkway, Suite E, Springfield, OR 97477, or via the internet at: <http://www.blm.gov/or/districts/eugene/plans/eugenermp.php>. Copies of the ROD/Approved RMP are

available for public inspection at the above-listed address.

FOR FURTHER INFORMATION CONTACT: Panchita Paulete, Planning and Environmental Coordinator, telephone 541-683-6976; address 3106 Pierce Parkway, Suite E; Springfield, OR 97477; email BLM_OR_EU_Mail@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: Interaction with the public regarding this RMP began in 2011. The BLM worked with three cooperating agencies: the US Army Corps of Engineers, the City of Eugene Parks and Open Space Division, and The Confederated Tribes of the Grand Ronde. The RMP establishes direction for approximately 1,340 acres of BLM-administered lands in and near the city of Eugene in Lane County, Oregon; the planning area did not previously have an RMP. The planning area is made up of acquired lands and survey hiatuses. The Approved RMP describes the actions that will meet desired resource conditions for threatened and endangered species and habitat management, while providing other benefits. The Preferred Alternative, described in the October 2011 Draft RMP/Draft Environmental Impact Statement (EIS), was modified to increase acreage within the Prairie Restoration Area land use allocation for threatened and endangered species management, to provide increased opportunities for recreation, and to provide for coordinated management in traditional use plant collection and was carried forward as the Proposed RMP in the Final EIS (November 2014). No protests were received on the Proposed RMP/Final EIS.

The Governor of Oregon was provided a formal, 60-day review period to determine if the Proposed RMP/Final EIS was consistent with existing state or local plans, programs, and policies. No inconsistencies were identified.

There are two implementation decisions in the Approved RMP which are appealable under 43 CFR part 4: (a) designation of travel management networks, including identifying the specific roads and trails that are available for public use and the limitations on use of roads and trails and (b) continued application of the

Final Supplementary Rules for Public Land within the West Eugene Wetlands, Eugene District, Oregon, published in the **Federal Register** on July 28, 2005, and adoption of the application of these rules throughout the planning area on BLM-managed lands. Any party adversely affected may appeal within 30 days of publication of this Notice of Availability. The appeal should state the specific decision(s) being appealed. The appeal must be filed with the Eugene District Manager at the above-listed address.

Please consult the appropriate regulations (43 CFR, part 4, subpart E) for further appeal requirements.

Authority: 40 CFR 1506.6, 40 CFR 1506.10, 43 CFR 1610.2.

Kathryn Stangl,

Eugene District Manager.

[FR Doc. 2015-12187 Filed 5-19-15; 8:45 am]

BILLING CODE 4310-33-P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[LLNV952000

L14400000.BJ0000.LXSSF2210000.241A;
13-08807; MO #4500079470; TAS: 15X1109]

Filing of Plats of Survey; NV

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The purpose of this notice is to inform the public and interested State and local government officials of the filing of Plats of Survey in Nevada.

DATES: *Effective Dates:* Unless otherwise stated filing is effective at 10:00 a.m. on the dates indicated below.

FOR FURTHER INFORMATION CONTACT: Michael O. Harmening, Chief, Branch of Geographic Sciences, Bureau of Land Management, Nevada State Office, 1340 Financial Blvd., Reno, NV 89502-7147, phone: 775-861-6490. 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:

1. The Plat of Survey of the following described lands will be officially filed at the Bureau of Land Management (BLM) Nevada State Office, Reno, Nevada on the first business day after thirty (30) days from the publication of this notice:

This plat, in 3 sheets, representing the dependent resurvey of a portion of the south and west boundaries, a survey of a portion of the subdivisional lines and metes-and-bounds surveys of certain boundary lines in sections 28, 29, 30 and 31, Township 13 North, Range 27 East, Mount Diablo Meridian, under Group No. 941, was accepted May 14, 2015. This survey was executed at the request of the Bureau of Land Management, Carson City District Office, Nevada, to facilitate the conveyance of certain public lands to the Municipality of Yerington, Nevada, as authorized in the National Defense Authorization Act of Fiscal Year 2015 (Pub. L. 113-291).

The survey listed above is now the basic record for describing the lands for all authorized purposes. These records have been placed in the open files in the BLM Nevada State Office and are available to the public as a matter of information. Copies of the survey and related field notes may be furnished to the public upon payment of the appropriate fees.

Dated: May 14, 2015.

Michael O. Harmening,

Chief Cadastral Surveyor, Nevada.

[FR Doc. 2015-12217 Filed 5-19-15; 8:45 am]

BILLING CODE 4310-HC-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 14-25]

The Main Pharmacy; Decision and Order

On October 7, 2014, Administrative Law Judge (ALJ) Christopher B. McNeil issued the attached Recommended Decision (hereinafter, R.D.). Therein, the ALJ found it undisputed that Respondent no longer holds a Texas Pharmacy License and is thus not authorized to dispense controlled substances in the State in which it seeks registration under the Controlled Substances Act (CSA). R.D. at 6. The ALJ thus concluded that Respondent is not a “practitioner” within the meaning of the CSA and is therefore not entitled to be registered. R.D. at 7 (citing 21 U.S.C. 802(21) & 823(f)). Accordingly, the ALJ granted the Government’s Motion for Summary Disposition and recommended that I deny its application.

The ALJ did not, however, address the Government’s further contention that it was also entitled to summary disposition because Respondent’s proposed business model of shipping

filled controlled substance prescriptions to a patient’s prescribing physician rather than directly to the patient, violates federal law. *See generally* R.D.; *see also* Mot. for Summ. Disp., at 5-6. The Government takes exception to the ALJ’s failure to address the issue,¹ arguing that the ALJ “should have also reached the merits of this case and granted summary disposition to the Government on the additional basis that Respondent intends to dispense controlled substances to non-ultimate users in violation of the [CSA] and its implementing regulations.” Gov. Exceptions, at 1.

As support for its contention, the Government argues that I should reach the issue because it “was fully briefed by the parties,” “there is no dispute as to any material fact,” and “the issue is likely to recur with the Respondent” because its “owner has stated his intent to reapply for a state license and pursue opening the pharmacy.” *Id.* at 2. Finally, the Government argues that “requiring the parties to revisit this issue as part of a future case would be a waste of resources, given that this issue has been briefed and is now ripe for disposition.” *Id.*

While Respondent agrees with the Government,² I reject the parties’

¹ Following the issuance of the Recommended Decision, Respondent’s counsel filed a pleading entitled: “Notice of Appeal.” Therein, Respondent requests that the record be prepared and forwarded “to the appropriate Appeals Court.” Notice of Appeal, at 1. Respondent did not, however, file exceptions to the ALJ’s decision as provided for in the Agency’s regulations. *See* 21 CFR 1316.66. As for its “Notice of Appeal,” the ALJ’s Recommended Decision is not a final decision of the Agency and thus, the filing of the record in “the appropriate” court, whatever that maybe, is premature. In the event Respondent files a Petition for Review of this Decision and Order, which is the final decision of the Agency, the Agency will comply with Rule 17 of the Federal Rules of Appellate Procedure.

² Respondent asserts that the issue of its proposed business model is ripe for review because “[e]very time [it] applies for a State license all [the Government] has to do is to sit on the application for a period of six months or more and Respondent will have to close [the] Pharmacy. [The Government] can then assert that Respondent has no State license and should be barred from going forward and hence evade review.” Resp. Answer to Movant’s Mot. for Summ. Disp., at 3.

Respondent’s position apparently stems from the Texas Pharmacy Act and a regulation of the Texas Board of Pharmacy which authorize disciplinary action against the holder of a pharmacy license if the Board finds that the holder has “failed to engage in or ceased to engage in the business described in the application for a license.” Tex. Occ. Code § 565.002(7); *see also* 22 Tex. Admin. Code § 291.11(a)(1) (“Failure to engage in the business described in the application for a license” means the holder of a pharmacy license has not commenced operating the pharmacy within six months of the date of issuance of the license.”).

However, Respondent does not explain why it could not have opened for business and dispensed non-controlled drugs while it challenged the denial of its application.

contentions. Here, even assuming that further factual development is not necessary and that the parties have fully briefed the issue, Respondent's professed intent to reapply for a state license remains speculative, and until such time as Respondent obtains a new state license (and a new Texas DPS registration), it is not authorized to handle controlled substances under state law and cannot obtain a DEA registration. *See Texas v. United States*, 523 U.S. 296, 300 (1998) ("A claim is not ripe for adjudication if it rests upon contingent future events that may not occur as anticipated, or indeed may not occur at all.") (int. quotations and citations omitted). Thus, were I to adopt Respondent's position, it would still not be entitled to a registration.

Moreover, were I to adopt the Government's position, so long as the Respondent does not hold the requisite state authority and is not entitled to be registered, my decision would be an advisory opinion.³ While an administrative agency is not subject to the case or controversy requirements of Article III, relevant authority suggests that in the event Respondent sought judicial review of the decision, the federal courts would lack jurisdiction to review that part of the decision. It is settled, however, that where the federal courts lack the power to review an agency decision because of intervening mootness, the court vacates the agency's order. *See A.L. Mechling Barge Lines, Inc. v. United States*, 368 U.S. 324, 329 (1961) (vacating administrative orders which had become unreviewable in federal court); *see also American Family Life Assurance Co. v. FCC*, 129 F.3d 625, 630 (D.C. Cir. 1997) ("Since *Mechling*, we have, as a matter of course, vacated agency orders in cases that have become moot by the time of judicial review."). *See also Samuel H. Albert*, 74 FR 54851, 54852 (2009). Thus, it is unclear how ruling on the issue would preserve the Agency's resources.

Whether this is deemed to be an issue of mootness, because Respondent once held the requisite state license but chose to surrender it, or ripeness, because Respondent has not obtained a new state license (which is a prerequisite to registration, *see* 21 U.S.C. 802(21), 823(f)), the same result would likely obtain on judicial review. Under these circumstances, the issue raised by

Respondent's proposed business model is not suitable for adjudication in this proceeding.

I therefore adopt the ALJ's Recommended Decision⁴ and will deny Respondent's application.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 28 CFR 0.100(b), I order that the application of The Main Pharmacy, for a DEA Certificate of Registration as a Retail Pharmacy, be, and it hereby is, denied. This Order is effective immediately.

Dated: May 1, 2015.

Michele M. Leonhart,

Administrator.

Paul E. Soeffing, Esq., for the Government.
Nemuel Pettie, Esq., for the Respondent.

ORDER GRANTING THE GOVERNMENT'S MOTION FOR SUMMARY DISPOSITION AND RECOMMENDED RULING, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

Nature of the Case and Procedural History

Christopher B. McNeil, Administrative Law Judge. On August 18, 2013, The Main Pharmacy, the respondent in this case, submitted an application to the Drug Enforcement Administration (DEA) seeking a new DEA retail pharmacy registration that would permit the dispensing of Schedules II through V controlled substances.¹ Acting "by and on behalf of the Main Pharmacy,"² "Attorney/Applicant"³ Nemuel E. Pettie, Esq., sought this registration for use at 1226 S. Main Street, Fort Worth, Texas 76109.⁴ The pending DEA application number for this application is W13068660A.⁵

On August 18, 2014, the Deputy Administrator of the Drug Enforcement Administration, Office of Diversion Control, filed an Order to Show Cause proposing to deny the application pursuant to 21 U.S.C. 824(a)(1), (3) and (4) and 21 U.S.C. 823(f).⁶ As grounds for revocation, the Government alleges that Respondent materially falsified its DEA application, does not have the authority to handle controlled substances in the State of Texas, and that Respondent's registration would be inconsistent with the public interest.⁷

On September 9, 2014, Respondent, through its Applicant, Nemuel E. Pettie, Esq., filed a timely request for hearing.⁸ Respondent does not dispute that The Main

Pharmacy does not possess a pharmacy license issued by the Texas State Board of Pharmacy.⁹ Instead, Respondent asserts that the issue is not moot as Respondent plans to re-apply for another Pharmacy License.¹⁰ The required professional license that had permitted Main Pharmacy to provide retail pharmacy services in Texas was terminated on approximately July 28, 2013 after The Main Pharmacy notified the Texas State Board of Pharmacy that The Main Pharmacy was closed.¹¹

I received the Government's Motion for Summary Disposition on September 10, 2014, with proof of service upon Respondent, accompanied by supporting documentation. In my Order of September 10, 2014, I directed the Government to provide evidence to support the allegation that Respondent lacks state authority to handle controlled substances. The factual premise relied upon by the Government in support of its motion is that Respondent does not have a pharmacy license issued by the Texas State Board of Pharmacy, the state in which Respondent seeks to be registered.¹² Additionally, in the same Order, I provided Respondent the opportunity to respond to the Government's Motion for Summary Disposition.¹³ That response was due by September 24, 2014.¹⁴ On September 22, 2014, I received Respondent's timely response.¹⁵ The Government exercised its right to reply to the response and submitted a reply on September 25, 2014.¹⁶ Drawing from the motion and briefs submitted, I find as follows:

Issue

The substantial issue raised by the Government rests on an undisputed fact. The Government asserts that Respondent's application must be summarily denied because Respondent does not have a pharmacy license issued by the state in which it intends to operate.¹⁷ Under DEA precedent, an application for a retail-pharmacy DEA Certificate of Registration must be summarily denied if the applicant is not authorized to handle controlled substances in the state in which it seeks DEA registration.¹⁸ Unless from the pleadings now

⁹ Respondent's Request for Hearing at 2.

¹⁰ *Id.*

¹¹ Order to Show Cause at 2.

¹² Government's Motion for Summary Disposition dated Sept. 10, 2014 at 1–2.

¹³ Order Authorizing Briefs Regarding Summary Disposition dated Sept. 10, 2014 at 1.

¹⁴ *Id.*

¹⁵ Respondent's Answer to Movant's Motion for Summary Disposition dated Sept. 22, 2014 at 1.

¹⁶ Government's Reply to Respondent's Answer to Government's Motion for Summary Disposition dated Sept. 25, 2014 at 1.

¹⁷ Government's Motion for Summary Disposition at 6–8.

¹⁸ *See* 21 U.S.C. 801(21), 823(f), 824(a)(3); *see also House of Medicine*, 79 FR 4959, 4961 (DEA 2014); *Deanwood Pharmacy*, 68 FR 41662–01 (DEA July 14, 2003); *Wayne D. Longmore, M.D.*, 77 FR 67669–02 (DEA November 13, 2012); *Alan H. Olefsky, M.D.*, 72 FR 42127–01 (DEA August 1, 2007); *Layfe Robert Anthony, M.D.*, 67 FR 15811 (DEA May 20, 2002); *George Thomas, PA-C*, 64 FR 15811–02 (DEA April 1, 1999); *Shahid Musud Siddiqui, M.D.*, 61 FR 14818–02 (DEA April 4, 1996); *Michael D.*

Continued

⁴ I note, however, that the Order to Show Cause was issued by the Deputy Assistant Administrator, Office of Diversion Control.

¹ Order to Show Cause dated Aug. 18, 2014 at 1.
² Respondent's Request for Hearing dated Sept. 9, 2014 at 1.

³ *Id.*

⁴ *Id.* at 4.

⁵ Order to Show Cause at 1.

⁶ *Id.*

⁷ *Id.*

⁸ Respondent's Request for Hearing dated Sept. 9, 2014 at 1, received by DEA Sept. 10, 2014.

³ This is not a case where an applicant, that lacks state authority, has also previously engaged in actionable misconduct under the public interest factors. Under those circumstances, denying an application on both grounds does not present an issue of either mootness or ripeness as it relies on acts that have been committed and not speculation as to a future course of conduct.

before me there is a material issue regarding Respondent's authority to handle controlled substances in Texas, the application must be denied summarily, without a hearing.

Respondent's Contentions

In Respondent's Answer to Movant's Motion for Summary Disposition, Respondent never disputed the Government's contention that The Main Pharmacy was not currently licensed by the State of Texas to operate a pharmacy.¹⁹ Instead, Respondent asserted that the Government is barred by the equitable doctrine of "clean hands" from moving for summary disposition.²⁰ Respondent, utilizing the diction of Professor Ori Herstein of Cornell University, defines unclean hands as "[a]ny willful conduct that is iniquitous, unfair, dishonest, fraudulent, unconscionable, or performed in bad faith."²¹

Respondent stated that the Texas State Pharmacy Board requires that a pharmacy be open and in operation within six months of the issuance of its license.²² Respondent alleged that the Drug Enforcement Administration's failure to approve The Main Pharmacy's DEA registration in a "reasonable time" forced Respondent to close The Main Pharmacy to avoid disciplinary proceedings by the Texas State Pharmacy Board.²³ As a result of the DEA's failure to act, Respondent seeks to prohibit summary disposition by the doctrine of unclean hands.²⁴

Respondent alternatively argues that the case should not be dismissed under the doctrine of *Southern Pacific Terminal Co. v. I.C.C.*, 219 U.S. 498 (1911). Respondent cites *Southern Pacific Terminal Co.* for the proposition that a case is not moot when it presents an issue "capable of repetition, yet evading review."²⁵

Scope of Authority

On August 18, 2014, the Deputy Administrator of the Drug Enforcement Administration, Office of Diversion Control, filed an Order to Show Cause proposing to deny the application pursuant to 21 U.S.C. 824(a)(1), (3) and (4) and 21 U.S.C. 823(f).²⁶

The case before me is presented under a grant of authority to recommend that the Administrator either grant or deny Respondent's application for a DEA retail-

pharmacy license. Pursuant to 21 U.S.C. 823(f), the DEA may grant such an application only to a pharmacy "practitioner." Under 21 U.S.C. 802(21), a "practitioner" must be "licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices or does research, to distribute [or] dispense . . . controlled substance[s]." Given this statutory language, the DEA Administrator does not have the authority under the Controlled Substances Act to grant a registration to a practitioner if that practitioner is not authorized to dispense controlled substances.²⁷

Respondent asserted that the Government is barred by the equitable doctrine of "clean hands" from moving for summary disposition.²⁸ However, DEA Administrative Law Judges lack the authority to exercise equitable powers when making their decisions. The one and only purpose in this type of proceeding for a DEA Administrative Law Judge is to determine whether under 21 U.S.C. 823(f), a practitioner's application to dispense controlled medications is consistent with the public interest.²⁹ Agency precedent supports this premise. In *James Dell Potter, M.D.*, respondent attempted to invoke the principle of equitable estoppel to argue that the DEA could not revoke his registration, as the DEA previously granted him a registration.³⁰ In the opinion, DEA Administrator Francis M. Mullen, Jr. stated that:

[The] DEA is charged by statute to protect the public. [P]rinciples of equitable estoppel cannot be applied to deprive the public of the protection of a statute because of the mistaken action, or lack of action, on the part of public officials. . . . Generally, a governmental unit is not estopped when functioning in a governmental capacity [citation omitted].³¹

Therefore, the protection of the public is preeminent, and the Agency is limited in its authority to direct relief under equitable principles.

In a case that has strong parallels to the case at hand, *Saihb S. Halil, M.D.*, a doctor faced with an order to show cause made the argument that the Government is estopped from taking adverse action based upon its failure to process his application in a timely manner.³² Deputy Administrator Donnie R. Marshall agreed with DEA ALJ Gail Randall in finding the chronology of the case "troubling" as it took 13 months for the Government to respond after the initial reply to the OTSC.³³ However, Judge Randall cited

Potter for the proposition that estoppel does not deprive the public of the protection of a statute because of lack of action.³⁴ Deputy Administrator Marshall further agreed with Judge Randall's statement that "[a]lthough worthy of consideration and concern, such lack of timeliness does not overcome the public interest in this case. Equitable estoppel does not operate under these circumstances to preclude the DEA from protecting the public health and safety."³⁵

Respondent's alternative argument, that this is a case "capable of repetition, yet evading review," does not compel a contrary outcome.³⁶ Respondent faults the Government for the delay that led to Respondent voluntarily surrendering its state pharmacy license.³⁷ However, as noted by the Government in the Government's Reply to Respondent's Answer to Government's Motion for Summary Disposition, Respondent could have "stocked and dispensed non-controlled substances while its DEA application was pending."³⁸

The Government does not directly address the premise that The Main Pharmacy is intended to "cater to accident victims only."³⁹ Presumably, a pharmacy catering exclusively to accident victims would likely face substantial limitations if it was unable to deliver critical medication to its customers. Nonetheless, The Main Pharmacy chose this business model, doing so while being subject to the regulatory environment established under the Controlled Substances Act. Despite these limitations, there is no factual basis for finding the pharmacy could not have conducted a legally "sufficient" number of transactions while it waited for its DEA Registration.

Facts

Given this body of law, the material fact here, indeed the sole fact of consequence, is whether Respondent is authorized by the State of Texas to dispense controlled substances. Where, as here, no material fact is in dispute, there is no need for an evidentiary hearing and summary disposition is appropriate.⁴¹ The sole question of fact before me can be addressed, and has been addressed, by the pleadings submitted to me by the parties. Our record includes no dispute regarding the Government's contention that the authority of The Main Pharmacy to dispense prescription medication in Texas was voluntarily withdrawn on approximately July 28, 2014.⁴²

Lawton, M.D., 59 FR 17792-01 (DEA April 14, 1994); *Abraham A. Chaplan, M.D.*, 57 FR 55280-03 (DEA November 24, 1992). See also *Bio Diagnosis Int'l*, 78 FR 39327-03, 39331 (DEA July 1, 2013) (distinguishing distributor applicants from other "practitioners" in the context of summary disposition analysis).

¹⁹ Respondent's Answer to Movant's Motion for Summary Disposition at 2.

²⁰ *Id.*

²¹ *Id.* See Herstein, Ori J. "A Normative Theory of the Clean Hands Defense." (2001) Cornell Law Faculty Publications. Paper 210. <http://scholarship.law.cornell.edu/facpub210>, p.3.

²² Respondent's Answer to Movant's Motion for Summary Disposition at 2. See Tex. Admin. Code 291.9 (2012).

²³ Respondent's Answer to Movant's Motion for Summary Disposition at 2.

²⁴ *Id.*

²⁵ Respondent's Answer to Movant's Motion for Summary Disposition at 3.

²⁶ Order to Show Cause at 1.

²⁷ See *Abraham A. Chaplan, M.D.*, 57 FR 55280-03, 55280 (DEA November 24, 1992), and cases cited therein. In *Chaplan*, DEA Administrator Robert C. Bonner adopts the ALJ's opinion that "the DEA lacks statutory power to register a practitioner unless the practitioner holds state authority to handle controlled substances." *Id.*

²⁸ Respondent's Answer to Movant's Motion for Summary Disposition at 2.

²⁹ 21 U.S.C. 823(f).

³⁰ *James Dell Potter, M.D.*, 49 FR 9970-01 (DEA Mar. 16, 1984).

³¹ *Id.* at 9971.

³² *Saihb S. Halil, M.D.*, 64 FR 33319-01 (DEA June 22, 1999).

³³ *Id.* at 33319-33320.

³⁴ *Id.* at 33320.

³⁵ *Id.*

³⁶ Respondent's Answer to Movant's Motion for Summary Disposition at 3.

³⁷ *Id.* at 2.

³⁸ Government's Motion for Summary Disposition dated September 25 at 2.

³⁹ Respondent's Request for Hearing at 2.

⁴⁰ Respondent's Answer to Movant's Motion for Summary Disposition, Exhibit 1.

⁴¹ See *Michael G. Dolin, M.D.*, 65 FR 5661 (DEA February 4, 2000); see also *Philip E. Kirk, M.D.*, 48 FR 32887 (DEA July 19, 1983), *aff'd sub nom. Kirk v. Mullen*, 749 F.2d 297 (6th Cir. 1984).

⁴² Government's Motion for Summary Disposition at 6.

The reasons for withdrawal are not material, given the statutory language set forth above.

Analysis, Findings of Fact and Conclusions of Law

In determining whether to grant the Government's Motion for Summary Disposition, I am required to apply the principle of law that holds such a motion may be granted in an administrative proceeding if no material question of fact exists:

It is settled law that when no fact question is involved or the facts are agreed, a plenary, adversary administrative proceeding involving evidence, cross-examination of witnesses, etc., is not obligatory—even though a pertinent statute prescribes a hearing. In such situations, the rationale is that Congress does not intend administrative agencies to perform meaningless tasks (citations omitted).⁴³

In this context, I am further guided by prior decisions before the DEA involving certificate holders who lacked licenses to distribute or dispense controlled substances. On the issue of whether an evidentiary hearing is required, “it is well settled that when there is no question of material fact involved, there is no need for a plenary, administrative hearing.”⁴⁴ Under this guidance, the Government's motion must be sustained unless a material fact question has been presented.

The sole determinative fact now before me is that Respondent lacks a Texas pharmacy license. In order for a pharmacy to receive a DEA registration authorizing it to dispense controlled substances under 21 U.S.C. 823(f), it must meet the definition of “practitioner” as found in the Controlled Substances Act.⁴⁵ Such an entity must be “licensed, registered, or otherwise permitted by . . . the jurisdiction in which he practices . . . to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice.”⁴⁶ Delegating to the Attorney General the authority to determine who may or may not be registered to perform these duties, Congress permitted such registration only to “practitioners” as defined by the Controlled Substances Act.⁴⁷

As cited by the Government in its Motion for Summary Disposition, there is substantial authority both through agency precedent and through decisions of courts in review of that precedent, holding that an application for a retail pharmacy DEA registration is dependent upon the applicant having a state license to dispense controlled substances.⁴⁸ Under the doctrine before me, the

Government meets its burden of establishing grounds to deny an application for registration upon sufficient proof establishing the applicant does not possess a state pharmacy license. That proof is in the record before me, and it warrants the summary denial of Respondent's application for a DEA Certificate of Registration.

I am mindful of the arguments raised by Respondent in its Answer to Movant's Motion, including the fact that Respondent's lack of a pharmacy license is based on Respondent's voluntary withdrawal of its pharmacy license to avoid state sanctions as a result of delays by the DEA.⁴⁹ These difficulties do not, however, change the fact that without a state pharmacy license, Respondent is not a “practitioner” and cannot be granted a Certificate of Registration. Equitable principles, even were they available in this forum, fail to lead to a different outcome. As made clear in *Potter* and *Halil*, the lack of timeliness in processing an application for a DEA Certificate of Registration does not overcome the public interest.

Some care should be taken to assure the parties that the actions taken in this administrative proceeding conform to constitutional requirements. I have examined the parties' contentions with an eye towards ensuring all tenets of due process have been adhered to. There is, however, no authority for me to evaluate the facts that underlie Respondent's contentions. In the proceedings now before me, the only material question was answered by Respondent in its Request for Hearing. Further, while the Order to Show Cause sets forth a non-exhaustive summary of facts and law relevant to a determination that granting this application would be inconsistent with the public interest under 21 U.S.C. 823(f), the conclusion, order and recommendation that follow are based solely on a finding that Respondent is not a “practitioner” as that term is defined by 21 U.S.C. 802(21), and I make no finding regarding whether granting this application would or would not be inconsistent with the public interest.

Order Granting the Government's Motion for Summary Disposition and Recommendation

I find there is no genuine dispute regarding whether Respondent is a “practitioner” as that term is defined by 21 U.S.C. 802(21), and that based on the record the Government has established that Respondent is not a practitioner and is not authorized to dispense controlled substances in the state in which it seeks to operate under a DEA Certificate of Registration. I find no other material facts at issue, for the reasons set forth in the Government's Motion for Summary Disposition. Accordingly, I GRANT the Government's Motion for Summary Disposition.

Upon this finding, I ORDER that this case be forwarded to the Administrator for final disposition and I RECOMMEND the Administrator DENY Respondent's application for a DEA Certificate of Registration.

Date: October 7, 2014.

Christopher B. Mcneil,
Administrative Law Judge.

[FR Doc. 2015–12128 Filed 5–19–15; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Keith Ky Ly, D.O.; Decision and Order

On January 24, 2013, I, the Administrator of the Drug Enforcement Administration, issued an Order to Show Cause and Immediate Suspension of Registration (hereinafter, OTSC–ISO or Order) to Keith Ky Ly, D.O. (Respondent), of Mountlake Terrace, Washington. GX 2, at 1. The Order proposed the revocation of Respondent's DEA Certificate of Registration, which authorizes him to dispense controlled substances in schedules II through V, as a practitioner, as well as the denial of any pending applications to renew or modify his registration, on the ground that his “continued registration is inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f).” *Id.*

More specifically, the OTSC–ISO alleged that on February 2, 2012, law enforcement officers arrested Respondent's girlfriend, who was then driving his vehicle, for driving with a suspended license and that during a search of the vehicle, found “one pound of marijuana, approximately \$3,900 cash in a vacuum sealed bag located in [her] purse, \$5,000 cash located in a hidden compartment, and three prescription bottles containing controlled substances located in” her backpack. *Id.* at 2. The Order further alleged that Respondent had issued one of the prescriptions found in the backpack to an employee, and that during an interview when he attempted to recover the vehicle, Respondent stated that he lived with his girlfriend, that she worked at his medical practice, and that she and the employee whose medication was found in the backpack “often shared medications.” *Id.* The Order then alleged that this showed that Respondent had “knowledge of illegal activity occurring between [his] employees and [took] no corrective action.” *Id.*

Next, the OTSC–ISO alleged that law enforcement officers discovered that several premises owned by Respondent were being used as marijuana-grow houses. *Id.* More specifically, the Order alleged that: (1) On May 30, 2012, the Renton, Washington fire department responded to a fire at his Quincy

⁴³ *NLRB v. International Assoc. of Bridge*, 549 F.2d 634, 638 (9th Cir. 1977) (quoting *United States v. Consolidated Mines & Smelting Co., Ltd.*, 455 F.2d 432, 453 (9th Cir. 1971)).

⁴⁴ See *Michael G. Dolin, M.D.*, 65 FR 5661 (DEA February 4, 2000); *Jesus R. Juarez, M.D.*, 62 FR 14945 (DEA March 28, 1997); see also *Philip E. Kirk, M.D.*, 48 FR 32887 (DEA July 19, 1983), *aff'd sub nom. Kirk v. Mullen*, 749 F.2d 297 (6th Cir. 1984).

⁴⁵ 21 U.S.C. 802(21).

⁴⁶ *Id.*

⁴⁷ 21 U.S.C. 823(f).

⁴⁸ Government's Motion for Summary Disposition at 7 and cases cited therein.

⁴⁹ Respondent's Answer to Movant's Motion for Summary Disposition at 2.

Avenue property and seized approximately 700 marijuana plants; (2) on July 5, 2012, state and local law enforcement officers obtained a search warrant for his property located at 20118 14th Avenue NE., Shoreline, Washington, and seized approximately 489 marijuana plants and six bags of processed marijuana; (3) on July 6, 2012, state and local law enforcement officers executed a search warrant at Respondent's personal residence in Bothell, Washington, and "seized \$12,000 in cash, two firearms, marijuana grow documents, approximately 15 grams of processed marijuana, and multiple prescription bottles containing pills," including an unlabeled bottle containing hydrocodone, and a bottle containing clonazepam, which Respondent had prescribed for patient R.M.; and (4) on July 7, 2012, state and local law enforcement obtained a search warrant for his property located at 5006 104th Place NE., Marysville, Washington and seized marijuana leaves and grow equipment. *Id.* at 2–3.

Next, the OTSC–ISO alleged that on July 13, 2012, DEA personnel "conducted an inspection and audit at [Respondent's] registered address." *Id.* at 3. The Order alleged that Respondent had a 75 percent shortage of both testosterone 200mg/ml and phentermine 37.5mg, as well as a 14 percent shortage of hydrocodone 10/500mg. *Id.* Based on the audit results, the Order further alleged that Respondent "failed to maintain accurate and complete records and failed to account for these controlled substances." *Id.* (citing 21 U.S.C. 827(a)(1) and 842(a)(5); 21 CFR 1301.71, 1304.03, 1304.04 (a) & (g), and 1304.21). The Order then alleged that Respondent had committed additional recordkeeping violations, in that he "failed to take and maintain an initial or biennial inventory of all stocks of controlled substances on hand," "failed to record essential elements on approximately 128 dispensing records," "failed to maintain a dispensing/administration log for testosterone and Testim samples, located during the on-site inspection," and "failed to maintain all Schedule III–V acquisition invoices and record the dates of receipt[] on the invoices." *Id.* at 3–4 (citations omitted).

Finally, the OTSC–ISO alleged that Respondent "failed to make required dispensing reports" to the Washington State Prescription Monitoring Program "on approximately 45 separate occasions from January to July 2012." *Id.* at 4. As the legal basis for this allegation, the Government noted that Washington State "requires a dispensing physician to report to the . . . PMP all instances in which he or she dispenses

more than a 24-hour supply of controlled substances." *Id.* (citing Wash. Rev. Code § 70.225.020; Wash. Admin. Code § 246–470–030).

Based on the above, I made a preliminary finding that Respondent "illegally manufactured controlled substances in violation of state and federal law, illegally possessed and distributed highly addictive controlled substances . . . and ha[d] generally failed to maintain effective controls to guard against theft and prevent diversion of controlled substances." *Id.* I therefore ordered that Respondent's registration be suspended effective immediately. *Id.* (citing 21 U.S.C. 824(d)).

According to the Declaration of a DEA Diversion Investigator (DI), on January 28, 2013, DEA Special Agents and DIs went to Respondent's registered location and personally served him with the OTSC–ISO, along with "a sample request for hearing form." DI Declaration, at 9. According to the DI, later that same day, he also hand-delivered a copy of the OTSC–ISO and the hearing request form to Respondent's "attorney at the time." ¹ *Id.*

The OTSC–ISO plainly advised that: (1) "[w]ithin 30 days after the date of receipt of this Order to Show Cause and Immediate Suspension of Registration, you may file with the DEA a written request for a hearing in the form set forth in 21 CFR 1316.47"; (2) "[i]f you fail to file such a request, the hearing shall be cancelled in accordance with paragraph 3"; (3) "[s]hould you decline to file a request for a hearing . . . you shall be deemed to have waived the right to a hearing and the DEA may cancel such hearing"; (4) "[c]orrespondence concerning this matter, including requests [for a hearing] should be addressed to the Hearing Clerk, Office of Administrative Law Judges [OALJ] . . . 8701 Morrissette Drive, Springfield, VA 22152"; and (5) "[m]atters are deemed filed upon receipt by the Hearing Clerk." GX 2, at 4–5 (citations omitted). Notwithstanding this, Respondent did not file a request for hearing with the Office of Administrative Law Judges until April 4, 2013. GX 4, at 1.

The matter was then assigned to an Administrative Law Judge (ALJ), who

¹ The courts are clear that service of an initial pleading on an attorney does not constitute adequate service unless a party has granted authority to the attorney to accept process on his behalf. *See, e.g., United States v. Ziegler Bolt & Parts Co.*, 111 F.3d 878, 881 (Fed. Cir.1997). There being no such evidence showing that Respondent granted such authority to the attorney, I rely only on the DI's statement that Respondent was personally served.

ordered that the proceeding be terminated because Respondent had "failed to timely request a hearing and failed to assert good cause for his 36-day delay." *Id.* at 2. Thereafter, on April 18, 2013, Respondent, who was now represented by counsel (a different counsel than identified by the DI in his declaration), filed a motion to reconsider and re-open. GX 5. Therein, Respondent requested a full hearing on the allegations, as well as "additional time to file his Request for Hearing based on this motion showing of good cause." *Id.* at 1.

In the motion, Respondent did "not contest that he was effectively served with a copy of the" OTSC–ISO. *Id.* at 2. He also did not dispute that his prior attorney "was in contact with [him] during and after the period for filing a timely appeal." *Id.* Rather, Respondent maintained that he "sent a letter requesting appeal of the [OTSC–ISO] to [a] local Seattle-based DEA agent . . ." by certified mail on February 4, 2013," who "did not respond to the appeal letter or inform Respondent that an appeal of the [OTSC–ISO] could not be perfected by sending it to him." *Id.* at 2–3. Respondent further asserts that he "sought the advice of and had several conversations with [his former] attorney," and that "[b]ased on these conversations, [he] 'filed' an appeal NOT with the DEA . . . Office of Administrative Law Judges, but instead with the Office of the Inspector General (OIG)," and that he faxed the appeal "to the OIG on February 20, 2013, and again on March 8, 2013." *Id.* at 3. According to Respondent, "[t]he OIG suggested [he] contact the DEA." *Id.*

Respondent further asserted that he "discussed the matter with an assistant in his office, who believed the correct place to file the appeal was with the office of the United States Attorney General." *Id.* Respondent stated that "[a]n 'appeal' was sent to that address on February 11, 2013." *Id.*

Next, Respondent contended that on March 14, 2013, he was advised by his then-counsel that the latter "and his partner had decided not to represent [him] in this . . . proceeding," but that "[t]his was after the request for hearing deadline had expired." *Id.* Respondent then contended that on March 28, he spoke with two Seattle-based DEA agents, "who told him he needed to file the request for hearing right away." *Id.* According to Respondent, he then "filed his request for hearing on April 4, 2013 with the DEA" OALJ. *Id.*

Respondent asserted that he "was confused about how and where to file his request for a hearing" and that "[t]he source of his confusion came from his

contacts with [his former] attorney . . . with his office assistant, and from the lack of response by [a DEA Agent], although a late effort to clarify the correct means to request a hearing was provided by the DEA agents.” *Id.* at 3–4. He further maintained that he attempted “in good faith to ask for a hearing” and that “[n]one of the alternatives employed by [him] were done for purposes of delay.” *Id.* at 4.

Respondent argued that his case is similar to that of *Steven J. Watterson*, 67 FR 67413 (2002). Therein, the Agency set aside a final order where a party had failed to file a request for a hearing based on “conflicting guidance” having been “given to” an Applicant by an Agency “official concerning how and when the matter would be resolved.” *Id.* at 67414. Respondent argued that *Watterson* stands for the proposition that “[g]ood cause” . . . to set aside and rescind a decision terminating a proceeding . . . require[s] a showing of both excusable neglect and a meritorious defense.” GX 5, at 5. He then argued that “[t]he acceptance and retention by” the DI of his appeal request “was misleading, particularly when [the DIs] actively encouraged [him] to file his appeal correctly AFTER the appeal period had lapsed,” and that “[t]his was a source of conflicting guidance for Respondent.” *Id.* at 6.

Respondent also relied on *Pincay v. Andrews*, 389 F.3d 853 (9th Cir. 2004) (en banc). There, a lawyer failed to file a notice of appeal within the thirty-day period provided for doing so in the Federal Rules of Appellate Procedure, based on his reliance on the erroneous advice of a paralegal that the notice of appeal need not be filed until sixty days after the issuance of a judgment, rather than the thirty days provided in the applicable Federal Rule of Appellate Procedure. *Id.* at 855. The Ninth Circuit held that the failure to timely file the notice of appeal constituted excusable neglect, notwithstanding its conclusions that the lawyer’s reliance on the paralegal’s reading of the rule was “negligent” and that the “lawyer’s failure to read an applicable rule is one of the least compelling excuses that can be offered.” *Id.* at 859. The court nonetheless held that the district court did not abuse its discretion in concluding that the lawyer’s untimely filing was the result of excusable neglect. *Id.* The court further noted that “the decision whether to grant or deny an extension of time to file a notice of appeal should be entrusted to the discretion of the district court because the district court is in a better position than” the appeals court to evaluate the relevant factors, and that the decision

was to be determined “within the context of the particular case,” which, in *Pincay*, had gone on for fifteen years. *Id.* However, the court also observed that “[h]ad the district court declined to permit the filing of the notice, we would be hard pressed to find any rationale requiring us to reverse.” *Id.*

Based on *Pincay*, Respondent argued that: (1) There is no prejudice to the Agency because his registration remains suspended; (2) the thirty-six day delay in filing his hearing request had no impact on the proceeding; (3) “the reason for the delay was confusion on his part,” that his conduct is no worse than that found excusable in *Pincay* and was “based in part on omissions by” the DI, and was not made in bad faith; and (4) that he acted promptly to rectify his untimely filing. GX 5, at 8–9. Accordingly, Respondent argued that he has shown good cause for setting aside the ALJ’s termination order. *Id.* at 9.

The ALJ granted Respondent’s motion for reconsideration but then denied his motion to reopen the proceedings. Order Granting Respondent’s Motion for Reconsideration and Denying Respondent’s Motion to Reopen the Case, at 10 (Order on Reconsideration) (GX 7). While concluding that she had jurisdiction to consider Respondent’s motion for reconsideration, the ALJ rejected Respondent’s contention that he had shown good cause for his untimely filing.

First, the ALJ rejected Respondent’s contention that under *Watterson*, he had demonstrated good cause because he had received “conflicting guidance” from the DI to whom he sent his “appeal” letter. *Id.* at 7. The ALJ found that *Watterson* was not controlling because, during the period in which Respondent could have filed his hearing request, the DI did not provide conflicting guidance but rather no guidance at all. *Id.* at 8. Indeed, the DI did not provide any advice to Respondent regarding his hearing request until he met with the DI on March 28, 2013. *Id.*

Next, the ALJ rejected Respondent’s contention that “good cause” existed to excuse his untimely filing because his former attorney “committed ‘excusable neglect.’” *Id.* More specifically, the ALJ noted that the excusable neglect standard of the Federal Rules of Appellate Procedure, see *Pincay*, and the Federal Rules of Bankruptcy Procedure (Rule 9006(b)(1)), which was discussed by the Supreme Court in *Pioneer Inv. Servs. v. Brunswick Assoc.*, 507 U.S. 380, 396 (1993), “do not govern

our [DEA] proceedings.”² Order on Reconsideration, GX 7, at 8. The ALJ further noted that even under *Pioneer*, “respondents can ‘be held accountable for the acts and omissions of their chosen counsel.’” *Id.* (quoting *Pioneer*, 507 U.S. at 397).

The ALJ found that Respondent was represented by another attorney “at the time [he] was served with the Order to Show Cause,” and that this attorney did not inform him that he would not represent him in the DEA proceeding until after the deadline had passed for filing his hearing request. *Id.* at 8–9. The ALJ then concluded that while the “[a]ttorney was negligent in failing to tell Respondent in a timely fashion that he would no longer represent [him], . . . Respondent cannot argue that he detrimentally relied on [the attorney] to send out the request for hearing.” *Id.* at 9. This was so because “Respondent, *himself*, sent out the letters to [the DI],³ OIG, and [the] Attorney General.” *Id.* The ALJ thus concluded “that Respondent was ultimately responsible for filing a timely request for hearing, despite his former attorney’s shortcomings.” *Id.*

Finally, the ALJ rejected Respondent’s contention that his “confusion . . . support[ed] a finding of ‘good cause.’” *Id.* As the ALJ explained, “[t]he clear language of the Order to Show Cause states that ‘[c]orrespondence concerning

² While it true that DEA has not adopted any of the various federal rules of procedure, it has frequently looked to those rules for guidance in interpreting its procedural rules. See *Bio Diagnostic Inc.*, 78 FR 39327, 39328–29 & n.1 (2013) (applying federal court decisions interpreting Fed. R. Civ. P. 56 (governing summary judgment), in determining whether summary disposition was appropriately granted in Agency proceeding); *Glenn D. Kreiger*, 76 FR 20020, 20021 n.3 (2011) (applying federal court decisions and holding that a challenge to the sufficiency of service of a Show Cause Order is waived if not raised in a respondent’s first responsive pleading). In this regard, it is noted that the Federal Rules of Civil Procedure have expressly adopted the “excusable neglect” standard for determining whether “good cause” exists to extend the time for “[w]hen an act may or must be done” when a “motion [is] made after the time has expired.” Fed. R. Civ. P. 6(b)(1). As agency decisions make clear, the good cause standard is not limited to those instances where a respondent or his attorney are blameless in failing to timely file a pleading. See, e.g., *Tony T. Bui*, 75 FR 49979, 49980 (2010) (finding good cause existed to excuse untimely filed hearing request where attorney used an incomplete address to mail the request but when the request was returned, promptly proceeded to mail it to the correct address).

³ Regarding the letter to the DI, the ALJ noted that Respondent wrote: “I am writing to you as an appeal for the immediate and urgent help in the matter of my DEA license reinstatement.” Termination Order, at 9 n.8 (quoting Motion for Reconsideration, Ex. 29, at 1). The ALJ further noted that “[w]hile Respondent’s intent may have been to request a hearing, Respondent did not explicitly express this intent in the letters he sent before April 4, 2013.” *Id.*

this matter, including requests referenced in paragraphs 1 [*i.e.*, a hearing request] and 2 above, should be addressed to the Hearing Clerk, Office of Administrative Law, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152.” *Id.* (quoting OTSC–ISO, at 5). Finding “that this language is an unmistakably clear explanation of where to send a request for hearing, especially for an educated professional, such as the Respondent,” the ALJ held that “Respondent’s confusion does not justify a finding of ‘good cause.’” *Id.*

The ALJ thus rejected Respondent’s contention that he had shown good cause to excuse his untimely filing. *Id.* She further concluded that “Respondent’s failure to file a timely request [constituted] a waiver of his right to a hearing under 21 CFR 1301.43(d).” *Id.* at 9–10. The ALJ thus denied Respondent’s motion to reopen the matter.

Thereafter, the Government forwarded a Request for Final Agency Action and the Investigative Record to me. Having reviewed the record, I adopt the ALJ’s finding that Respondent did not demonstrate good cause for his failure to file his hearing request within the thirty-day period as required by 21 CFR 1301.43(a).

As the ALJ explained, the OTSC–ISO provided a clear explanation as to the procedure to be followed for filing a hearing request. That procedure required that Respondent or his representative file his hearing request with the “Hearing Clerk, Office of Administrative Law Judges, Drug Enforcement Administration, 8701 Morrisette Drive, Springfield, VA 22152,” and that “[m]atters are deemed filed upon receipt by the Hearing Clerk.” GX 2, at 5.

Moreover, the OTSC–ISO included an attachment entitled: “REQUEST FOR HEARING.” *Id.* at 6. The attachment states that “[a]ny person desiring a hearing with regard to an Order to Show Cause must, within thirty (30) days from receipt of the Order to Show Cause, file a request for a hearing in the following format.” *Id.* The attachment then provides a sample form, with the following address block: DEA Headquarters, Office of the Administrative Law Judges, Hearing Clerk, 8701 Morrisette Drive, Springfield, Virginia 22152.

Id. Notably, neither the OTSC–ISO, nor the attachment, directed Respondent, if he desired a hearing, to file his hearing request with DEA field personnel, the Office of Inspector General, or the Attorney General himself.

Also unavailing is Respondent’s reliance on *Pincay v. Andrews* to argue “good cause” exists to excuse his untimely filing because either he or his lawyer committed “excusable neglect.”⁴ Motion for Reconsideration, GX 5, at 7. As the Supreme Court explained in *Pioneer*, “inadvertence, ignorance of the rules, or mistakes construing the rules do not usually constitute excusable neglect.” 507 U.S. at 392. Moreover, as the Ninth Circuit noted in *Pincay*, the “failure to read an applicable rule is one of the least compelling excuses that can be offered.” 389 F.3d at 859. Indeed, as the Ninth Circuit noted in *Pincay*, “had the district court declined to permit” the appellant to file his notice late, it “would [have] be[en] hard pressed to find any rationale requiring us to reverse.” *Id.*

In his affidavit, Respondent asserts that he “sought the advice of and had several conversations with” his former attorney “concerning the OSC and filing an appeal,” and that “[b]ased on these conversations, I ‘filed’ an appeal NOT with the DEA . . . Office of the Administrative Law Judges, but instead with the Office of the Inspector General.” Respondent’s Declaration, at 9. To the extent Respondent seeks to rely on the advice he received from his former attorney to support a showing of good cause, his vague assertions do not establish that he was ever told not to comply with the instructions on the OTSC–ISO. Nor does Respondent assert that his former attorney ever agreed to represent him in this matter, let alone that he agreed to file a request for a hearing on Respondent’s behalf. To the extent Respondent relies on his own confusion as the reason for his untimely filing, *see* Mot. For Recon., at 8; there is no reason to excuse his neglect when the OTSC–ISO was personally served on him and set forth, with unmistakable clarity, the procedures to be followed for requesting a hearing.⁵

⁴ While the ALJ interpreted Respondent’s excusable neglect argument as being based on his former attorney’s failure to tell him that he would not represent Respondent until after the deadline had passed, Respondent’s argument appears to rely on his own confusion as to where to file the hearing request and not on the aforesaid conduct of the attorney.

⁵ As for Respondent’s letters to the OIG and the Attorney General, Respondent did not submit a copy of any of these letters with his motion. *See generally* Attachments to Respondent’s Motion. Indeed, the only letter relevant to this issue which Respondent submitted for the record (other than his appeal request) was a copy of an April 4, 2013 letter *he received* from the OIG, which “acknowledge[d] receipt of [his] correspondence dated July 11, 2011” and explained that his “complaint has been forwarded to” the DEA “Office of Professional Responsibility.” *Id.* at Ex. 31. Obviously, this letter

Respondent further argues that “[t]he acceptance and retention by [the DI] of the appeal request . . . was misleading, particularly when he and [another DI] actively encouraged [him] to file his appeal correctly AFTER the appeal period had lapsed” and that [t]his was a source of conflicting guidance for” him. *Id.* at 6. However, as the ALJ noted, this argument goes nowhere because Respondent does not claim that he had any discussion with the DI regarding the manner for properly filing his hearing request within the thirty-day period, let alone that he was given misleading advice as to how to file his request.⁶ Indeed, nothing prevented Respondent from filing a separate hearing request with the Office of Administrative Law Judges during the thirty-day period. I therefore reject Respondent’s contention that his untimely filing should be excused because he relied on “conflicting guidance” he received from agency personnel. *See Watterson*, 67 FR at 67413.

Accordingly, I hold that Respondent has failed to demonstrate good cause to excuse his failure to timely file his hearing request. I therefore find that Respondent has waived his right to a hearing on the allegations and issue this Decision and Order based on the Investigative Record (including Respondent’s Declaration) submitted by the Government. I make the following findings.

Findings of Fact

Respondent was the holder of DEA Certificate of Registration #BL6283927, pursuant to which he was authorized, prior to the Immediate Suspension of his registration, to dispense controlled substances in schedules II through V as a practitioner, at the registered address of 6603 220th Street SW., Mountlake Terrace, Washington 98043. GX 1.

could not have been a response to a misfiled hearing request given that it referenced his correspondence, which was dated approximately eighteen months before he was even served with the OTSC–ISO. Nor, even if the OIG’s letter was misdated, does it seem likely that it was prepared in response to a hearing request, given that it referred to his “complaint” and referred it to the “Office of Professional Responsibility.” *Id.*

As for Respondent’s assertion that he “discussed the matter . . . with an assistant in [his] office, who believed that the correct place to send the appeal was to the office of the Attorney General,” Resp. Decl., at 9; this begs the question of why he did not discuss where to file his appeal with the attorney (who had also received a copy of the OTSC–ISO) he was then consulting with.

⁶ So too, if there was evidence that the DI had told Respondent that he would forward his hearing request to the Office of Administrative Law Judges and failed to do, I would order that a hearing be granted. Respondent, however, makes no such claim, but rather, relies only on the DI’s silence during the period for requesting a hearing.

Respondent's registration was due to expire on March 31, 2014. *Id.* However, according to the registration records of the Agency, on March 13, 2014, Respondent submitted an application to renew his registration. While under the Agency's regulation, his renewal application was untimely because he was subject to an Order to Show Cause and Immediate Suspension of Registration and did not submit the application "at least 45 days before the date on which [his] registration [was] due to expire," 21 CFR 1301.36(i), and thus his registration has expired, his application remains pending before the Agency.

Respondent is also licensed by the State of Washington (as well as by the States of Texas and California) as an Osteopathic Physician. Resp. Declaration, at 1. According to Respondent, he has never been subject to discipline by any state licensing body. *Id.* However, Respondent has been subject to discipline by the Texas Medical Board. Moreover, while this matter was pending, the Washington Board of Osteopathic Medicine and Surgery issued Respondent an Ex Parte Order of Summary Action which suspended his state license to practice as an osteopathic physician and surgeon. *In re Keith Ky Ly* (Wash. Bd. Osteopathic Med. & Surg., Sep. 22, 2014) (Ex Parte Order of Summary Action, at 1).

With respect to the Texas Medical Board, on May 20, 2011, Respondent entered into an Agreed Order. *See In re Application for Licensure By Keith Ly, D.O.*, at 6 (Tx. Med. Bd. 2011). Therein, the Texas Board found that Respondent failed to report on his application for a Texas Medical License that in February 1990, while undergoing his "residency training," he had been "placed on probation" for being late and missing shifts, as well as for failing to report a 2007 arrest. *Id.* at 2. While the Board granted Respondent a license, it also assessed an administrative penalty of \$5,000 and placed him on probation for two years.⁷ *Id.* at 3–4.

Accordingly, I find that notwithstanding his statement, Respondent has been subject to

⁷ Based on the Texas Board's action, the Washington Board filed a Statement of Allegations against Respondent. *See In re Keith K. Ly*, No. M2010–1665, Statement of Allegations and Summary of Evidence (Wash. Dept. Health, Oct. 12, 2012). However, these allegations were settled in a Stipulation To Informal Disposition, the terms of which included that it "is not [a] formal disciplinary action." *See Stipulation To Informal Disposition, In re Ly*, at 2. However, the proceeding was still subject to reporting to the Health Integrity and Protection Databank and the National Practitioner Databank. *Id.*

discipline by a state licensing body. While the basis of the Texas Board's action does not provide a reason under the CSA for DEA to take any action against Respondent's registration, Respondent's statement was nonetheless false and clearly offered to influence the decision of the Agency to grant him a hearing on the allegations. Accordingly, I consider Respondent's lack of candor in assessing the credibility of the various assertions contained in his declaration.

The Arrest of Respondent's Girlfriend

According to the DI, on February 2, 2012, Respondent's girlfriend (TB),⁸ who was driving his Mercedes Benz SL 65,⁹ was stopped by local police, cited for driving under a suspended license, and arrested. DI Decl., at 1; Resp. Decl., at 3. Respondent corroborated that the car was his, when in his declaration he addressed the allegation and stated, *inter alia*, that on January 24, 2012, he had withdrawn \$5000 from his bank account to pay for the remodeling of his clinic and left the money "in the small hidden compartment space of the car." Resp. Decl., at 3. Accordingly, I find that Respondent's statements corroborate the DI's assertion that the car was owned by Respondent.

Following the arrest of Respondent's girlfriend, the police apparently impounded his car, and upon searching it, found one pound of marijuana,¹⁰ the aforesaid \$5000, and a backpack which contained pain medication. *Id.*; DI Decl., at 2.¹¹ As for the marijuana, Respondent asserted that it belonged to a medical marijuana patient (LHE) who was a friend of TB, and points to a statement from the purported owner of the marijuana. Resp. Decl., at 3; *see also* Resp. Mot., at Ex.1. Therein, LHE stated that she had an engine problem with her car and that she borrowed Respondent's car from TB "for a few hours to pick-up

⁸ According to Respondent, TB has lived with him "for the past 2 years" and "is now [his] wife." Resp. Decl., at 5. Moreover, TB worked in Respondent's clinic. Resp. Decl., at Ex. 4.

⁹ According to the DI's affidavit, the car was registered to Respondent. DI's Decl., at 1. While the DI's affidavit offers no explanation as to the basis of knowledge for this assertion, Respondent, in his declaration, stated that a friend of TB "had borrowed the car the previous day without my knowledge." Resp. Decl., at 3. I further note that in a March 3, 2012 letter to a local narcotic task force and the King County Prosecuting Attorney's Office, Respondent claimed that he owned the car and sought its return. Resp. Decl., at Ex.4. Accordingly, I find that Respondent owned the car that TB was driving when she was stopped and arrested.

¹⁰ In his statement, Respondent does not dispute that the arresting authorities found a one pound bag of marijuana. Resp. Decl., at 3.

¹¹ According to the DI, the police also found \$3900 in cash in a vacuum sealed bag in TB's purse. DI Decl., at 2.

. . . one [m]arijuana prescription bag" from a marijuana collective. Resp. Mot., at Ex. 1. According to LHE, she "was in a hurry to return the car to [TB and] forget [sic] to remove the bag behind the driver seat." *Id.* However, LHE's statement is unsworn, and given that the purported reason for borrowing Respondent's car was to obtain the marijuana, I find her story that she left a one pound bag of marijuana¹² in the car because she was in such a hurry to return it to be utterly ludicrous.¹³

As for the cash, Respondent offered two explanations for its source. First, he maintained that the day before, a patient paid him \$5000 cash as a deposit for a liposuction procedure. Resp. Decl., at 3. Respondent also produced an unsworn letter from the purported patient to this effect and a form entitled: "SmartLipo & Coolsculpting Price Quote." *Id.* at Ex. 2. While the latter purports to show that the patient paid a \$5000 deposit in cash, the date of the deposit clearly appears to have been altered. *See id.*

Second, as found above, Respondent maintained that he had withdrawn \$5,000 from his bank account on January 24, 2012 to pay for clinic remodeling, and that he had placed the money "in the small hidden compartment space of the car." Resp. Decl., at 3. To support his claim, Respondent produced a bank statement showing that he made a cash withdrawal of \$5,000. Resp. Ex. 3. However, numerous entries in the statement, including Respondent's various balances for both his checking and savings account, are blacked out. *Id.*

Putting aside that Respondent offered two different stories as for why so much cash was found in his car, I find neither explanation credible. As for the claim that the money was from a patient who had paid \$5,000 cash the day before for a procedure, the patient's statement is unsworn and thus lacks even the most basic indicia of reliability. Moreover, on the price quote form, the date of the patient's deposit was clearly written over. Also, even acknowledging that the patient's procedure was likely not covered by insurance, it seems most unlikely that the patient would pay this

¹² According to data collected by the Agency, during the period in which TB was stopped, one pound of marijuana had a street value of \$1500 to \$1800 in the Seattle area. At .5 grams per joint, one pound would be enough to make approximately 900 joints.

¹³ I further note that in his March 3, 2012 letter to a local narcotics task force and the King County Prosecuting Attorney's Office, in which he sought the return of his car, while Respondent again denied knowledge of the marijuana, he made no mention of the story that LHE had borrowed the car from his girlfriend.

amount in cash rather than by check or credit card.

As for his second story, it also seems most unlikely that Respondent would pay to remodel his clinic with cash (rather than check or credit card), let alone be carrying that much cash around in his car for nine days. By contrast, carrying large sums of cash is consistent with engaging in the distribution of marijuana.

In his declaration, the DI also asserted that the search of the vehicle found “multiple prescription bottles containing pills,” and that one of the bottles bore a label indicating that the drugs had been prescribed to T.V., “an office employee of” Respondent. DI’s Decl., at 2 (citing GX 9). The DI further stated that “[t]wo of the bottles found in the vehicle . . . were unlabeled and contained phentermine and phendimetrazine.” *Id.* (citing GX 10). Finally, the DI asserted that when Respondent “attempted to recover his vehicle, he told law enforcement officers that his employees often shared their medication.” *Id.*

Respondent did not dispute that drugs were found in TB’s backpack. Rather, he asserted that they “belonged to my office manager,” that he had prescribed the drugs “for her liposuction procedure pain a few months prior,” and that the drugs were “left at my house when she visited for [a] dinner party.” Resp. Decl., at 3. Respondent then maintained that “[a]s a medical doctor, I do not encourage nor allow any patients to share medication” and that he “would absolutely terminate my employee if found engaging in sharing medication and would report them to the authorities.” *Id.* Respondent did not, however, explain when the purported dinner party had occurred.

Consistent with Respondent’s admission, the record does include a photograph of a prescription vial; its label lists the patient as a person whose name corresponds with the initials T.V., the drug as hydrocodone/acetaminophen, and Respondent as the prescriber. See GX 9, at 1.¹⁴ Moreover,

¹⁴ Government Exhibit 9, however, contains seven additional photographs, including: (1) A photograph of two unlabeled vials (only one of which clearly contains tablets); (2) a photograph of two plastic bags, which purportedly contain phentermine and a red document, the date of which is unclear; (3) a photograph of a plastic bag containing a drug similar in appearance to the drug in the previous photograph; (4) a photograph of a vial containing yellow capsules and orange tablets, the label of which had been removed; (5) a vial bearing a label for a prescription issued by Respondent for clonazepam to a patient whose initials are R.M.; (6) six bottles bearing manufacturer’s labels (several of which are labelled as professional samples) for Viagra, Topiramate, Ultram ER, and Meridia; and (7) two vials, whose

while the photograph does not show whether there were pills remaining in the vial, in his declaration, Respondent does not dispute that the vial contained pain medication, which hydrocodone is. I thus find that substantial evidence supports a finding that Respondent’s girlfriend unlawfully possessed hydrocodone, which had been prescribed to another person.

In support of the DI’s assertion that two unlabeled vials which contained phentermine and phendimetrazine were also seized, the DI cited Government Exhibit 10, but without regard to the specific page. However, in his declaration, the DI offered no statement to the effect that he participated in the search of Respondent’s car, nor otherwise set forth the basis of his knowledge for making this assertion. Nor does the record contain any affidavits or police reports prepared by those officers who did participate in the arrest and search, nor other documents such as an inventory of the search, a chain of custody, and lab test results, which would support the DI’s assertion.¹⁵

Indeed, while Government Exhibit 10 contains eight photographs, in reviewing this matter it is apparent that the exhibit is not limited to the evidence that was seized following the search of Respondent’s car, but also contained photographs of evidence that may well have been seized during several of the searches described below. Most significantly, the Exhibit contains two photographs of vials (one showing two vials, the other showing a single vial) which were missing their labels, with no identification of when and from whom the vials were seized. Finally, while at least two of the vials appear to contain tablets (the third vial being murky), the Government provided no evidence (such as lab test results) explaining the basis for the DI’s

labels list Respondent as the prescriber, his girlfriend T.B. as the patient, and the drugs as lorazepam and hydrocodone/acetaminophen, with pills being visible only in the latter vial. Generally, the DI’s declaration offers no statements linking these photographs to the various items which were purportedly seized during the various searches of Respondent’s car and properties he owned.

Moreover, Government Exhibits 8, 9, 10, 11a, 11b, 13, 14, and 15 each contain the exact same set of eight photographs, although not necessarily in the same order. Providing multiple copies of the exact same set of photographs does not, however, make the first set of photographs any more probative of the facts for which they were offered.

¹⁵ Even giving weight to the DI’s assertion that Respondent “purchased these items [*i.e.*, phentermine and phendimetrazine] on August 5, 2011 from Distributor A.F. Hauser,” DI’s Decl., at 5 (¶ 34), this is not enough to overcome the insufficiency of the evidence with respect to the assertion that these drugs were seized during the February 2, 2012 search.

assertion that these vials contained phentermine and phendimetrazine.

The Searches of Respondent’s Properties

As noted above, the Show Cause Order also alleged that state and local law enforcement officers conducted searches of four different premises which Respondent owned, and found marijuana plants at his properties which were located in Renton and Shoreline, Washington, as well as six bags of processed marijuana at the latter property. GX 2, at 2. In addition, the Show Cause Order alleged that marijuana grow documents and “15 grams of processed marijuana” were found at Respondent’s personal residence, and that both marijuana grow equipment and marijuana leaves were found at a fourth property he owns. *Id.* at 3.

In his declaration, the DI made various assertions with respect to each of the searches. For example, with respect to the May 30, 2012 search of the Renton residence, the DI stated that the Renton Fire Department had responded to an electrical fire at the premises, which “is owned by” Respondent and “discovered a large marijuana grow,” and that thereafter, “[t]he Renton Police Department executed a search warrant of the residence and seized approximately 700 marijuana plants.” DI Decl., at 2. The DI further stated that Respondent “told law enforcement that he rented the [premises] to [one] Jack Tran,” but that the police “were unable to locate and/or identify Mr. Tran.” *Id.* at 3. While all of this may be true, here again, the DI’s declaration offers no statement to the effect that he participated in the search, nor otherwise sets forth the basis of his knowledge.

With respect to the July 5, 2012 search of the Shoreline residence, the DI stated that it was owned by Respondent, and that during the search by state and local law enforcement, “approximately 489 marijuana plants and six (6) bags of processed marijuana” were seized. *Id.* at 3. The DI further stated that TB and three other “marijuana tenders were arrested leaving the Shoreline residence,” that TB “admitted” to the police “that she was learning to grow marijuana at the Shoreline residence,” and that two “of the marijuana tenders arrested at the Shoreline residence possessed loose phentermine tablets in their pockets.” *Id.* (citing GX 11).¹⁶ Here

¹⁶ As explained below, while Respondent denies knowledge as to how his properties were being used, he does not dispute that marijuana was being grown at the various properties. Thus, his

too, all of this may be true, but the DI's affidavit offers nothing bordering on substantial evidence to support any of these assertions.¹⁷

The DI further asserted that L.E. was one of the marijuana tenders arrested during this search, and that using the Washington State Prescription Monitoring Program, "[i]t was discovered . . . that in June 2012, [Respondent] prescribed 30 dosage units of 10/500 mg hydrocodone to L.E." *Id.* Citing Government Exhibit 12, the DI further stated that he "verified the prescriptions [sic] by obtaining a hard copy of the prescription through" the pharmacy which filled it. *Id.* at 3–4. The

declaration corroborates the basic thrust of the DI's assertions.

That being said, the DI's affidavit contains numerous assertions for which there is no foundation to conclude that they are based on the DI's "personal knowledge" as that term is commonly understood. Indeed, many of the DI's assertions regarding the searches of Respondent's properties appear to be based on hearsay statements, the reliability of which cannot be assessed because the DI did not identify the source of the information and the Government did not include various documents (such as police reports, search inventories, and test results) in the record.

More specifically, the DI asserts that TB and three other persons were arrested during the search of the Shoreline residence; that during an interview with law enforcement, TB admitted that she was learning how to grow marijuana; and that two of the persons had loose phentermine tablets in their pockets. Again, the DI offered no statement to the effect that he participated in either the search of the Shoreline residence or the interview of TB. Nor did he set forth any other basis for these assertions.

As for the two marijuana tenders who purportedly possessed loose phentermine, the DI further asserted that "[s]tate law requires the labeling of dispensed medication" and that "[t]he lack of labeled prescription bottles suggests the controlled substances were diverted." DI's Decl., at 3. This too may be true, but there is no evidence in the record establishing the names of these individuals and that they obtained the controlled substances from Respondent. Indeed, while the DI cited GX 11 as support for his assertion that these individuals possessed phentermine, this exhibit simply contains a series of photographs including two of white tablets (one of which contains a red form which is illegible), various prescription vials (some of which contain pills, others which it is unclear if they do) and bottles containing various drug samples. Even assuming that the white tablets are phentermine (even though there is no evidence they were tested), nothing in the record establishes from whom and when these tablets were seized.

¹⁷ Here too, even giving weight to the DI's assertion that Respondent "purchased this exact item [*i.e.*, more phentermine] on March 16, 2012 from Distributor A.F. Hauser." DI Decl., at 5 (¶ 35), this evidence does not overcome the insufficiency of the evidence with respect to the assertion that these drugs were seized from the marijuana tenders during the search of the Shoreline residence. And because the evidence is insufficient to establish that loose phentermine was seized from the two marijuana tenders who were purportedly at the Shoreline residence, the assertions of the DI that: (1) One of the tenders "was never seen by" Respondent, and (2) that while one of the tenders was seen by Respondent, he was not prescribed any controlled substance, *id.* at 5–6 (¶ 36), is insufficient to establish that Respondent unlawfully distributed the phentermine to either person.

DI then stated that on July 13, 2012, he subpoenaed "L.E.'s patient chart from" Respondent, but that "[t]he office staff could not locate a patient chart for L.E., nor could they find his/her name in the electronic medical records." *Id.* at 4.

Government Exhibit 12 is a copy of a prescription issued by Respondent on June 28, 2012 for thirty (30) tablets of Lortab (hydrocodone/acetaminophen) 10/500. *See* GX 12. However, the prescription was issued to a patient whose initials are H.L., and not L.E. *See id.* Thus, the prescription does not support the DI's assertion, and the Government points to no other evidence that Respondent prescribed a controlled substance to a patient whose name corresponds with the initials of L.E., let alone that he violated the CSA's prescription requirement in doing so. *See* GX 2, at 2, ¶ 3–b. (OTSC–ISO).

Regarding the July 6, 2012 search of Respondent's and TB's residence (which is owned by the former), the DI asserted that state and local law enforcement seized "firearms, marijuana grow documents, approximately 15 grams of processed marijuana, and multiple prescription bottles containing pills." DI Decl., at 4. The DI then stated that Investigators found "an unlabeled" vial, "which contained hydrocodone"; one labeled vial, "which contained clonazepam that [Respondent] prescribed to patient R.M. in 2010"; and two "stock bottles that contained Meridia and diazepam"; even though Respondent "was not, nor has ever been, registered with DEA at his Bothell residence." *Id.* (citing GXs 13, 14, and 15).

As for the unlabeled prescription bottle which purportedly contained hydrocodone, here again, the DI's Declaration is devoid of any statement that he was present during the search and there is no other evidence establishing that the vials were seized from Respondent's residence. And while GX 13 contains a photograph of two vials, with pills that are barely visible in the vials, there is no photograph of the pills outside of the vials, which might have shown that the pills bore the NDC Code for hydrocodone. Nor is there any evidence establishing that the pills were tested by a laboratory and found to be hydrocodone.¹⁸

¹⁸ Even giving weight to the DI's assertion that Respondent "purchased this item [*i.e.*, hydrocodone] on March 16, 2012 from Distributor A.F. Hauser, Inc.," DI Decl., at 6 (¶ 37); this statement likewise does not overcome the lack of substantial evidence establishing that these drugs were seized during the search of Respondent's residence.

As for the DI's assertion that the police also seized a vial containing clonazepam, here again, there is no evidence either that the DI was present during the search of Respondent's residence or that a vial containing this drug was seized during that search. And while the record contains a photograph of a vial, which bears a label listing Respondent as the prescriber, the drug as clonazepam, and the patient's name corresponding with the initials R.M., there is no evidence establishing that any pills were in the vial, let alone that the pills were clonazepam.¹⁹

Turning to the DI's assertion that Respondent "also possessed two (2) stock bottles that contained Meridia and diazepam," here again, there is no evidence establishing that the DI participated in the search of Respondent's residence, or any other evidence establishing that these drugs were seized during that search. To be sure, the Government cites to an exhibit, which contains several photographs, including one which shows six white bottles (several of which are clearly marked as professional samples) which bear the manufacturer's label for such drugs as Viagra, Topiramate, Ultram ER, and Meridia. *See* GX 15, at 1. However, of these drugs, only Meridia (sibutramine) is a controlled substance under federal law, 21 CFR 1308.14(e), and putting aside the absence of any evidence as to where and when this drug was seized, here again, there is no evidence that there actually was any of the drug in the bottle at the time it was seized. As for the DI's assertion that a stock bottle of diazepam was also seized during the search of Respondent's residence, here too, there is no evidence (indeed, not even a photograph of the bottle) to support the DI's contention.

Finally, the DI stated that on July 7, 2012, state and local law enforcement executed a search warrant at a fourth residence which is owned by Respondent and located in Marysville, Washington. DI Decl., at 5. The DI further stated that during the search, the officers "seized some marijuana grow equipment and marijuana leaves." *Id.* Here again, the DI's affidavit does not establish the basis of his knowledge.

Regarding the searches of the properties other than his residence, Respondent acknowledged that he owned "three rental properties." Resp. Decl., at 3. He also acknowledged that

¹⁹ In his Declaration, Respondent denied that he "ha[s] or store[s] any [h]ydrocodone or [c]lonazepam at home." Resp. Decl., at 5. He further stated that "[t]he prescription bottles are prescribed for my wife for her liposuction procedures post-operational pain where she had four liposuction procedures performed from 7/9/11 to 11/3/12." *Id.*

“one of the rental houses had an electrical burn that shed light on the others that had illegal activities.” *Id.* at 4. He then asserted that he “had irresponsible tenants that took advantage of the locations by cultivating [m]arijuana for 6 months without [his] knowledge” and that he “do[es] not personally inspect, supervise, or manage the rentals on a regular basis,” because he works six days a week in his medical practice, and that “[w]hen the rent is timely paid with no complaints that need repair, [he has] no need to bother tenants at their home.” *Id.* at 3–4. Later in his declaration, Respondent stated that “[i]f something is broke they send me a bill for repair and I deduct it from the rent.” *Id.* at 5.

On May 22, 2013, Respondent was indicted in United States District Court for the Western District of Washington and charged with conspiracy to manufacture and distribute marijuana. *DI Decl.*, at 11; *see also* GX 31. Moreover, on October 22, 2013, a superseding indictment was filed against Respondent and his girlfriend.

The superseding indictment alleged that Respondent and others conspired to grow marijuana at several residential properties and that Respondent “made at least three of those properties available . . . for the purpose of manufacturing marijuana,” that he “purport[ed] to rent [the houses] to others, knowing that the persons listed as ‘tenants’ for these properties did not, in fact, reside there and/or did not pay rent,” that he and his co-conspirators “set up large-scale marijuana grows for the purpose of manufacturing marijuana within the houses” and “caused the electrical power in these houses to be diverted around the meters, thus stealing power to run the marijuana grows,” and that he and his co-conspirators “recruited and directed others to help grow and harvest the marijuana plants, and maintain the houses and yards at these properties.” Superseding Indictment, at 2, *United States v. Thi Nguyen Tram Bui and Keith Ky Ly*, No CR13–157JCC (W.D. Wash. 2013) (citing, *inter alia*, 21 U.S.C. 841(a)(1) and (b)(1)(A), 846). The Indictment further charged Respondent with three counts of manufacturing marijuana at his properties in Renton, Shoreline and Marysville, Washington, as well as three counts of maintaining drug-involved premises. *Id.* at 4–7 (citing 21 U.S.C. 841(a)(1) and (b)(1)(B); 856(a)(1) and 856(b)). The indictment also set forth additional allegations regarding the quantities of marijuana plants and/or harvested marijuana that were seized during the searches of his Renton and Shoreline properties, as

well as the quantity of marijuana which was seized from his girlfriend. *Id.* at 3.

Respondent went to trial; the jury found him guilty on all counts.²⁰ On December 19, 2014, the United States District Court convicted Respondent on each of the above counts and sentenced him to 60 months of imprisonment, imposed a four-year term of supervised release following his release from imprisonment, imposed an assessment of \$1,000, and ordered that various property be forfeited. Judgment, at 1–6, *United States v. Keith K. Ly* (W.D. Wash. Dec. 19, 2014).

The DEA Investigation

According to the DI’s affidavit, on July 13, 2012, DEA Investigators visited Respondent’s registered location and upon obtaining his consent, conducted an inspection. *DI’s Decl.*, at 6; *see also* GX 20 (Notice of Inspection manifesting Respondent’s consent to the inspection and witnessed by the DI). As part of the inspection, the Investigators asked Respondent to produce his records, including his controlled substance inventories, dispensing and administration logs, invoices, returns, distributions, as well as theft and loss reports. *Id.*

The DIs determined that Respondent “failed to take and maintain an initial or biennial inventory of all stocks of controlled substances on hand.” *Id.* While Respondent produced a dispensing log, which covered the period from December 23, 2010 to July 11, 2012, according to the DI, 128 of the entries lacked required information. *Id.* More specifically, the DI asserted that 82 entries did not have the patient’s address, the name of the controlled substance, the finished form, and the dispenser’s initials. *Id.* at 6–7. According to the DI, another 46 entries lacked the patient’s address, name of the controlled substance, the quantity dispensed, and the dispenser’s initials. *Id.* at 7.

As part of the record, the Government submitted a copy of Respondent’s dispensing log. GX 21. A review of the log corroborates the DI’s assertion that many of the entries which record the dispensing of controlled substances lack various items of information required by federal law, including the patient’s address and the dispenser’s initials. *See id.* at 6–9. As for the contention that numerous entries did not contain the name of the controlled substance that was dispensed, it is true that numerous entries were missing the “Medication ID

²⁰ Respondent was also charged and convicted of three counts of wire fraud, based on claims he made to an insurance company.

Sticker.” *Id.* at 1–5. Yet the Government produced no evidence to prove that these dispensings actually involved controlled substances as opposed to non-controlled drugs.

The DI also asserted that Respondent “failed to maintain or provide any dispensing/administration records for Testosterone and Testim samples located at the registered location.” *DI Decl.*, at 7. The DI further asserted that Respondent did not “maintain[] at least four Schedule III–V acquisition invoices and by not recording the dates of receipt on at least five invoices.” *Id.*²¹

The DIs also conducted an audit of the controlled substances which were located at Respondent’s registered location. *Id.* In his declaration, the DI stated that “DEA used an initial inventory date of January 1, 2012, beginning of business, and noted that the initial inventory was ‘zero’ due to the lack of an initial or biennial inventory.” *Id.* To determine the amounts of the various drugs Respondent purchased, the DIs relied on “a summary of the invoices provided by distributor A.F. Hauser”; they also used his dispensing log to determine the amounts that he dispensed. *Id.* The DI further stated that he used “the closing inventory assembled by DEA investigators during the on-site inspection.” *Id.*

The DI then asserted that the “audit revealed large shortages of testosterone, phentermine, phendimetrazine, and a 14% shortage or[sic] hydrocodone.” *Id.* More specifically, the DI asserted that Respondent had a shortage of 300 mg of Testosterone 200 mg/ml, 6,028 tablets of phentermine 37.5 mg,²² 2,102 tablets of phendimetrazine 35 mg, and 71 tablets of hydrocodone 10/500 mg. *Id.* at 8.

The Government also submitted a document which appears to be the aforesaid summary of Respondent’s controlled substance purchases from A.F. Hauser between January 1, 2010 and July 24, 2012, *see* GX 16, as well as the audit computation chart. GX 23. Significantly, the audit chart lists the initial inventory date as “1–1–2010 COB” and not January 1, 2012 as set

²¹ The DI also stated that during the inspection, Respondent did not provide any “Report[s] of Theft or Loss of Controlled Substances” (DEA Form 106). *DI Decl.*, at 7. He also reviewed all of the hard copy Theft and Loss Reports on file with the Seattle Field Office, as well as queried the Drug Theft Loss database, which gathers all of the Form 106s which are submitted online, and determined that Respondent had not submitted any such reports. *Id.*

²² According to the DI’s declaration, the shortage was 6,028 tablets. *DI Decl.*, at 8. Based on the audit chart, which lists the shortage as 6,028 tablets, GX 23, I conclude that the former figure is a typographical error.

forth in the DI's declaration. *Compare* GX 23 with DI Decl., at 7.

This disparity has a material impact on the accuracy of the audit results. For example, according to the DI's declaration (and the computation chart), Respondent was short more than 6,000 dosage units of phentermine. Yet, according to the summary of Respondent's purchases and the invoices, Respondent only purchased 3,000 dosage units of phentermine during 2012. Thus, if—as stated by the DI—the beginning date of the audit period was January 1, 2012 and zero was assigned as the opening inventory, Respondent could not have been short 6,000 dosage units.

So too, in his declaration, the DI asserted that Respondent was short more than 2,100 phendimetrazine tablets (the same figure listed on the computation chart, which also lists 3,000 dosage units as having been purchased). However, the Government's other evidence shows that Respondent did not purchase any phendimetrazine during 2012. *See* GX 16. Here again, Respondent could not have been short 3,000 dosage units if the beginning date of the audit period was January 1, 2012, as stated by the DI in his sworn declaration.

As for the testosterone, while there is evidence that Respondent also purchased testosterone in February 2012, the data as presented in the computation chart suggests that he purchased 400 10ml bottles and that he could not account for 300 bottles. *See* GX 23 (listing drug as "Testosterone 200mg/ml—10 ml bottle" and listing the "[t]otal purchased" as 400.) However, the Government's other evidence, *i.e.*, the listing of Respondent's purchases, which according to the DI was prepared by A.F. Hauser, lists the quantity of Respondent's purchases as only "2.00." GX 19. Thus, here again, there is reason to question the reliability of the audit results.²³

With respect to the remaining drugs, there is evidence that Respondent purchased 500 dosage units of hydrocodone during 2012 (GX 19) and was short 71 tablets. GX 23. There is also evidence that at the time of the July 2012 inspection, Respondent had on hand 21 Testim 1% samples. While the DIs concluded that Respondent had an overage of these 21 samples, there is no evidence as to who distributed the samples to him and there is no evidence the DIs asked Respondent for any of the

²³ Moreover, even if the entry in the computation chart was actually intended to be 400mg (or two bottles) as opposed to 400 bottles, at most Respondent would not be able to account for 1.5 bottles.

documentation establishing the amount of Testim that was distributed to him.²⁴ Finally, the Government's evidence shows that in March 2012, Respondent purchased 1,000 dosage units of Lorazepam, GX 16, and the computation chart indicates that the audit balanced with respect to this drug. GX 23.

In his declaration, the DI further asserted that Respondent failed to report to the State of Washington's Prescription Monitoring Program (PMP), "at least 45 occasions from January through July 2012" in which he "dispensed more than a 24-hour supply of controlled substances." DI Decl., at 8. According to the DI, this was a violation of Washington law. *Id.* The Government did not, however, submit the PMP reports which establish the basis for its assertion.

Regarding this allegation, Respondent stated that he "was not aware of this Washington State law requirement . . . [and] thus cannot have . . . repeatedly failed" to comply or to have shown a "consistent disregard" for this requirement. Resp. Decl., at 8. Respondent then stated that "I am now made fully aware and will comply with the law. This is not an intentional violation." *Id.*²⁵

Discussion

Under the CSA, "[a] registration pursuant to section 823 of this title to manufacture, distribute, or dispense a controlled substance . . . may be suspended or revoked by the Attorney General upon a finding that the registrant . . . has committed such acts as would render his registration under section 823 of this title inconsistent with the public interest as determined under such section." ²⁶ 21 U.S.C. 824(a)(4). The Act further provides that in determining "the public interest" with respect to a practitioner's

²⁴ It is further noted that while the computation chart contains a column for the "Total Purchased," which was added to the "Initial Inventory" to arrive at the "Amount Accountable For," samples are not typically purchased and the chart contains no column for other means of acquisition. GX 23.

²⁵ Based on the DI's Declaration, the Government proposes that I make a factual finding that following the issuance of the Immediate Suspension Order, Respondent "issued at least three (3) prescriptions to two (2) separate patients on February 1, March 2, and March 30, 2013, in violation of the Order." Request for Final Agency Action, at 5 (citing DI's Declaration at 9–10). However, in its Request for Final Agency Action, the Government does not propose that I make any conclusion of law based on this conduct. *See id.* at 6–12. Accordingly, I do not consider this conduct.

²⁶ Pursuant to 28 CFR 0.100(b), this authority has been delegated by the Attorney General to the Administrator of the Drug Enforcement Administration.

application, the following factors be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.

(3) The [registrant's] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f).

"[T]hese factors are . . . considered in the disjunctive." *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). It is well settled that I "may rely on any one or a combination of factors, and may give each factor the weight [I] deem appropriate in determining whether a registration should be revoked." *Id.*; *see also MacKay v. DEA*, 664 F.3d 808, 816 (10th Cir. 2011); *Volkman v. DEA*, 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005). Moreover, while I am required to consider each of the factors, I "need not make explicit findings as to each one." *MacKay*, 664 F.3d at 816 (quoting *Volkman*, 567 F.3d at 222 (quoting *Hoxie*, 419 F.3d at 482)).²⁷

The Government has the burden of proving, by a preponderance of the evidence, that the requirements for revocation or suspension pursuant to 21 U.S.C. 824(a) are met. 21 CFR 1301.44(e). This is so even in a non-contested case.

In this matter, I have considered all of the factors. While I find that some of the allegations are not supported by substantial evidence, I nonetheless find that the Government's evidence with respect to factors one, two, three, and four establishes that he has committed acts which render his registration "inconsistent with the public interest." 21 U.S.C. 823(f). While I have also considered Respondent's declaration with respect to the various allegations, I conclude that he has not presented sufficient evidence to rebut this conclusion. Accordingly, I will affirm the suspension of his registration and

²⁷ "In short, this is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest; what matters is the seriousness of the registrant's misconduct." *Jayam Krishna-Iyer*, 74 FR 459, 462 (2009). Accordingly, as the Tenth Circuit has recognized, findings under a single factor can support the revocation of a registration. *See MacKay*, 664 F.3d at 821.

further order that his pending application be denied.

Factor One—The Recommendation of the State Licensing Board

As found above, on September 22, 2014, the Washington Board of Osteopathic Medicine and Surgery issued Respondent an Ex Parte Order of Summary Action, pursuant to which, his authority to practice medicine in the State was suspended. Under the CSA, a practitioner's possession of authority to dispense controlled substances under the laws of the State in which he seeks registration is a prerequisite to obtaining a registration. *See* 21 U.S.C. 823(f) ("The Attorney General shall register practitioners . . . to dispense . . . controlled substances . . . if the applicant is authorized to dispense . . . controlled substances under the laws of the State in which he practices."); *see also id.* § 802(21) (defining "[t]he term 'practitioner' [to] mean[] a physician . . . licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices . . . to . . . dispense . . . [or] administer . . . a controlled substance in the course of professional practice").

Because Respondent is no longer authorized by the State of Washington to practice medicine and dispense controlled substances, he is not authorized to hold a registration in that State. This provides reason alone to deny his application. However, because the Government also seeks a final order based on the allegations of the Order to Show Cause and Immediate Suspension of Registration, I address the evidence with respect to the other public interest factors.

Factor Two—Respondent's Experience in Dispensing Controlled Substances

The Government contends that Respondent unlawfully distributed controlled substances to various persons who were arrested during the search of his Shoreline property. Req. for Final Agency Action, at 10 (citing, *inter alia*, 21 U.S.C. 841(a)(1)). More specifically, the Government contends that Respondent "prescribed hydrocodone . . . to an individual arrested at the Shoreline" property and could "not locate a patient file at [his] registered location for this particular individual." *Id.* Based on the Investigators' "determin[ation] that [Respondent] also purchased the loose phentermine tablets located on individuals at the Shoreline residence on March 16, 2012, despite the fact that he could not produce patient records when requested by law enforcement," the Government also apparently contends that Respondent

unlawfully distributed the tablets to these individuals. *Id.* at 11.

Neither of these allegations is proved by substantial evidence. As for the allegation regarding the hydrocodone prescription, as found above, in his Declaration, the DI repeatedly referred to this person as L.E. Yet to support the allegation, the Government offered a copy of a prescription which was issued to a patient whose initials are H.L. and not L.E. Moreover, the Government points to no other evidence that Respondent even prescribed hydrocodone (or any controlled substance for that matter) to a person whose initials are L.E. Thus, the allegation is unsupported by substantial evidence.

As for the allegation that the phentermine was found on two persons who were arrested during the Shoreline search and was distributed to them by Respondent, while the Government produced evidence that Respondent had ordered phentermine from his distributor several months earlier, the evidence offered to establish that phentermine was found on these individuals was limited to the DI's assertion that it was. The DI did not, however, offer any basis for concluding that he personally participated in the search—notwithstanding his assertion that his declaration was based on "personal knowledge"—nor otherwise explain the basis for his statement. Finally, the Government offered no other evidence to prove this assertion such as a police report, an affidavit of the arresting officer, or an inventory of the items found during the search conducted incident to the purported arrest of these individuals. The allegation therefore fails for lack of substantial evidence.

The evidence further shows that Respondent purchased controlled substances including hydrocodone with acetaminophen, phentermine, phendimetrazine, testosterone, and lorazepam, which he dispensed directly to his patients. Under federal law, Respondent was required upon "first engag[ing] in the . . . dispensing of controlled substances, and every second year thereafter, [to] make a complete and accurate record of all stocks thereof on hand." 21 U.S.C. 827(a)(1). Also, under federal law, because he engaged in the dispensing of the controlled substances, Respondent was required to "maintain, on a current basis, a complete and accurate record of each such substance . . . received, sold, delivered, or otherwise disposed of by him." *Id.* § 827(a)(3). DEA regulations further require that a dispenser maintain a record "of the number of units or

volume of such finished form dispensed, including the name and address of the person to whom it was dispensed, the date of dispensing, the number of units or volume dispensed, and the written or typewritten name or initials of the individual who dispensed or administered the substance on behalf of the dispenser." 21 CFR 1304.22(c). Finally, under this regulation, Respondent was required to maintain records of the controlled substances he acquired, to include "[t]he name of the substance"; "[e]ach finished form . . . and the number of units or volume of finished form in each commercial container"; and "[t]he number of units of finished forms and/or commercial containers acquired from other persons, including the date of and number of units and/or commercial containers in each acquisition to inventory and the name, address, and registration number of the person from the units were acquired." *Id.* § 1304.22(a)(2)(i), (ii), and (iv).

Here, I give no weight to the audit results given the numerous problems found above, including the conflict in the Government's evidence as to what the DIs used as the beginning date for the audit period. Nonetheless, I find that the DI's declaration establishes that during the July 2012 inspection, Respondent could not produce the required inventories for the controlled substances he was handling, and was thus in violation of 21 U.S.C. 827(a)(1).²⁸ Moreover, the DI's declaration establishes that while Respondent was engaged in dispensing controlled substances, many of the entries for his phentermine dispensings lacked the patient's address and the name or initials of the person who did the actual dispensing.²⁹ Thus, Respondent violated the CSA and DEA regulations for these reasons as well.³⁰ *See* 21 U.S.C. 827(a)(3); 21 CFR

²⁸ Regarding the lack of inventories, Respondent stated that he "ha[d] invoices from [his distributor] as my initial inventory." Resp. Decl., at 7. Contrary to Respondent's contention, under the CSA, the requirement to take and maintain complete and accurate inventories is separate from the requirement to maintain records of the controlled substances a registrant acquires. *Compare* 21 U.S.C. 827(a)(1) *with id.* § 827(a)(3); *compare also* 21 CFR 1304.11 *with id.* § 1304.22. I therefore reject Respondent's contention. I further note that during the inspection, the DI found that Respondent did not have all of the invoices.

²⁹ While in his declaration Respondent states that this information was in the patient charts and that there is only limited space in his dispensing log, *see* Resp. Decl., at 7; DEA regulations require that the patient's address be documented in the dispensing log. 21 CFR 1304.22(c).

³⁰ As for the various entries in the dispensing log which lacked the name of the drug, because the Government provided no evidence that the dispensings involved controlled substances, I place

1304.22(c). Finally, the DI's declaration establishes that Respondent lacked complete records of the controlled substances he acquired from his distributor, in violation of 21 U.S.C. 827(a)(3), as well as 21 CFR 1304.22(c). See also 21 CFR 1304.22(a)(2)(i), (ii), and (iv).

As both the Agency and the federal courts have explained, recordkeeping is one of the CSA's fundamental features for preventing the diversion of controlled substances. See *Gonzales v. Raich*, 545 U.S. 1, 14 (2005) ("The CSA and its implementing regulations set forth strict requirements regarding . . . recordkeeping."); *United States v. Poulin*, 926 F. Supp. 246, 250 (D. Mass. 1996) ("The [CSA] focuses on recordkeeping, in an attempt to regulate closely the distribution of certain substances determined by Congress to pose dangers, if freely available, to the public at large.") (int. quotations and citation omitted); *Paul H. Volkman*, 73 FR 30630, 30644 (2008) ("Recordkeeping is one of the CSA's central features; a registrant's accurate and diligent adherence to this obligation is absolutely essential to protect against the diversion of controlled substances.").

Respondent's recordkeeping violations alone are sufficiently egregious to support the conclusion that he "has committed such acts [which] render[ed] his registration . . . inconsistent with the public interest." 21 U.S.C. 824(a)(4); see also *Volkman*, 73 FR at 30644 (holding that recordkeeping violations alone can support revocation or denial of an application).

Factor Three—Respondent's Conviction Record Under Federal and State Laws Related to the Manufacture, Distribution, and Dispensing of Controlled Substances

As found above, following a jury trial, on December 19, 2014, Respondent was convicted by the United States District Court on seven felony counts related to the manufacture and distribution of marijuana, including conspiracy to distribute or manufacture marijuana, three counts of manufacturing marijuana, and three counts of

maintaining drug involved premises.³¹ Each of these convictions provides reason alone to deny his application. And under the doctrine of collateral estoppel, the convictions also preclude any challenge to the allegations that he was engaged in the unlawful manufacture of marijuana. See *Robert L. Daugherty*, 76 FR 16823, 16830 (2011).

Factor Four—Compliance With Applicable Laws Related to Controlled Substances

With respect to this factor, the Government raises three main allegations. First, based on the various searches, the Government argues that Respondent possessed and was engaged in the manufacture of marijuana, a schedule I controlled substance. Request for Final Agency Action, at 8–9 (citing 21 U.S.C. 841(a)(1), 844(a); 812(c)). Second, the Government alleges that during the search of Respondent's residence, several vials of controlled substances were found including one each of clonazepam and hydrocodone, the latter being in an unlabeled vial, as well as stock bottles of Meridia and diazepam, and that Respondent's possession of the drugs violated federal law because he was not registered at his residence. *Id.* (citing 21 U.S.C. 844(a); 21 CFR 1301.75(b)). Third, the Government alleges that Respondent violated state law by failing to report to the Washington Prescription Monitoring Program some 45 instances in which he dispensed more than a twenty-four hour supply of a controlled substance. *Id.* at 9.

As for the latter allegation, Respondent did not dispute that he had failed to report various dispensings to the State's PMP. Resp. Decl., at 8. Rather, he claimed his violations were unintentional because he was unaware of the law but would now comply. *Id.*

However, this is not a valid defense as the Washington courts follow the traditional rule that ignorance of the law is no excuse. See *State v. Reed*, 928 P.2d 469, 471 (Wash. Ct. App. 1997) (other citation omitted). Accordingly, I find that Respondent violated Washington law by failing to report various dispensings to the State's PMP. See Wash. Rev. Code § 70.225.020(2).

As for the allegations pertaining to the controlled substances that the police found during the search of Respondent's residence, I conclude that the Government did not provide substantial evidence to support the allegations with respect to any of the four drugs (Meridia, diazepam, clonazepam (in a vial indicating that Respondent had prescribed the drug to R.M.) or hydrocodone (in an unlabeled vial)). With respect to the diazepam, the Government produced absolutely no evidence that the drug was even seized during the search. With respect to the Meridia, the Government's evidence was limited to a photograph of a white professional sample bottle and the DI's unsupported assertion, with no other evidence to establish that the bottle was seized from Respondent's residence, let alone that there were any pills in the bottle when it was seized.

So too, with respect to the hydrocodone and clonazepam, there is no evidence other than photographs and the DI's unsupported assertion that these drugs were seized during the search of Respondent's residence. To be sure, in his declaration, Respondent stated that he prescribed the hydrocodone and clonazepam to his wife for several procedures. However, Respondent explicitly denied having or storing clonazepam or hydrocodone at his home and his statements do not constitute an admission of any part of this allegation. Accordingly, these allegations fail for lack of substantial evidence.

I also find that substantial evidence supports the remaining marijuana-related allegation—that on February 2, 2012, Respondent violated federal law by possessing marijuana, and that he did so with the intent to distribute. Most significantly, it is undisputed that upon the February 2, 2012 arrest of TB, (Respondent's then live-in girlfriend and now wife), who was then driving his car, the police impounded his vehicle and during the subsequent search of the vehicle found one pound of marijuana and \$5,000 in cash; the police also found \$3,900 in cash in TB's purse.

As found above, the street value of the marijuana was approximately \$1,500 to \$1,800, and the quantity would provide approximately 900 joints. Respondent denied having any knowledge of the marijuana, asserting that it had been left in his car by LHE, a friend of TB and a purported medical marijuana patient who TB allowed to borrow his car, and provided an unsworn statement from LHE to this effect. However, as I found above, her statement (that she left the marijuana in the car because she was in

no weight on this evidence. As for the Government's assertion that Respondent failed to maintain a "dispensing/administration log for testosterone and Testim samples," Request for Final Agency Action, at 8; there is no evidence that he dispensed any Testim samples. As for the testosterone, the evidence does suggest that Respondent administered approximately 300 mg or 1.5 vials without documenting the administrations in his dispensing log. See 21 CFR 1304.03(d).

³¹ As to the latter offense, the CSA renders it unlawful to "knowingly use[] or maintain any place, whether permanently or temporarily, for the purpose of manufacturing, distributing, or using any controlled substance." 21 U.S.C. 856(a)(1). As the evidence shows that Respondent used and maintained the three properties for the purpose of manufacturing marijuana and not simply as places to use the drugs, I conclude that his convictions for maintaining drug-involved premises fall within factor three.

such a hurry to return the car to TB and forgot it) is utterly ludicrous.³² I therefore reject Respondent's explanation for why the police found one pound of marijuana in his car.

Moreover, given the closeness of the relationship between Respondent and TB in that they were living together and that TB also worked for him, I find it implausible that Respondent lacked knowledge of the marijuana. Rather, I find that Respondent had the ability to exercise dominion or control over the marijuana through TB and thus constructively possessed the drug. See *United States v. Sanders*, 341 F.3d 809, 816 (8th Cir. 2003) (“To prove constructive possession, the government had to present evidence that appellants had knowledge and ownership, dominion or control over the contraband itself, or dominion over the vehicle in which the contraband is concealed.”) (quoting *Ortega v. United States*, 270 F.3d 540, 545 (8th Cir. 2001)).

So too, Respondent's attempt to explain the presence of the large sum of cash (nearly \$9,000) that was found in his car and on his wife's person does not persuade. As for the money which was purportedly paid by a patient the day before as a deposit on a liposuction procedure, as found previously, while the “Price Quote” document indicates that the patient paid a \$5,000 cash deposit, the date was clearly written over. And while the purported patient provided a letter to support Respondent, it too was unsworn.

As an additional explanation for why so much money was found in his car, Respondent stated that the money had been withdrawn to pay for remodeling his clinic. To support this claim, Respondent submitted a copy of a bank statement (on which the various balances are blacked out), which documents that he made a withdrawal *nine days* before his girlfriend was arrested. However, Respondent offered no further evidence to support this contention, and in any event, his explanation begs the question of why he would risk the potential theft or loss of a large sum of cash, rather than pay for the purported remodeling with a check or credit card.

I therefore find that both the quantity of the marijuana (which would provide a single person with three joints a day for approximately ten months), and the large amount of cash which was found

in Respondent's vehicle, support a finding that the marijuana was intended for distribution. See *United States v. Collins*, 412 F.3d 515, 519 (4th Cir. 2005) (holding that “intent to distribute can be inferred from a number of factors, including . . . the quantity of drugs” and “the amount of cash seized with the drugs.”). I further find that Respondent “had the right to exercise dominion and control over” the marijuana “either directly or through” TB. *United States v. Staten*, 581 F.2d 878, 883 (D.C. Cir. 1978). I therefore find that Respondent knowingly possessed marijuana with the intent to distribute it.³³ See 21 U.S.C. 841(a)(1).

Based on Respondent's violation of federal law by possessing marijuana with the intent to distribute, as well as his admitted failure to report multiple dispensings of controlled substances to the Washington PMP, I find that factor four also supports a finding that he has committed acts which rendered his registration “inconsistent with the public interest.”³⁴ 21 U.S.C. 823(f) & 824(a)(4).

Sanction

Under Agency precedent, where, as here, “the Government has proved that a registrant has committed acts inconsistent with the public interest, the registrant must ‘‘present sufficient mitigating evidence to assure the Administrator that [he] can be entrusted with the responsibility carried by such a registration.’’’ *Medicine Shoppe—Jonesborough*, 73 FR 364, 387 (2008) (quoting *Samuel S. Jackson*, 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller*, 53 FR 21931, 21932 (1988))). “Moreover, because ‘past performance is the best predictor of future performance,’ *ALRA Labs, Inc. v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995), [DEA] has repeatedly held that where a

registrant has committed acts inconsistent with the public interest, the registrant must accept responsibility for [his] actions and demonstrate that [he] will not engage in future misconduct.” *Medicine Shoppe*, 73 FR at 387; see also *Jackson*, 72 FR at 23853; *John H. Kennedy*, 71 FR 35705, 35709 (2006); *Prince George Daniels*, 60 FR 62884, 62887 (1995). See also *Hoxie*, 419 F.3d at 483 (“admitting fault” is “properly consider[ed]” by DEA to be an “important factor[]” in the public interest determination). So too, in making the public interest determination, “this Agency also places great weight on an [applicant's] candor, both during an investigation and in [a] subsequent proceeding.” *Robert F. Hunt*, 75 FR 49995, 50004 (2010) (citing *The Lawsons, Inc., t/a The Medicine Shoppe Pharmacy*, 72 FR 74334, 74338 (2007) (quoting *Hoxie*, 419 F.3d at 483) (“Candor during DEA investigations properly is considered by the DEA to be an important factor when assessing whether a . . . registration is consistent with the public interest.”)).

Moreover, while a registrant must accept responsibility and demonstrate that he will not engage in future misconduct in order to establish that granting his application for registration is consistent with the public interest, DEA has repeatedly held these are not the only factors that are relevant in determining whether to grant or deny an application. See, e.g., *Joseph Gaudio*, 74 FR 10083, 10094 (2009); *Southwood Pharmaceuticals, Inc.*, 72 FR 36487, 36504 (2007). Obviously, the egregiousness and extent of a registrant's misconduct are significant factors in determining the appropriate disposition. Cf. *Jacobo Dreszer*, 76 FR 19386, 19387–88 (2011) (explaining that a respondent can “argue that even though the Government has made out a *prima facie* case, his conduct was not so egregious as to warrant revocation”); see also *Paul H. Volkman*, 73 FR 30630, 30644 (2008); *Gregory D. Owens*, 74 FR 36751, 36757 n.22 (2009).

Moreover, as I have noted in several cases, “[n]either *Jackson*, nor any other agency decision, holds . . . that the Agency cannot consider the deterrent value of a sanction in deciding whether a registration should be [suspended or] revoked,” or whether an application should be denied. *Gaudio*, 74 FR at 10094 (quoting *Southwood*, 72 FR at 36503 (2007)); see also *Robert Raymond Reppy*, 76 FR 61154, 61158 (2011); *Michael S. Moore*, 76 FR 45867, 45868 (2011). This is so, both with respect to the respondent in a particular case and the community of registrants. See *Gaudio*, 74 FR at 10095 (quoting

³² As also noted, in a March 3, 2012 letter to the local prosecutor in which Respondent sought the return of his car, he denied having any knowledge of the marijuana that was found therein. See Resp. Decl., at Ex. 4. Yet he made no mention of LHE's story. See *id.*

³³ In his Declaration, Respondent disputed that he owned the marijuana plants, the processed marijuana, and related items that were seized in the searches of his three properties. See Resp. Decl., at 3 (“I have three rental properties. I had irresponsible tenants that took advantage of the locations by cultivating Marijuana for 6 months without my knowledge.”). He also claimed that because he was a busy physician, who did not bother his tenants if they paid their rent and did not request repairs, he “did not know of . . . nor . . . in any way participate in the growing of marijuana at these rental houses.” *Id.* at 4. Based on Respondent's convictions for conspiracy to manufacture marijuana, unlawful manufacture of marijuana at each of the three grow houses, and maintaining drug-involved premises at each of the three residences, I reject his assertions as utterly false.

³⁴ Having already addressed the various false statements regarding the marijuana-related allegations which Respondent has made in his declaration, I deem it unnecessary to repeat this discussion under factor five.

Southwood, 71 FR at 36504). *Cf. McCarthy v. SEC*, 406 F.3d 179, 188–89 (2d Cir. 2005) (upholding SEC’s express adoption of “deterrence, both specific and general, as a component in analyzing the remedial efficacy of sanctions”).

As found above, the Government has established that Respondent: 1) committed multiple recordkeeping violations in that he did not have required inventories, was missing invoices, and his dispensing log lacked required information; 2) was engaged in the manufacture and distribution of marijuana; and 3) failed to report multiple dispensings of controlled substances to the Washington PMP. I find that the proven misconduct is sufficiently egregious to affirm the Order of Immediate Suspension and to deny his pending application to renew his registration. *See, e.g., Moore*, 76 FR at 45870 (imposing one-year suspension on physician who manufactured marijuana, notwithstanding ALJ’s finding that physician accepted responsibility and demonstrated he would not engage in future misconduct).³⁵ I further find that the Agency’s interest in deterring similar acts on the part of both Respondent and others supports the denial of his pending application.

Having carefully reviewed Respondent’s declaration, I further find that Respondent has not accepted responsibility for his misconduct. Regarding his recordkeeping violations, Respondent entirely denied that he failed to keep the required inventories and that he was missing various invoices. Moreover, he further claimed that the reason his dispensing log was missing essential information such as patient addresses was because there was no room to make these entries. Yet in DEA’s experience, thousands of other registrants who engage in dispensing have no problem complying with the latter requirements.

With respect to the marijuana allegations, Respondent offered the far-fetched story that the marijuana belonged to an acquaintance of his wife,

³⁵ In *Moore*, I agreed with the ALJ’s finding that the physician’s conduct in manufacturing and distributing marijuana supported revocation of his registration. 76 FR at 45866. However, I also agreed with the ALJ’s finding that the physician had accepted responsibility for his misconduct and demonstrated that he would not engage in future misconduct. *Id.* By contrast, here, the record establishes that in addition to his marijuana-related misconduct, for which he disingenuously denies any responsibility, Respondent also committed multiple recordkeeping violations and violated state law by failing to report numerous dispensings to the State PMP. Also, in contrast to *Moore*, I find that Respondent has not accepted responsibility for his misconduct.

who had borrowed his car to obtain her medical marijuana but who was in such a hurry to return the car that she forgot to retrieve it even though it was her medicine. So too, Respondent’s alternative explanations for why thousands of dollars of cash were found in his car defy credulity. Similarly, his claim that he was unaware of the marijuana growing activities which were being conducted at not one, not two, but three of his properties, is clearly disingenuous.³⁶ Accordingly, based on his various false statements regarding the marijuana-related activity, as well as his blatantly false assertion that he has never been subject to discipline by a state licensing authority (all of which are clearly material to the outcome of this proceeding), I further find that Respondent lacks candor.

Based on his failure to acknowledge his misconduct, his failure to offer any credible evidence of remedial efforts, and his lack of candor, I conclude that Respondent has failed to present sufficient evidence to rebut the Government’s *prima facie* showing that his registration would be “inconsistent with the public interest.” 21 U.S.C. 823(f); *see also id.* 824(a)(4). Therefore, I will affirm the issuance of the Order of Immediate Suspension and order that any pending application to renew Respondent’s registration be denied.

ORDER

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a), as well as 28 CFR 0.100(b), I affirm the Order of Immediate Suspension of DEA Certificate of Registration BL6283927, issued to Keith Ky Ly, D.O. I further order that the application of Keith Ky Ly, D.O., to renew his registration, be, and it hereby is, denied. This Order is effective June 19, 2015.

Dated: May 11, 2015.

Michele M. Leonhart,

Administrator.

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³⁶ With regard to his failure to report dispensings to the Washington PMP, Respondent claimed that he was unaware of the law. However, the legislation which created the Washington PMP was enacted in 2007, more than four years earlier, and as a physician who engaged in the highly regulated activity of dispensing controlled substances, Respondent was obligated to keep abreast of legislation and regulatory developments applicable to his medical practice. Moreover, while Respondent asserted that he is now aware of the requirement and will comply in the future, his various statements regarding the events at issue (including that he had never been disciplined by a state board) support a finding that he lacks candor. Accordingly, I give no weight to his statement that he would comply with the State’s PMP reporting requirement in the future.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 11–71]

Cove Inc., D/B/A Allwell Pharmacy; Decision and Order

On April 23, 2013, Administrative Law Judge Christopher B. McNeil (hereinafter, ALJ) issued the attached Recommended Decision.¹ Neither party filed exceptions to the ALJ’s Recommended Decision.

Having reviewed the record in its entirety and the Recommended Decision, I have decided to adopt the ALJ’s findings of fact and conclusions of law, except as discussed below. I further adopt the ALJ’s recommended order that Respondent’s application be denied.

As explained in the ALJ’s Recommended Decision, in making the public interest determination, Congress directed the Agency to consider “the applicant’s experience in dispensing . . . controlled substances.” 21 U.S.C. 823(f)(2). The evidence showed that Respondent’s President and majority owner is Mrs. Ogechi Abalihi, and that while Mrs. Abalihi is a registered nurse, she is not a pharmacist and has no experience working in a retail pharmacy. Moreover, when questioned both during the pre-registration investigation and at the hearing as to whether she was familiar with the federal controlled-substance recordkeeping and security requirements for retail pharmacies, Mrs. Abalihi responded by stating, in essence, that those matters would be addressed by the pharmacist she would retain. Tr. 143–46. In her testimony, Mrs. Abalihi also made clear that she lacks knowledge of these requirements as they pertain to retail pharmacies, stating that “if there’s a requirement for me to do anything, know these things, study them, I will do them. But when I applied I was not made to understand that I need to know all this.” *Id.* at 144.

This is truly a remarkable answer, which fully demonstrates why granting Respondent’s application “would be inconsistent with the public interest.” 21 U.S.C. 823(f). Notwithstanding that the Order to Show Cause specifically alleged that the Agency’s investigation found Mrs. Abalihi “had no knowledge of DEA regulations pertaining to the handling of controlled substances and related security requirements,” ALJ Ex. 1, at 1; she still lacked knowledge of these requirements when she testified

¹ The ALJ’s Recommended Decision is cited as R.D.; all citations to the Recommended Decision are to the slip opinion issued by the ALJ.

some two years later.² While neither the Controlled Substances Act (CSA), nor the Agency's regulations, prohibits a pharmacy, which is owned by a non-pharmacist, from holding a DEA registration, the holder of the registration is ultimately accountable for ensuring compliance by its pharmacists with the requirements of the CSA and the Agency's regulations. *See United States v. Southern Union Co.*, 630 F.3d 17, 31 (1st Cir. 2010), *rev'd on other grounds*, 132 S.Ct. 2344 (2012) (quoted in *Holiday CVS, L.L.C., d/b/a CVS/ Pharmacy Nos. 219 and 5195*, 77 FR 62315, 62317 (2012) (“[T]hose who manage companies in highly regulated industries are not unsophisticated. . . . It is part of [a company’s] business to keep abreast of government regulation.”)).

It is indisputable that absent knowledge of the CSA and the Agency's regulations, a registrant cannot properly supervise its pharmacists to protect against the diversion of controlled substances.³ Thus, Mrs. Abalihi's admitted lack of knowledge of these requirements provides reason alone to conclude that granting Respondent's application “would be inconsistent with the public interest.” 21 U.S.C. 823(f).

I further adopt the ALJ's conclusion that the evidence with respect to factor five—such other conduct which may threaten public health and safety—supports the denial of Respondent's application. More specifically, the ALJ found that both Mrs. Abalihi and Ms. Taylor, who purportedly was to be Respondent's pharmacist-in-charge, made materially false statements to the Investigators when they were questioned regarding who would act as Respondent's pharmacist. However, upon review of the record, including the pleadings, I adopt the ALJ's conclusion only with respect to Ms. Taylor.

The evidence showed that when DEA Diversion Investigators (DI or DIs) asked Mrs. Abalihi who would manage the

pharmacy, she stated that Ms. Jacinta Taylor would do so. Tr. 34. Subsequently, the DIs interviewed Ms. Taylor, who is a licensed pharmacist (and the owner of ten percent of Respondent) and who stated that she would be the pharmacist-in-charge at Respondent. *Id.* at 38. Ms. Taylor also told the DIs that she would order the controlled substances and that the pharmacy would be open from nine to six on weekdays and nine to one on Saturday. *Id.* at 38–39.

However, during the interview, Ms. Taylor told the DIs that she had a full time position at a Sweetbay Pharmacy in Tampa, and worked between the hours of ten to eight. *Id.* at 39. A DI further testified that according to the State Pharmacy Board, Ms. Taylor was not listed as Respondent's supervising pharmacist. *Id.* When the DI asked Ms. Taylor “about that,” she replied that “she would leave Sweetbay if and when [Respondent] started to make money.” *Id.* at 40.

The DIs then asked Ms. Taylor who would be Respondent's pharmacist-in-charge given her full time position at Sweetbay and intent to continue working there until Respondent became profitable; Ms. Taylor identified a Ms. Mustafa, a co-worker at Sweetbay. *Id.* However, when the DIs told Ms. Taylor that they wanted to talk to Ms. Mustafa, Ms. Taylor stated that she did not think that Ms. Mustafa would want to be interviewed and added, “[w]ell, perhaps she won't work there.” *Id.* at 41. Subsequently, one of the DIs called Mrs. Abalihi and “asked her to put [him] in touch with Ms. Mustafa.” *Id.* at 42. While Mrs. Abalihi stated that she would contact Ms. Mustafa and either get her phone number for the DI “or have her call” him, he never received a call from Ms. Mustafa. *Id.*

Ms. Taylor did not testify at the hearing. However, in an affidavit, Ms. Taylor stated that she “was caught ‘flat footed’ ” by the question and “thought” that Ms. Mustafa, “another pharmacist who worked at Sweetbay, . . . might be willing to serve such role.” RX 7, at 2. Ms. Taylor further acknowledged that at the time of the interview, she “had not made formal arrangements for [a] replacement and had not yet asked Ms. Mustafa whether she would be willing to fulfill such role, but thought that Ms. Mustafa would be so willing.” *Id.* Moreover, in her testimony, Ms. Abalihi stated that she did not know Ms. Mustafa, that she had never spoken with her, and that there was “no plan” to have her work at Respondent. Tr. 138–39. And when asked by the ALJ whether in March 2011, Ms. Taylor had told her “that she would be relying on Ms.

Mustafa,” Mrs. Abalihi answered that Taylor “did not say she would be relying on Ms. Mustafa, no. She said the name came to her when this question was thrown to her. She wasn't expecting it, but the name came to her.” *Id.* at 161.

Notwithstanding her assertion that she was caught flatfooted, Ms. Taylor's affidavit, as well as Ms. Abalihi's testimony, establishes that Taylor had no basis in fact for her statement to the Investigators that Ms. Mustafa would be Respondent's pharmacist-in-charge until Ms. Taylor decided to start working there. Accordingly, Ms. Taylor's statement was false. Moreover, her statement was materially false in that it had the capacity to influence the Agency's decision to grant Respondent's application, because of the obvious need to determine whether those who will actually engage in dispensing activities on behalf of a proposed pharmacy registrant, hold the necessary state license and have not previously violated federal or state laws related to controlled substances. *See* 21 U.S.C. 823(f)(2) & (4) (directing Agency to consider the applicant's experience in dispensing controlled substances and compliance with applicable laws related to controlled substances); *see also* 21 CFR 1301.76(a) (“The registrant shall not employ, as an agent or employee who has access to controlled substances, any person who has been convicted of a felony offense relating to controlled substances or who, at any time, had an application for registration with the DEA denied, had a DEA registration revoked or has surrendered a DEA registration for cause.”).

I do not, however, adopt the ALJ's legal conclusion that Mrs. Abalihi made a material misrepresentation when she subsequently agreed to provide Ms. Mustafa's contact information rather than disclose that she knew nothing about Ms. Mustafa's role with the pharmacy. R.D. at 32. In support of his reasoning, the ALJ explained that “[i]f Ms. Abalihi intended on using contract pharmacists at the start of Allwell's operation, she had an affirmative duty to say so when DEA investigators asked her about the role Ms. Mustafa was to play. By her silence, and by promising to provide contact information for Ms. Mustafa, Ms. Abalihi misled the investigators.” *Id.*

It may be that Ms. Abalihi misled the investigators, but the record is far from clear on this point. More specifically, while the record establishes that the DI called Ms. Abalihi and asked her about getting contact information for Ms. Mustafa, the record does not establish that the Investigator ever specifically “asked her about the role Ms. Mustafa

² While Ms. Abalihi testified that she was not told prior to her interview with the DIs that “she needed to study anything,” Tr. 136, the Show Cause Order clearly provided notice that her lack of knowledge of DEA regulations was at issue.

³ Pharmacies which handle controlled substances are subject to extensive recordkeeping and security requirements. *See* 21 CFR 1301.75–1301.76 (security requirements); *id.* §§ 1304.03–1304.06; 1304.21–1304.22 (recordkeeping and reporting requirements). In addition, as the ALJ explained, their pharmacists are charged with the responsibility of dispensing only those prescriptions which are “issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.” 21 CFR 1306.04(a). *See also generally* 21 CFR part 1306 (setting forth various other requirements pertaining to prescriptions and the dispensing of controlled substances by pharmacies).

was to play.” Most significantly, the Government never alleged in either the Show Cause Order or its pre-hearing statements that Ms. Abalihi made a materially false statement or materially misled the DIs when she promised to get Ms. Mustafa’s contact information. Nor did the Government make any such argument in its post-hearing brief.⁴ Accordingly, because the Government never provided notice in the charging documents that it intended to litigate the issue and makes no claim that the issue was litigated by consent, I reject the ALJ’s conclusion that Mrs. Abalihi materially misled the Investigators.⁵ See *Kenneth Harold Bull*, 78 FR 62666, 62674 (2013); *CBS Wholesale Distributors*, 74 FR 36746, 36749–50 (2009). That being said, the material misrepresentation of Ms. Taylor, who owned ten percent of Respondent and who was designated by Respondent’s majority owner as its pharmacist-in-charge, is properly charged to Respondent and supports the denial of its application under factor five.

Moreover, even as of the date of the hearing, the Agency still does not know who will be Respondent’s pharmacist-in-charge. Beyond Ms. Taylor’s statement that she did not intend to leave her job at Sweetbay Pharmacy until Respondent is profitable, the evidence further showed that at the time of the hearing, Ms. Taylor had left the Tampa area and was working at a pharmacy in Orlando. RX E; Tr. 156–57. Moreover, Ms. Taylor did not testify at the hearing. Because Respondent has failed to provide material information as to who will be its pharmacist-in-charge and oversee the dispensing of the controlled substances and compliance with the Agency’s various regulations, I hold that the Agency had demonstrated that granting its application “would be inconsistent with the public interest.” 21 U.S.C. 823(f).

* * * * *

In the Show Cause Order, the Government also alleged as a basis for denial of the application that “Mrs. Abalihi’s husband participated in [the] unlawful dispensing of controlled substances that were prescribed over the Internet by physicians who did not personally examine the patients” and

⁴ For the same reason, I need not decide whether, even assuming that Ms. Abalihi lacked the intent to deceive when she told the Investigators that she would obtain Ms. Mustafa’s contact information, she had a duty to correct any erroneous information she provided the Investigators upon being told by Ms. Taylor that there was no plan for Ms. Mustafa to work at Respondent.

⁵ I reject ALJ Finding of Fact number 5 and Conclusion of Law number 5 only to the extent they are based on the statements of Ms. Abalihi.

that “[t]his dispensing occurred while he was a pharmacist at a pharmacy that surrendered its DEA registration in December 2007 because of these illicit dispensing practices.” ALJ Ex. 1, at 1. The Show Cause Order further alleged that Mrs. Abalihi’s husband told the Agency’s Investigators “that these dispensing practices were lawful and that he intended to apply for a DEA registration to open his own retail pharmacy.” *Id.* at 1–2.

The parties stipulated that Mrs. Abalihi’s husband, Alfred Abilihi “is a registered pharmacist, [and] was a pharmacist at Moon Lake pharmacy who dispensed controlled substances based on unlawful internet prescriptions prior to Moon Lake Pharmacy surrendering its DEA registration on December 17th, 2007.” Tr. 11–12. The evidence shows that on November 29, 2007, a DEA Investigator received an anonymous phone call from a pharmacist who had worked at Moon Lake for one day, GX 6C, at 1; the pharmacist alleged that “the pharmacy was engaging in internet drug trafficking of [h]ydrocodone.” Tr. 74. Accordingly, on December 7, two DIs went to the pharmacy, which was located in New Port Richey, and “after several minutes of examination . . . found that the pharmacy was solely engaged in internet drug trafficking of [h]ydrocodone and some [s]chedule IV drugs such as Xanax and Valium,” in violation of 21 CFR 1306.04(a). *Id.* at 75.

The DI further testified that after “a few minutes of investigation,” he and another DI “discovered that there were two physicians,” one located in Virginia and one located in New York City, “who had sent . . . hundreds of prescriptions for [h]ydrocodone to Moon Lake Pharmacy for filling” and that the purported patients were located “throughout the 50 states of the United States.” *Id.* at 77–78. The DI further explained that “there was no contact between the patients and the so-called physicians” and “[e]verything was based on the submission of a credit card number,” with the “payment of several hundred dollars to a company that used [Moon Lake] to fill the prescriptions” and that “Moon Lake . . . was getting \$75 per filled [h]ydrocodone prescription.” *Id.* at 78.

According to the DI, the pharmacy was not open to the public and it “was extremely small, it looked like 600 square feet” with “no seating area for walk-ins.” *Id.* at 79. Also, “[t]here was no over-the-counter merchandise” and “no merchandise . . . other than the controlled substances.” *Id.* Continuing, the DI explained that “[t]here was essentially nothing except the

compounding equipment, a fax machine, a scale, the counter, [and] little else.” *Id.*

The DI identified one Vivian Alberto as the owner of the pharmacy. *Id.* at 78. However, Ms. Alberto was not a licensed pharmacist. *Id.* Indeed, the only pharmacist the Investigators encountered at Moon Lake was Mr. Alfred Abalihi. *Id.* at 80. According to the DI, he and his partner approached Mr. Abalihi and stated that they had found “hundreds of prescriptions being filled for people that have no contact with two physicians, one in Virginia [and] one in New York.” *Id.* at 84. After telling Mr. Abalihi that he was “creating these labels, [and] you know what’s going on,” the DI asked him if he thought “it’s legal that the patients are far removed from the doctors with no contact and they’re getting [h]ydrocodone.” *Id.* at 85. Mr. Abalihi replied that he did not see a problem with filling the prescriptions and that “it was legal and . . . ethical to do so.” *Id.* at 80. The DI further testified that while interviewing Mr. Abalihi, the latter stated that “he would like to open up his own pharmacy.” *Id.* at 81.⁶

Mr. Abalihi testified that he worked for Moon Lake for only “a few days,” before the Investigators showed up and that he had obtained the job through a temporary staffing agency. Tr. 98–99. He further maintained that he did not know that Ms. Alberto was the owner because “she speaks only Spanish” and he does not. *Id.* at 102. He then claimed that prior to the Investigators’ inspection of Moon Lake, no one at the pharmacy had explained how the prescriptions arrived there and that he had “no” idea how the patients obtained the prescriptions and that a Web site was used as part of the prescribing process. *Id.* at 102–03. And when asked whether he had any recollection that there was anything wrong with the prescriptions he filled for Moon Lake, Mr. Abalihi answered: “No, I can’t recollect.” *Id.* at 103–04.

In his testimony, Mr. Abalihi denied telling the Investigators that what he was doing was legal, as well as that he intended to open his own pharmacy. *Id.* at 104. He also claimed that the DIs “didn’t even tell me why they were there,” although he also asserted that they told him that “we didn’t come here for you. If the pharmacy manager did what we told him to do the last time we came we wouldn’t have been here.” *Id.*

⁶ Six days later, Ms. Alberto voluntarily surrendered Moon Lake’s DEA registration. Tr. 82. As the DI explained, he requested that Ms. Alberto surrender Moon Lakes’ registration “because everything [Ms. Alberto] was doing was criminal.” Tr. 83.

at 100–01.⁷ Yet, the evidence establishes that the DIs encountered Mr. Abalihi on their first visit to Moon Lake Pharmacy. GX 6C, at 2 (¶ 4).

On cross-examination, Mr. Abalihi repeatedly maintained that he could not remember if he had dispensed prescriptions for hydrocodone or if hydrocodone was the main drug that was being dispensed at Moon Lake. *Id.* at 110–11. Indeed, Abalihi maintained that he could not recall having looked at any of the prescriptions he filled, did not know the size of the pharmacy, and could not recall whether Moon Lake was “set up as a typical retail pharmacy” and was “selling other merchandise.” *Id.* at 112. He also maintained that he did not discuss with anybody “how they operate[d]” and that “[i]f the only thing is that prescriptions were filled and brought to me to check, and I checked.” *Id.*⁸ Moreover, when asked if he “knew [that] what was going on at Moon Lake Pharmacy; that the operation was illegal with what they were doing with hydrocodone,” Mr. Abalihi answered: “I didn’t say, sir.” *Id.* at 120.

Mr. Abalihi also testified that he had tried to subsequently open his own pharmacy, but had withdrawn his application for a DEA registration after his then-attorney advised him that DEA intended to deny his application. *Id.* at 106. Moreover, Mr. Abalihi testified that he does not intend to work or otherwise operate Respondent and that he “just wanted . . . to advise my wife how to do things,” and he “would have loved to work there, but the DEA wouldn’t allow me to.” *Id.* at 108. He further maintained that during the week, he works full time as a pharmacist at a Miami area pharmacy, and comes home to Tampa on the weekends. *Id.* at 109.

Mr. Abalihi acknowledged that his wife had filed her application after he had withdrawn his application. *Id.* at 122. When asked if he had advised his wife regarding her application, he answered: “I’m her husband. I knew she was going to apply to open a pharmacy.” *Id.* After testifying that he

⁷ It is undisputed that Mr. Abalihi was never subjected to discipline by the Florida Board of Pharmacy.

⁸ When asked on cross-examination, whether as a Florida-based pharmacist, he would not fill a prescription issued by a New York doctor for a patient who lives in Georgia, Mr. Abalihi answered:

It depends. If I see a prescription—and I call the doctor and verify that that prescription came there. I don’t know if the doctor has met the patient. The onus lies on the doctor to make sure that he sees his patient, and my own is to make sure that the prescription is authentic.

Tr. 114. However, Mr. Abalihi then testified that he did not recall that he ever called and asked a physician if he/she had contact with the patient when he worked at Moon Lake. *Id.* at 114–15.

did not have an ownership interest in Respondent and was neither a director nor officer of it, Mr. Abalihi further asserted he does not “have any hand in running” the pharmacy. *Id.* at 123.

Likewise, Mrs. Abalihi asserted that she did not make her husband a co-owner of Respondent because he “had tried in the past” to “open a pharmacy” and was told by his counsel to withdraw his DEA application. Tr. 133. She further asserted that DEA has “blacklisted” her husband. *Id.* Mrs. Abalihi offered no testimony that her husband would not work at the pharmacy.

According to Respondent’s Exhibit C, which is a License Verification printout from the Florida Department of Health, Mr. Abalihi has a clear and active pharmacist license in the State of Florida, and has not been subject to discipline or a public complaint. RX C, at 1. Yet the License Verification printout also lists Mr. Abalihi’s address of record as 1947 W. Dr. Martin Luther King Jr. Blvd. in Tampa, Florida. *Id.* This is the same address as Respondent. See RX B. Moreover, the License Verification printout does not list any secondary locations for Mr. Abalihi. *Id.* at 2.

The ALJ rejected the Government’s contention that Respondent’s application should be denied because Mr. Abalihi’s “past negative history” in dispensing controlled substances “has a clear nexus” to his wife’s application. R.D. at 28–30 (citing Govt’s Proposed Findings of Fact, Conclusions of Law, and Argument in Respondent to Respondent’s Brief, at 10 (citing *Matthew D. Graham*, 67 FR 10229 (2002)). The ALJ rejected the Government’s argument, noting that in *Graham*, the Agency had denied the application based on the misconduct of the applicant’s business partner, who had previously surrendered a DEA registration for distributing large quantities of list I chemicals while having reasonable cause to believe they would be used to manufacture a controlled substance. See *id.* at 29.

The ALJ thus reasoned that *Graham* was distinguishable because “unlike the business plan presented by Ms. Abalihi, the registrant in *Graham* was economically tied to the third party” but “Ms. Abalihi presented a business plan that expressly removed Mr. Abalihi from all phases of the proposed pharmacy’s operation” and he “would not directly participate as an officer or owner of” Respondent. *Id.* While noting that Ms. Abalihi offered no testimony that “she would prohibit her husband from working in the pharmacy,” the ALJ credited her statement “that she would

keep her husband ‘apart from ownership and management’ of the pharmacy.” *Id.* The ALJ further reasoned that “having considered the affidavit of Mr. Abalihi,⁹ and having considered the testimony from both Mr. and Mr. [sic] Abalihi, I find sufficient credible and un rebutted evidence to conclude Mr. Abalihi does not intend to perform a significant role in the operation of” Respondent. *Id.*

As for Mr. Abalihi’s involvement at Moon Lake Pharmacy, the ALJ noted that he shared the same sense as the DIs “that anyone in Mr. Abalihi’s position would have had reason to question the legitimacy of the operation” as well as the DIs’ “sense of incredulity that Mr. Abalihi would have failed to recognize the illegal nature of what was going on at Moon Lake, even though his stay there was brief.” *Id.* at 29–30. After noting that Mr. Abalihi “was not charged with any misconduct arising out of his service at Moon Lake,” the ALJ explained that while “Mr. Abalihi may have unwisely told the DEA investigators that Moon Lake’s operations were legal . . . I cannot conclude from that piece of evidence that [he] was knowingly advancing Moon Lake’s criminal enterprise when the DEA arrived.” *Id.* at 30.

Notwithstanding “that the parties . . . stipulated that Mr. Abalihi dispensed controlled substances based on unlawful Internet prescriptions during his short tenure at Moon Lake,” the ALJ explained that “the most we can say for certain is that Mr. Abalihi was the pharmacist who was present when the DEA agents arrived at Moon Lake and brought its operation to an end.” *Id.* And noting that Mr. Abalihi’s record “since then is unblemished,” the ALJ reasoned that “his plan to avoid direct involvement with [Respondent] adequately attenuates the link between him and the proposed pharmacy.” *Id.*

I reject the ALJ’s conclusion that Mr. Abalihi was not knowingly advancing Moon Lake’s criminal enterprise when DEA arrived. Indeed, this conclusion is irreconcilable with the ALJ’s finding that there is “sufficient credible evidence to conclude Mr. Abalihi was aware that the practices¹⁰ in this pharmacy were illegal.” R.D. at 28. Moreover, as the ALJ found, the evidence shows that Mr. Abalihi committed criminal conduct by knowingly dispensing controlled substance prescriptions which were issued outside of the usual course of

⁹ Having reviewed Mr. Abalihi’s affidavit, I am at a loss as to what statement it contained that the ALJ found so persuasive on this issue.

¹⁰ While I agree with the ALJ’s finding, I do not rely on the DI’s assertion that the pharmacy’s compounding activities were illegal.

professional practice and lacked a legitimate medical purpose. See 21 U.S.C. 841(a)(1); 21 CFR 1306.04(a).

Here, in addition to the stipulation that Mr. Abalihi dispensed controlled substances based on unlawful internet prescriptions, a DI testified that upon arriving at the pharmacy and reviewing the prescriptions, he found that the prescriptions were solely for hydrocodone, a schedule III controlled substance, and drugs such as Xanax and Valium, which are schedule IV benzodiazepines. Tr. 75. Most significantly, the evidence showed that the Investigators found that hundreds of prescriptions were being filled that had been written for controlled substances by two physicians, one of whom was located in Virginia and the other New York, and that the patients were located throughout the fifty States of the U.S. *Id.* at 77–78; 84. Moreover, the pharmacy did not have an area for walk-in patients, had no over-the-counter merchandise, and indeed, sold no merchandise other than controlled substances. *Id.* at 79.

Under 21 CFR 1306.04(a), “[a] prescription for a controlled substance . . . must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of . . . professional practice.” Moreover, while “[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner . . . a corresponding responsibility rests with the pharmacist who fills the prescription.” *Id.* Accordingly, “[a]n order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. 829] and the person knowingly filling such a purported prescription . . . shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.” *Id.*¹¹

¹¹ Well before Mr. Abalihi filled prescriptions for Moon Lake, several federal appeals courts had upheld the convictions of pharmacists under 21 U.S.C. 841(a)(1) for filling prescriptions which were issued over the internet by physicians, who did not practice in the same State where the patients resided, and who did not physically examine the patients, because the physician did not establish a legitimate doctor-patient relationship with the patient. See *United States v. Nelson*, 383 F.3d 1227, 1231–32 (10th Cir. 2004); *United States v. Fuchs*, 467 F.3d 889, 899–900 (5th Cir. 2006). So too, DEA had issued numerous decisions holding that both the act of prescribing over the internet, as well as the act of dispensing a prescription issued over the internet, by a physician who has either engaged in the unlicensed practice of medicine or failed to establish a legitimate doctor-patient relationship, violates 21 CFR 1306.04(a) and constitutes an unlawful distribution under 21 U.S.C. 841(a)(1). See *United Prescription Services, Inc.*, 72 FR 50397,

As held in numerous Agency decisions, under the Controlled Substances Act, “it is fundamental that a practitioner must establish a bonafide doctor-patient relationship in order to act ‘in the usual course of . . . professional practice’ and to issue a prescription for a ‘legitimate medical purpose.’” See, e.g., *David A. Ruben, M.D.*, 78 FR 38363, 38380 (2013) (citing *United States v. Moore*, 423 U.S. 122, 142–43 (1975); other citations omitted). So too, DEA has held that a physician who engages in the unauthorized practice of medicine, such as by prescribing controlled substances to patients who reside in a State where he/she is not licensed to practice, acts outside of the usual course of professional practice and therefore violates the CSA for this reason as well. *United Prescription Services*, 72 FR 50397, 50407 (2007) (“A controlled-substance prescription issued by a physician who lacks the license necessary to practice medicine within a State is therefore unlawful under the CSA.”). As the Supreme Court has explained: “In the case of a physician, [the CSA] contemplates that *he is authorized by the State to practice medicine* and to dispense drugs in connection with his professional practice.” *Moore*, 423 U.S. at 140–41 (emphasis added).

Thus, I reject the ALJ’s portrayal of Mr. Abalihi as a hapless bystander who was in the wrong place at the wrong time when the DIs arrived at Moon Lake. To the contrary, as the ALJ found, there was “sufficient credible evidence to conclude [that he] was aware that the practices in this pharmacy were illegal.” R.D. at 28. Indeed, the respective locations of the two prescribing physicians and the patients, who were located through the country, made it clear to Mr. Abalihi that the prescriptions lacked a legitimate medical purpose and were issued outside of the usual course of professional practice. 21 CFR 1306.04(a). Moreover, even if it was not immediately apparent to Mr. Abalihi that he was aiding and abetting a criminal enterprise, surely at some point during his first day at Moon Lake a

50407–09 (2007); *Trinity Health Care Corp., d/b/a Oviedo Discount Pharmacy*, 72 FR 30849, 30855 (2007); *EZRX, LLC*, 69 FR 63178, 63181 (2004); see also *William R. Lockridge, M.D.*, 71 FR 77791 (2006); *Marvin L. Gibbs, Jr., M.D.*, 69 FR 11658 (2004); *Rick Joe Nelson, M.D.*, 66 FR 30752 (2001).

Moreover, in 2001, DEA issued a Guidance Document warning of the potential illegality of dispensing controlled substances based on prescriptions which were obtained through the internet and telephone consultations. *DEA, Dispensing and Purchasing Controlled Substances over the Internet*, 66 FR 21181, 21182–83 (2001).

reasonable pharmacist would have reached this conclusion, and in any event, Mr. Abalihi went back to the pharmacy a second day.¹²

In short, the evidence shows that Mr. Abalihi violated his corresponding responsibility and the CSA by filling prescriptions which lacked a legitimate medical purpose and were issued outside of the usual course of professional practice. *Id.*; see also 21 U.S.C. 841(a)(1). Moreover, Mr. Abalihi’s testimony makes clear that he still does not understand the scope of his obligations in dispensing controlled substances. As found above, when asked if he would not fill a prescription written by a New York physician for a patient who lives in Georgia, he testified, in essence, that if he called the doctor and the doctor verified the prescription, he wouldn’t “know if the doctor ha[d] met the patient” and that “[t]he onus lies on the doctor to make sure that he sees his patient.” Tr. 114.

Not only did Mr. Abalihi offer no testimony that he had called either of the doctors whose prescriptions he filled while at Moon Lake, his understanding of the scope of his obligations under federal law has been repeatedly rejected by both this Agency and multiple United States Courts of Appeal. As the Fifth Circuit has explained, “[v]erification by the issuing practitioner on request of the pharmacist is evidence that the pharmacist lacks knowledge that the prescription was issued outside the scope of professional practice. But it is not an insurance policy against a fact-finder’s concluding that the pharmacist had the requisite knowledge despite a purported but false verification.” *United States v. Hayes*, 595 F.2d 258, 261 (5th Cir. 1979). Thus, simply calling a physician to verify a prescription is not enough because a pharmacist has “the responsibility not to fill an order that purports to be a prescription but is not a prescription within the meaning of the statute because he knows [or has reason to know] that the issuing practitioner issued it outside the scope of medical practice.” *Id.* (quoted in *East Main Street Pharmacy*, 75 FR 66149, 66164 (2010)); see also *United States v. Henry*, 727 F.2d 1373, 1379 (5th Cir. 1984); *Medic-Aid Pharmacy*, 55 FR 30043,

¹² The ALJ “note[d] that Mr. Abalihi was not charged with any misconduct arising out of his service at Moon Lake.” R.D. at 30. As has been repeatedly explained, this is totally irrelevant because there are any number of reasons why neither a prosecutor nor a state licensing body may bring charges. See *Robert L. Dougherty, M.D.*, 76 FR 16823, 16833n.13 (2013). Rather, what matters is his underlying misconduct.

30044 (1990); *Frank J. Bertolino*, 55 FR 4729, 4730 (1990).

Nor—notwithstanding that it is couched as being based on credibility findings—do I find persuasive the ALJ's conclusion that the link between Mr. Abalihi and Respondent is adequately attenuated because Mrs. Abalihi has kept her husband "apart from [the] ownership and management of" Respondent and Mr. Abalihi "plan[s] to avoid direct involvement with" the pharmacy. R.D. at 29–30. While *Graham* is undoubtedly distinguishable from this case, it does not reflect the limits of the Agency's authority to deny an application or revoke an existing registration based on the misconduct of a third party, particularly where that third party is a family relation of the applicant's principal. Indeed, in numerous cases—none of which are discussed in the Recommended Decision—the Agency has either revoked existing registrations or denied applications of pharmacies based on the closeness of the relationship between a person who diverted controlled substances or committed other serious CSA violations and another party who is either the applicant or new owner of a pharmacy.

Accordingly, the Agency has held that it "may look to who exerts influence over the registrant" in determining whether to deny an application or revoke a registration. *See, e.g., City Drug Co.*, 64 FR 59212, 59214 (1999). As the Agency explained in *City Drug*: "sometimes the bonds linking the former owner to the new owner are too close to ensure that the former owner will have no influence over the operation of the pharmacy." *Id.* (citing *Monk's Pharmacy*, 52 FR 8988, 8989 (1987) and *Carriage Apothecary, Inc.*, 52 FR 27599, 27599 (1987)).

In *Monk's Pharmacy*, the Agency denied an application of a pharmacy, noting that the former owner, who had been convicted of a felony relating to controlled substances, had transferred ownership to his children and to a third-party, who was a registered pharmacist. 52 FR at 8988. The Agency denied the application, noting "that the bonds linking the convicted [former pharmacy owner] with his children and the subject pharmacy are too close to permit a reasonable certainty that he will have no authoritative voice in its operation." *Id.* at 8989.

So too, in *Carriage Apothecary*, the pharmacy's owner, who had committed recordkeeping violations, had transferred the stock of the corporation which owned the pharmacy to his children. 52 FR at 27599. Noting that "[t]he Administrator has long held that

he can look behind a corporate façade to determine who makes the decisions concerning the controlled substance business of a pharmacy," the Agency revoked the pharmacy's registration, holding that while the pharmacy was now owned by the children of the former owner, neither child was a pharmacist, and the former owner "continues to exert influence or control over [the pharmacy] through the family-held corporation." *Id.*

Moreover, in *Unarex of Plymouth Road, d/b/a Motor City Prescription and Unarex of Dearborn, d/b/a/Motor City Prescription Center*, 50 FR 6077 (1985), two pharmacists, who had been convicted of CSA violations (conspiracy and unlawful distribution), had transferred both their ownership interests and their respective office or directorship to their spouses. Noting that both pharmacists "share[d] indirectly in the profits of" the two pharmacies, the Agency revoked the registration of both pharmacies, holding that "[i]t is appropriate that both registrations be revoked in light of this continued benefit" received by the pharmacists.¹³ *Id.* at 6079.

Lawsons & Sons Pharmacy and Fenwick Pharmacy, 48 FR 16140 (1983), involved two pharmacies whose pharmacist was convicted of unlawfully distributing controlled substances. At the time of the proceeding, the pharmacist's wife owned 100 percent of one of the pharmacies and fifty percent of the other.¹⁴ Therein, the registrants provided an affidavit from the pharmacist's wife "stat[ing] that she is an active and knowledgeable officer of each of the corporations and has come to understand the operation of the pharmacies," and that "she ha[d] great trust in the two pharmacists she ha[d] hired to run these pharmacies and that her husband has withdrawn from [his] involvement in the pharmacies"; the registrants also provided an affidavit from one of the registrant's managing pharmacists stating that he understood that the convicted pharmacist's wife would "discourage" her husband "from entering the store" upon his release from incarceration. *Id.* at 16141. The Agency nonetheless rejected the registrants' evidence and revoked both registrations, holding that while the convicted pharmacist's wife "has always had some administrative duties

in the store, she is not a trained pharmacist and relies on the advice of the managing pharmacists at both stores. In light of [the convicted pharmacist's] past activities, the Acting Administrator cannot conclude that he will not attempt to exert some form of control over one or both of the pharmacies." *Id.*

Here, the totality of the circumstances leads me to reject the ALJ's conclusion that the link between Mr. Abalihi and Respondent is too attenuated to support (in addition to the other bases set forth above) the denial of the latter's application.¹⁵ Notably, Mrs. Abalihi submitted the application only after Mr. Abalihi was informed (by his attorney) that the local DEA field office intended to deny his application and he withdrew it.¹⁶

Indeed, Mrs. Abalihi admitted that the reason she did not make her husband a co-owner was because of his prior failed attempt to obtain a DEA registration. Tr. 133. So too, while Mr. Abalihi was not made a shareholder of Respondent, he is married to Respondent's principal owner and would thus share, at least indirectly, in any of Respondent's profits. *See Unarex*, 50 FR at 6079. Mr. Abalihi would thus have a strong economic incentive to exercise influence over Respondent's operation.¹⁷ *See id.*

¹⁵ The ALJ "question[ed] whether there is a sufficient link established between Mr. Abalihi's past work at Moon Lake Pharmacy and Cove, Inc.'s proposal to operate" Respondent. R.D. at 28; *see also id.* at 31 ("[T]he facts shown here do not establish the kind of ties that link Mr. Abalihi's past brief involvement with Moon Lake's illegal operation to the operation proposed by the Respondent here.").

To the extent the ALJ was suggesting that to the deny the application on this basis, the Government must show that Mrs. Abalihi intended to operate Respondent as a pharmacy which filled prescriptions obtained by soliciting customers over the internet and which were issued by physicians who did not establish a valid doctor-patient relationship with the customers, the Government was not required to make such a showing. Rather, it was only required to show that Mr. Abalihi had committed violations of the CSA and that there was reason to believe that he would exert influence or control over Respondent's operation.

¹⁶ While the Abalihis maintain that they have been "blacklisted" by DEA, Tr. 98 & 133; instead of withdrawing his application, Mr. Abalihi could have challenged the proposed denial of his application and would have been entitled to a hearing. *See* 21 U.S.C. 824(c). At that hearing, he could have challenged the Government's evidence as well as put forward evidence relevant to the issue of whether his registration would be consistent with the public interest. *See id.* § 823(f).

¹⁷ While in *Graham*, there clearly was a business arrangement between the applicant and his partner (who had diverted list I chemicals), consistent with the cases discussed above, I reject the ALJ's reasoning that *Graham* is distinguishable on ground that "unlike the business plan presented by Ms. Abalihi, the registrant in *Graham* was economically tied to the third party." R.D. at 29. Contrary to the ALJ's understanding, the Abalihi's marriage

¹³ While the Administrator noted that one of the pharmacists continued to work in one of the stores, and thus declined to believe that this pharmacist "no longer exerts influence over the operation" of the pharmacy, no such evidence was presented as to the second store. 50 FR at 6079.

¹⁴ The Agency's decision does not state who owned the other fifty percent of this pharmacy.

Moreover, notwithstanding that Mr. Abalihi was not made a shareholder or officer, Mrs. Abalihi offered no testimony that he would not work at the pharmacy. R.D. at 29. Indeed, Respondent's own evidence shows that Mr. Abalihi listed Respondent as his address of record for his pharmacist license with the Florida Department of Health.¹⁸ RX C. Thus, while Mr. Abalihi claimed that he had no intention of working at Respondent, he offered no explanation for the inconsistency between his testimony and his action in listing Respondent as his address of record. Moreover, given Mr. Abalihi's claim, it is strange that he signed the return receipt card, manifesting service of the Show Cause Order, which was mailed to Respondent at its physical location of 1947 W. Dr. Martin Luther King Blvd. See GX 1, at 2. Thus, while the ALJ found credible Mr. Abalihi's testimony that he did not intend to work at Respondent, the ALJ never reconciled his finding with this evidence.

Finally, Ms. Taylor, who Mrs. Abalihi represented as being Respondent's pharmacist-in-charge, told the DIs that she did not intend to leave her then-position at Sweetbay Pharmacy until Respondent was profitable. Moreover, when questioned as to who would be the pharmacist during the interim period, Ms. Taylor gave the name of a person she had never asked. Ms. Taylor, who has since taken a position in Orlando, did not testify in the proceeding, and while she did submit an affidavit, the affidavit contains no statement that she still intends to become Respondent's pharmacist-in-charge. Indeed, Mrs. Abalihi still has not disclosed who will be Respondent's

establishes that Mr. and Mrs. Abalihi are economically tied. Cf. *Califano v. Jobst*, 434 U.S. 47, 54 (1977) ("Both tradition and common experience support the conclusion that marriage is an event which normally marks an important change in economic status."); *Women Involved in Farm Economics v. USDA*, 876 F.2d 994, 1005 (D.C. Cir. 1989) (noting with approval the assumption that "whatever their roles, married men and women constitute one economic unit").

While I conclude that Mrs. Abalihi submitted the pending application as part of a ruse by the Abalihis to obtain a registration after Mr. Abalihi withdrew his application, and that the Abalihis planned all along for Mr. Abalihi to be Respondent's pharmacist-in-charge, contrary to the ALJ's understanding, the Agency's case law does not require that the Government prove that Mr. Abalihi "intend[ed] to perform a significant role in the operation of" Respondent. R.D. at 29.

¹⁸ Mr. Abalihi also testified that he was working full time at a pharmacy in Miami. Tr. 109. Yet he did not list this pharmacy as either his address of record or as a secondary location with the Florida Department of Health, see RX C, and I find it implausible that he would continue working full time in Miami if Respondent obtained a registration given the expense of hiring a pharmacist.

pharmacist-in-charge.¹⁹ The evidence thus suggests that the plan all along was for Mr. Abalihi to be Respondent's pharmacist-in-charge.

Accordingly, based on the record as a whole, I reject the ALJ's conclusion that the links between the applicant and Mr. Abalihi are sufficiently attenuated to conclude that he will exercise no influence or control over Respondent.²⁰ I further conclude that the record supports a finding that Mrs. Abalihi submitted the application as part of a ruse to obtain a registration after her husband withdrew his application. This finding provides additional reason to reject the application.²¹

ORDER

Pursuant to the authority vested in me by 21 U.S.C. 823(f), as well as 28 CFR 0.100(b), I order that the application of Cove, Incorporated, doing business as Allwell Pharmacy, for a DEA Certificate of Registration as a retail pharmacy, be, and it hereby is, denied. This order is effective immediately.

Dated: May 11, 2015.

Michele M. Leonhart,
Administrator.

Brian Bayly, Esq., for the Government
Daniel G. Musca, Esq., and *Brian C. Chase, Esq.*, for the Respondent

¹⁹ Notwithstanding that many of the Agency cases have involved pharmacies whose prior owners were convicted of criminal offenses, a criminal conviction of either the pharmacy or its pharmacist/owner is not required to sustain the denial of an application or the revocation of a registration. For example, in *Carriage Apothecary*, the pharmacy and pharmacist were not convicted of any offense but agreed to pay a civil penalty. 52 FR at 27599.

²⁰ I therefore reject the ALJ's finding of fact number seven. See R.D. at 34. I also reject the ALJ's conclusion of law number four. See *id.* at 35–36.

²¹ In one of Respondent's filings, it asserts that its case is "most analogous" to the Agency's decision in *Terese, Inc., D/B/A Peach Orchard Drugs*, 76 FR 46843 (2011). It's not. In *Terese*, the Government sought the revocation of the registration of a pharmacy, which was owned by the wife of a pharmacist, who along with his pharmacy, had been convicted of health care fraud and required to surrender his DEA registration as part of his sentence. While the Government argued that the pharmacy was simply the alter ego of a previous pharmacy, which had been subject to mandatory exclusion from federal health care programs by virtue of its conviction, see 21 U.S.C. 824(a)(5) and 42 U.S.C. 1320a–7(a), I noted that the respondent was not subject to mandatory exclusion but rather only permissive exclusion, and that Congress had not granted the Agency authority to revoke a registration on the latter basis. 76 FR at 46846–48.

While the Government also alleged that the former pharmacy and its pharmacist had diverted controlled substances, I rejected the allegation for lack of substantial evidence. *Id.* at 46846 & n.9. However, I also explained that "had the evidence established that [the owner's husband or the former pharmacy had] violated the CSA or state controlled substance laws, the Agency case law on piercing the corporate veil would authorize the revocation of [the] respondent's registration." *Id.*

RECOMMENDED RULINGS, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

Nature of the Proceeding

Christopher B. McNeil, Administrative Law Judge. On March 3, 2011, Ogechi E. Abalihi submitted a request on behalf of Cove, Inc., seeking a new retail pharmacy DEA Certificate of Registration, allowing it to dispense controlled substances through a business that would be known as Allwell Pharmacy in Tampa, Florida. On July 26, 2011, finding cause to believe this registration would be inconsistent with the public interest, the Drug Enforcement Administrator, through the Deputy Assistant Administrator, issued an order to show cause why the Administrator should not deny the application. In response, on August 22, 2011, the Respondent requested an extension of the time permitted to file a response, which was granted by DEA Administrative Law Judge Timothy J. Wing. Judge Wing thereafter received what he found to be a waiver of Cove, Inc.'s right to a hearing on the matter and terminated the administrative review Cove had requested.

In her review of the record, the Administrator concluded there were factual disputes that warranted further development and remanded the matter to the Office of Administrative Law Judges, with instructions to permit the parties to present evidence at a hearing to be conducted in Tampa, Florida. At this point, Judge Wing was no longer with the DEA Office of Administrative Law Judges, so Administrative Law Judge Gail Randall issued an order for prehearing statements. On December 3, 2012, prior to the submission of prehearing statements, Chief Administrative Law Judge John J. Mulrooney II reassigned the case from ALJ Randall to the undersigned, and I presided over an evidentiary hearing conducted in Tampa, Florida, on February 13, 2013.

Issue

The general issue to be adjudicated by the Administrator, with the assistance of this recommended decision, is whether the record as a whole establishes, by substantial evidence, that Cove, Inc.'s application for a Certificate of Registration with the DEA should be denied as inconsistent with the public interest, as that term is used in 21 U.S.C. § 823(f).

The issue arose after DEA investigators completed an evaluation of the evidence supporting Cove, Inc.'s application. In this evaluation, investigators learned that the 90 percent owner of Cove, Inc., Ogechi Abalihi, R.N., had no experience as a pharmacist and limited knowledge about DEA regulations pertaining to the retail distribution of controlled substances. Investigators also found that the ten percent owner of Cove, Inc., pharmacist Jacinta Taylor, was not planning on being present at the pharmacy until after it became profitable. The investigators noted that Ms. Taylor gave them conflicting information regarding who would serve as Allwell's pharmacist up to the time when Ms. Taylor would participate in the operation of the pharmacy. Investigators also

were concerned that Ms. Abalihi's husband, Alfred Abalihi, R. Ph., although not a Cove, Inc. shareholder or manager of Allwell, had been associated with a different pharmacy that had been compelled to surrender its DEA Certificate in 2007 due to illegal dispensing operations.

Based on the information presented to them in the course of Cove, Inc.'s application, the Diversion Investigators concluded that granting Cove, Inc. a Certificate of Registration would be inconsistent with the public interest, prompting the show cause order that would deny this application. The specific issue thus is whether by at least a preponderance of the evidence the Government has established that granting a DEA Certificate of Registration to Cove, Inc. would be inconsistent with the public interest, as that term is used in 21 U.S.C. 823(f).

After carefully considering the testimony elicited at the hearing, examining the admitted exhibits, evaluating the arguments of counsel, and weighing the record as a whole, I have set forth my recommended findings of fact, conclusions of law, and analysis below, recommending that the DEA deny Cove, Inc.'s Application for a Certificate of Registration.

Evidence

Allwell Pharmacy's proposed DEA-registered location is 1947 W. Dr. Martin Luther King, Jr. Blvd., Tampa, Florida 33609. The proposed DEA-registered location is not open for business or operating at this time as a pharmacy or other commercial business, but the pharmacy is licensed as a retail pharmacy in the State of Florida and retains a Florida community pharmacy license. Allwell Pharmacy's owner is Cove, Inc., and the corporation has two shareholders: Ogechi E. Abalihi, who owns 90 percent of the company, and Jacinta Taylor, who owns ten percent.¹

Ms. Abalihi has no experience either as a pharmacist or owning a retail pharmacy, but she does have extensive experience as a Registered Nurse licensed as such since 2001, and throughout such period has worked with controlled substances. Jacinta Taylor has extensive experience working as a Florida-licensed pharmacist, working as a pharmacist and dispensing controlled substances.²

Testimony from the DEA Diversion Investigators

Kenneth Boggess has been a Diversion Investigator for the DEA for 26 years.³ He graduated from the Federal Law Enforcement Training Center in 1980 and from the FBI Academy in 1986.⁴ In this course of study, he has become familiar with sections of the Code of Federal Regulations, with the identification of controlled substances, and with the means and processes of illegally diverting controlled substances.⁵ Throughout his tenure as a DEA Diversion Investigator, Mr. Boggess has participated in continuing

education courses and has participated in numerous investigations, including those pertaining to pharmacies.⁶

Investigator Boggess explained that he was involved in evaluating the application submitted by Cove, Inc., the Respondent in this matter.⁷ Part of that evaluation included meeting with one of Cove, Inc.'s two owners, Ogechi Abalihi.⁸ He said his first meeting with Ms. Abalihi took place on March 22, 2011, at the DEA's Tampa office, and that DEA Diversion Investigator Ira Wald also attended this meeting.⁹

According to Investigator Boggess, Ms. Abalihi obtained her nursing degree in Lagos, Nigeria, and moved to New York in 1992.¹⁰ He said that upon arriving in New York, Ms. Abalihi worked for a health care corporation, moving to Tampa in the early 2000s, where she began working with the Veterans Administration as a part-time nurse.¹¹

As part of the application investigation, Investigator Boggess said he questioned Ms. Abalihi about her plan to manage the proposed pharmacy. He said when he asked Ms. Abalihi who would actually manage Allwell Pharmacy, she told him it would be managed by the other co-owner, Jacinta Taylor.¹² According to Investigator Boggess, Ms. Abalihi is the 90 percent owner of Cove, Inc., and Ms. Taylor is the ten percent owner.¹³ Investigator Boggess said he questioned Ms. Abalihi about the business relationship between her and Ms. Taylor, and was told she met Ms. Taylor in 2010, in the course of treatment in a therapist's office.¹⁴

During the interview conducted on March 22, 2011, Investigator Boggess questioned Ms. Abalihi about how the proposed pharmacy would maintain its records and maintain compliance with DEA regulations concerning the dispensing of controlled substances.¹⁵ When asked, on cross examination, whether this kind of questioning was part of his "standard operating procedure," Investigator Boggess said yes, adding that Tampa "has significant problems with applicants here, and the Internet problems and this oxycodone problem."¹⁶ He explained that the questions he uses when evaluating an applicant have been generated through suggestions from DEA headquarters and from the experiences of DEA officers in Tampa, but that these questions are not published for public consumption.¹⁷ There was, however, some indication, according to Investigator Boggess, that word of the kind of questions being asked in these applications is getting around, such that the applicants "have a good idea what we're going to ask."¹⁸

Investigator Boggess explained that when he questions an applicant about the

applicant's knowledge of DEA regulations, he ends the inquiry if it is clear the person knows nothing about those regulations, because "there's no point in badgering someone."¹⁹ That appears to have been the case here, during his interview with Ms. Abalihi. He described his questions as being "simple," and gave as an example: "How do you plan on maintaining your invoices?"²⁰ Investigator Boggess said in response to the questions he posed regarding DEA regulations, Ms. Abalihi deferred all questions about controlled substances and about the security of those substances to Ms. Taylor, electing not to answer them herself.²¹ When asked who would be responsible for ordering controlled substances being dispensed in the pharmacy, Ms. Abalihi told Investigator Boggess that she intended to give Ms. Taylor power of attorney, and they would use either Harvard Drug or Cardinal as their wholesale supplier.²²

The following week, Investigator Boggess contacted Jacinta Taylor and met with her on March 30, 2011 at the DEA office in Tampa, along with Investigator Wald.²³ Investigator Boggess said after confirming her identity and her credentials as a pharmacist, he inquired about the proposed business operation.²⁴ He said Ms. Taylor confirmed that she met Ms. Abalihi "socially at some type of therapy session" in 2010.²⁵ He testified that Ms. Taylor initially told him she would be the pharmacist in charge of the pharmacy when it opened, and that she expected to be the person who would order controlled substances, most likely using Great Lakes Harvard Drug as the pharmacy's supplier.²⁶ She told him the pharmacy would be operating from 9:00 a.m. until 6:00 p.m., Mondays through Fridays, and from 9:00 a.m. until 1 p.m. on Saturdays, and would be closed on Sundays.²⁷

When Investigator Boggess considered these operating hours, he asked Ms. Taylor about her current employment and the hours she was on duty with that job, as a pharmacist at Sweetbay. According to Investigator Boggess, Ms. Taylor then acknowledged working at Sweetbay on a full-time basis, with hours from 10:00 a.m. until 8:00 p.m.²⁸ When this scheduling conflict was brought to Ms. Taylor's attention, Investigator Boggess said Ms. Taylor amended her previous answer: rather than stating she would be the pharmacist in charge of the pharmacy when it opened, she told him that she would leave her job at Sweetbay "if and when Allwell started to make money."²⁹ Investigator Boggess pursued this inquiry, asking Ms. Taylor who would be Allwell's pharmacist in charge in the meantime. In response, Ms. Taylor told

⁶ *Id.* at 31.

⁷ *Id.* at 32.

⁸ *Id.*

⁹ *Id.* at 32–33.

¹⁰ *Id.* at 33.

¹¹ *Id.* at 33–34.

¹² *Id.* at 34.

¹³ *Id.* at 36.

¹⁴ *Id.* at 34.

¹⁵ *Id.* at 35.

¹⁶ *Id.* at 60.

¹⁷ *Id.*

¹⁸ *Id.* at 61.

¹⁹ *Id.* at 64.

²⁰ *Id.*

²¹ *Id.* at 36.

²² *Id.*

²³ *Id.* at 37.

²⁴ *Id.* at 37–38.

²⁵ *Id.* at 38.

²⁶ *Id.*

²⁷ *Id.* at 38–39.

²⁸ *Id.* at 39.

²⁹ *Id.* at 40.

¹ Tr. at 10–11.

² *Id.*

³ Tr. at 30.

⁴ *Id.*

⁵ *Id.* at 32.

him the interim pharmacist in charge would be a coworker of hers, Dalya Mustafa.³⁰

When he learned that Ms. Taylor intended to use Ms. Mustafa as the interim pharmacist in charge of the applicant pharmacy, Investigator Boggess told Ms. Taylor he would need to interview Ms. Mustafa, given the significant role Ms. Mustafa would be playing with the new pharmacy.³¹ According to Investigator Boggess, at this point in the interview Ms. Taylor “stuttered and said, ‘Well, perhaps [Ms. Mustafa] won’t work there.’”³² At the conclusion of this interview, Investigator Boggess called Ms. Abalihi and asked if she would provide contact information so that he could call Ms. Mustafa and confirm the role she would be playing in the proposed pharmacy.³³ According to Investigator Boggess, Ms. Abalihi talked with Investigator Boggess on either the 30th or 31st of March 2011, and told him she would contact Ms. Mustafa and either have her call him or provide him with her phone number. Investigator Boggess said that despite this, Ms. Mustafa never contacted him and he heard nothing further from Ms. Abalihi regarding Ms. Mustafa.³⁴

In addition to inquiring of Ms. Abalihi how Cove, Inc. would ensure compliance with DEA controlled substance regulations, Investigator Boggess said he and Investigator Wald were also concerned about the role Alfred Abalihi—Ms. Abalihi’s husband—would play in the new pharmacy. Here, both Investigator Wald and Investigator Boggess described an investigation their office conducted four years earlier, involving Moon Lake Pharmacy. According to Investigator Boggess, during the initial interview on March 22, 2011 Investigator Wald told Ms. Abalihi that he had conducted an inspection of Moon Lake Pharmacy back in 2007, and that during this inspection Mr. Abalihi was the pharmacist on duty.³⁵ Investigator Boggess said that the inspection of Moon Lake had been prompted by information indicating it was illegally distributing controlled substances over the Internet.³⁶ Investigator Boggess said that during the inspection of Moon Lake, Mr. Abalihi told Investigator Wald that, while he knew nothing about the owner or operator of the pharmacy and was only working on a short-term contractual basis through his employer, HealthCare Consultants, he believed there was nothing illegal about what Moon Lake was doing and added that “he himself . . . wouldn’t mind opening a pharmacy” of his own.³⁷

The record reflects that Moon Lake surrendered its DEA Certificate of Registration shortly after this inspection, based on the investigators’ charge that the operation was illegal. The record also shows that Mr. Abalihi was then dispatched to serve as a temporary pharmacist at numerous other locations, as an employee of HealthCare

Consultants, all without incident or disciplinary action.

Investigator Boggess testified that at the conclusion of the investigation into Cove, Inc.’s application for DEA registration, DEA’s Diversion Group Supervisor, Roberta Goralczyk determined that the application should be denied.³⁸ He said he then spoke to both Ms. Abalihi and Ms. Taylor, and learned that Ms. Taylor wished to withdraw the application but that Ms. Abalihi would not drop the request for the DEA Certificate.³⁹ Investigator Boggess told Ms. Taylor, however, that as she was not the actual applicant, she could not withdraw the application.⁴⁰ He said that after this discussion, both Ms. Taylor and Ms. Abalihi spoke with him at the end of March, 2011 and asked for a list of the DEA’s objections, indicating that they both wished to have the application go forward.⁴¹

Investigator Boggess testified that as of January 2013, when he last drove past Allwell’s proposed location, the pharmacy had not opened.⁴² He added that five other pharmacies were operating within a few hundred yards of the proposed location, all in close proximity to St. Joseph’s Hospital.⁴³ He said he recently visited these pharmacies, and confirmed they all held DEA Certificates allowing them to dispense controlled substances.⁴⁴ Through this testimony, Investigator Boggess established there is an ongoing concern by pharmacists regarding the proliferation of pain medication prescriptions, particularly regarding OxyContin 15 and 30 mg. tablets.⁴⁵ On cross examination, Investigator Boggess confirmed that it is common for health care professionals and pharmacies to cluster around a hospital.⁴⁶ He also confirmed that there is no evidence to suggest St. Joseph’s Hospital is a “pill mill hospital,” nor did he believe there was evidence to suggest any of the pharmacies constituted problems for the DEA with respect to their dispensation practices.⁴⁷

During his visit to David’s Pharmacy on January 18, 2013, Investigator Boggess observed a sign on the divider between the pharmacy and the patients indicating that the pharmacy would not dispense oxycodone 15 or 30 mg. tablets.⁴⁸ He said he spoke with the owner, pharmacist David Cataya, and to Mr. Cataya’s wife, Carmen, about concerns the pharmacist had regarding the dispensing of controlled substances in this neighborhood.⁴⁹ He learned the pharmacist saw the trend for oxycodone had gone down, but that demand for hydromorphone (Dilaudid) had gone up such that it was now the drug of choice of drug seekers in their neighborhood.⁵⁰ As a

result, the pharmacist preferred to fill controlled substance prescriptions only for those individuals who could prove they lived in the neighborhood and who were his established customers.⁵¹

Investigator Boggess described making similar trips to and receiving similar input from four other nearby pharmacies, including Hillsborough River Compounding Pharmacy, run by Mr. Uba, Care Plus Pharmacy run by Mr. Bakari, CVS Pharmacy, run by Mr. Alicea, and Walgreens Pharmacy, run by Mr. Luu. In these interviews, Investigator Boggess learned that the nearby hospital did not generate many prescriptions for controlled substances.⁵² He also learned that while some of those he interviewed felt there was a high demand for oxycodone, not all found there to be a shortage.⁵³ Mr. Alicea reported attempts by drug seeking customers to seek out oxycodone and to attempt to learn the price charged for the drug, prompting Mr. Alicea to refuse to fill prescriptions for more than 100 dosage units of the drug, and to post a sign in the pharmacy stating “No Oxycodone,” in large print on an 8 by 11 sheet of paper at the pharmacy counter.⁵⁴ At the Walgreens Pharmacy, Mr. Luu reported there was a high demand for oxycodone, and that he would not fill prescriptions for Schedule II medications.⁵⁵

When asked on cross examination why he waited until 2013 to conduct these interviews with the nearby pharmacies, Investigator Boggess agreed that “the two-year delay is a good question, period, for this whole process,” but that he was working with 30 other applications at the time and the interviews were done when he “finally got around to [them]”.⁵⁶ He added, however, that there is no regulation that requires his office to avoid saturation of a market when evaluating an application for a pharmacy.⁵⁷ He specifically denied any practice of denying an application based on oversaturation in the Tampa Bay area.⁵⁸

DEA Diversion Investigator Ira Wald also testified. He stated he has been a Division Investigator for 38 years, having been hired in 1975 and having completed several months of initial training in DEA auditing techniques, legal procedure, and investigative techniques, with periodic refresher courses.⁵⁹ Mr. Wald stated that from this course of study, and based on his experience in investigating the application of pharmacies seeking DEA certification, he is familiar with the Code of Federal Regulations pertaining to the distribution and dispensing of controlled substances.⁶⁰

With respect to his concerns about the role Mr. Abalihi might play in the operation of Allwell Pharmacy, Investigator Wald testified that in 2007, after receiving an anonymous call about Moon Lake Pharmacy, he visited

³⁰ *Id.*

³¹ *Id.* at 41.

³² *Id.*

³³ *Id.* at 41.

³⁴ *Id.* at 42.

³⁵ *Id.* at 35.

³⁶ *Id.* at 35.

³⁷ *Id.*

³⁸ *Id.* at 43.

³⁹ *Id.*

⁴⁰ *Id.* at 44.

⁴¹ *Id.*

⁴² *Id.* at 45.

⁴³ *Id.*

⁴⁴ *Id.* at 45–46.

⁴⁵ *Id.* at 47–59.

⁴⁶ *Id.* at 65.

⁴⁷ *Id.* at 66–67.

⁴⁸ *Id.* at 47.

⁴⁹ *Id.* at 48.

⁵⁰ *Id.*

⁵¹ *Id.* at 50.

⁵² *Id.* at 49, 51.

⁵³ *Id.* at 51–55.

⁵⁴ *Id.* at 56.

⁵⁵ *Id.* at 59.

⁵⁶ *Id.* at 68.

⁵⁷ *Id.* at 69.

⁵⁸ *Id.* at 70.

⁵⁹ *Id.* at 72–3.

⁶⁰ *Id.* at 73–4.

the pharmacy at its location in New Port Richey, Florida.⁶¹ Investigator Wald said that after determining that the pharmacy was engaged in Internet trafficking of hydrocodone, Xanax, and Valium, and after determining there were violations of compounding regulations, Investigator Wald questioned the pharmacist present at the time of this visit—Alfred C. Abalihi, who is Ms. Abalihi's husband.⁶²

According to Investigator Wald, the pharmacy was small—about 600 square feet in size—and it did not appear it was open to the public, but was instead a compounding site.⁶³ Investigator Wald said the compounding room had thousands of hydrocodone capsules in a transparent two-gallon jug, along with 100 grams of pure hydrocodone powder.⁶⁴ According to Investigator Wald, this type of storage was a violation because “compounding by definition requires that the compounder, the pharmacist, make up the prescription[s] one at a time pursuant to need, not thousands beforehand pursuant to projected sales possibilities.”⁶⁵ According to Investigator Wald, when questioned about this operation, Mr. Abalihi stated he “saw no problem with it,” and stated “it was legal and proper, ethical to do so.”⁶⁶ Mr. Abalihi added that “he would like to open up his own pharmacy.”⁶⁷

When asked during cross examination about Moon Lake's compounding methods, Investigator Wald stated he did not know if compounding in advance based on anticipated need was permitted under Florida law, but knew that federal law forbids advanced compounding absent registration as a manufacturer.⁶⁸ Investigator Wald also acknowledged that upon his initial visit to Moon Lake Pharmacy, he did not see Mr. Abalihi actually compounding drugs, and from his review of the pharmacy records he did not see Mr. Abalihi listed as either the prescription department manager or as an officer or director of the pharmacy.⁶⁹

Investigator Wald explained that after meeting with Mr. Abalihi at Moon Lake Pharmacy he arranged to meet with the pharmacy's owner, Vivian Alberto.⁷⁰ During this meeting and a meeting that followed shortly thereafter, Investigator Wald requested and received the surrender of the pharmacy's DEA registration, putting the pharmacy out of business “because everything [Ms. Alberto] was doing was criminal.”⁷¹

Moon Lake Pharmacy surrendered its former DEA registration number, FM0523870, on or about December 17, 2007, because the pharmacy dispensed controlled substances based on illegal Internet prescriptions. The parties have stipulated

that Mr. Abalihi was a pharmacist at Moon Lake who dispensed controlled substances based on unlawful Internet prescriptions.⁷² The parties also have stipulated that Mr. Abalihi was never an owner, officer, pharmacist-in-charge, or prescription department manager of Moon Lake Pharmacy.⁷³

Regarding the initial investigation into Cove, Inc.'s application for a DEA Certificate of Registration for Allwell Pharmacy, Investigator Wald confirmed the testimony of Investigator Boggess regarding standard procedures in these investigations. He said it is normal for his office to quiz new DEA applications on their familiarity with DEA regulations.⁷⁴ Further, he said his office requires the applicants to meet with the investigators, to describe their operations, their backgrounds, and their professional expertise in operating a pharmacy—this because of the “many criminal violations coming from retail pharmacies.”⁷⁵

Investigator Wald confirmed the salient points addressed by Investigator Boggess. He recalled that during the initial interviews with Ms. Abalihi and Ms. Taylor, he and Investigator Boggess asked about the ownership of Cove, Inc., and about Ms. Abalihi's training, education, and experience with pharmacies in the past, and about how much of her attention she was going to devote to the pharmacy.⁷⁶ The record reflects that under her proposed business plan, Ms. Abalihi would operate the retail pharmacy herself, along with a co-owner who is a registered pharmacist and who would be responsible for dispensing controlled substances. He also confirmed Investigator Boggess's observation that St. Joseph's Hospital, which is near the location of the proposed Allwell Pharmacy, is not currently regarded as a “pill mill,” and that while it does generate prescriptions for controlled substances, it does not dispense them—patients who are treated at the hospital but who are not actually admitted to the hospital will, for the most part, fill their prescriptions off-site.⁷⁷

Testimony in Support of the Application

Testifying in support of Cove, Inc.'s application, Ogechi E. Abalihi stated that she has a diploma of Nursing from Lagos University Teaching Hospital as well as a diploma in Midwifery from University College Hospital. Ms. Abalihi obtained both degrees in Nigeria, where she worked between 1988 and 1992 as a Registered Nurse.⁷⁸ In addition, Ms. Abalihi has a Bachelor's Degree from City College New York, and in 2012 earned a Master's Degree in Nursing from the University of South Florida.⁷⁹ She explained that courses in the Master's program included pharmacology and advanced pharmacology, which covered

the legalities of prescribing controlled substances in Florida.⁸⁰

After moving from Nigeria to New York in 1992, Ms. Abalihi worked with the Health and Hospitals Corporation in Harlem Hospital for about ten years:⁸¹ “As a Registered Nurse, I worked in orthopedics, massage, I did a little bit of psychiatric nursing, I worked in [the] intensive care unit.”⁸² Ms. Abalihi said she had the knowledge and education associated with the professional standards of service as a Registered Nurse, including knowledge of medication inventorying, dispensing, and safekeeping.⁸³

Ms. Abalihi said she moved to Tampa in 2001, working both at the Veterans Administration Hospital there and operating a group home, between 2007 and 2010, as the home's Director of Nursing.⁸⁴ She said in this capacity she was involved with patients who had prescriptions for controlled substances, so she was responsible for inventory, dispensing, and safe handling of the drugs.⁸⁵ She currently works as a Registered Nurse at the Veterans Administration Hospital, in the hospital's critical care unit.⁸⁶ She described this as full-time work in the intensive care unit, the cardiac unit, and the surgical unit, where she is required to make sure prescription doses are correct, and has to understand medication side effects, “how it's going to impact my patient, and how much this patient can get at a particular time. Basically, standard nursing procedures for dispensing [and] safety [] of controlled substances.”⁸⁷

Ms. Abalihi testified that through her work as a nurse and through her formal education, she has been trained in dispensing controlled substances: “I inventory controlled substances as a Registered Nurse, and I have knowledge of safekeeping processes with relationship to [the] nursing profession.”⁸⁸ This experience, she said, includes “knowledge of inventory, safety of controlled drugs [,] and dispensing.”⁸⁹ She said she has held a nursing license from New York for over ten years, and has held her Florida license since 2001, and has never been disciplined by any governmental entity nor convicted of any crime.⁹⁰

Ms. Abalihi said she applied for a DEA Certificate of Registration in early 2011 so that Cove, Inc. could operate Allwell Pharmacy.⁹¹ She acknowledged she never has owned a retail pharmacy, has never worked in a pharmacy, and is not a licensed pharmacist, and as such she would not be dispensing controlled substances.⁹² She said the plan was to operate a standard retail community pharmacy with a co-owner who

⁸⁰ *Id.* at 128.

⁸¹ *Id.* at 126–7.

⁸² *Id.* at 127.

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ *Id.* at 127–28.

⁸⁶ *Id.* at 125, 128.

⁸⁷ *Id.* at 133.

⁸⁸ *Id.* at 125.

⁸⁹ *Id.* at 126.

⁹⁰ *Id.* at 140.

⁹¹ *Id.* at 129.

⁹² *Id.* at 141, 143.

⁶¹ *Id.* at 75.

⁶² *Id.* at 79.

⁶³ *Id.*

⁶⁴ *Id.* at 76.

⁶⁵ *Id.*

⁶⁶ *Id.* at 80.

⁶⁷ *Id.* at 81.

⁶⁸ *Id.* at 86.

⁶⁹ *Id.* at 88.

⁷⁰ *Id.* at 82.

⁷¹ *Id.* at 83.

⁷² *Id.* at 11–12.

⁷³ *Id.*

⁷⁴ *Id.* at 89.

⁷⁵ *Id.* at 89.

⁷⁶ *Id.* at 91.

⁷⁷ *Id.* at 92, 95.

⁷⁸ *Id.* at 125–6.

⁷⁹ *Id.* at 125.

was a pharmacist, and to serve as a supplier of drugs to assisted living facilities.⁹³ She explained that she had recently operated a group home, which she stated is “kind of assisted living,” and believed she could serve this kind of population.⁹⁴ She said she had no trouble obtaining a Florida state license to operate the pharmacy, and applied for a DEA Certificate of Registration shortly after obtaining a state license.⁹⁵

According to Ms. Abalihi, she and Jacinta Taylor own Cove, Inc., with Ms. Taylor owning ten percent and Ms. Abalihi owning 90 percent. Ms. Abalihi is the sole officer and director.⁹⁶ Ms. Taylor is a pharmacist licensed in Florida. Ms. Abalihi met Ms. Taylor socially, as both have children in the autism spectrum and met each other while taking their children to autism therapy.⁹⁷

Ms. Abalihi testified that when she was invited to the DEA to discuss her application, Investigator Wald referred to her husband, and told her “there were issues” with a pharmacy he had worked at.⁹⁸ Ms. Abalihi said she told Investigator Wald “[w]ell, I don’t know about that. I’m just doing this on my own.”⁹⁹ She testified that she told the investigators that Mr. Abalihi would not have anything to do with Allwell Pharmacy, and that she was “engaging the services of Jacinta Taylor, who is a licensed pharmacist, to be the one—the pharmacy manager or the prescriptions department manager, whichever one is being referred to.”¹⁰⁰ She told the investigators that Mr. Abalihi had been “blacklisted” from owning or operating a pharmacy.¹⁰¹

Ms. Abalihi said that at the conclusion of the interview, Investigator Boggess asked when she planned to open the pharmacy, and offered to provide whatever help she needed, leaving her assured that she “had a good interview.”¹⁰² She added, however, that she was never told that she needed to study anything about regulations pertaining to the DEA, so “whatever questions they asked me, I answer[ed] to the best of my knowledge. The ones I could not answer I refer[red] them to my prescription manager, you know those things that I knew I didn’t know anything about, for her to answer [.]”¹⁰³

By her own account, Ms. Abalihi recognized that she lacked the experience needed to operate a pharmacy if the pharmacy dispensed controlled substances. Recognizing this limitation, Ms. Abalihi testified that she would address this by engaging the services of a registered pharmacist to assist in the daily operation of the store. Ms. Abalihi said her familiarity and experience with controlled substances is based wholly on “nursing professional standards”. When asked on cross-examination whether she was “familiar with

the record-keeping requirements for controlled substances for a retail pharmacy,” she did not answer the question directly, but stated only “[a]gain, like I said, in terms of controlled substances my experience is with nursing.”¹⁰⁴ When asked about controlled substance regulations concerning biannual inventories, or concerning the different physical security requirements applicable to Schedule II controlled substances (in contrast with those applicable to Schedules III through V), Ms. Abalihi again would not answer the questions, but said questions and issues like these would have to be addressed by a pharmacist working at Allwell.¹⁰⁵ When asked what percentage of prescriptions she anticipated would be for controlled substances, Ms. Abalihi responded by saying that if anyone could answer that question, it would be the pharmacy manager, not herself.¹⁰⁶

Ms. Abalihi described the arrangement she entered into with the prospective pharmacist, Ms. Taylor. She agreed, during cross examination, that Allwell would have to completely rely on the pharmacist working there in order to ensure compliance with DEA controlled substances regulations.¹⁰⁷

Ms. Abalihi testified that the business plan for Allwell was to have it open and operational from 9:00 a.m. until 6:00 p.m. Monday through Friday, and from 9:00 a.m. to 1 p.m. on Saturdays, with the pharmacy closed on Sundays.¹⁰⁸ She acknowledged that when they were interviewed by the DEA investigators, Ms. Taylor was working at Sweetbay as a pharmacist, but stated that Ms. Taylor would come to work at Allwell as soon as Ms. Abalihi got the required license.¹⁰⁹

Ms. Abalihi acknowledged that presently, Ms. Taylor works full time as a pharmacist in Orlando, having moved from Tampa sometime after this application was filed.¹¹⁰ When asked whether she knew if Ms. Taylor was planning on moving back to Tampa if Cove, Inc. gets the Certificate it seeks for Allwell, Ms. Abalihi stated “We can’t say for sure until this whole thing is over. I mean I don’t expect her to, you know, just not do something with her life with this whole thing—I mean this whole thing has to be over for her to—that is my perception, for her to make a decision what she wants to do.”¹¹¹ She added that despite what Ms. Taylor told Investigator Boggess about the plan to use Ms. Mustafa as a second pharmacist, Ms. Abalihi did not know Ms. Mustafa, had never met her, and had never spoken with her.¹¹² She offered no explanation for telling the DEA investigators that she would either provide them with Ms. Mustafa’s contact information or have Ms. Mustafa contact them—actions which indicate that she was complicit in Ms. Taylor’s prevarication

regarding the purported plan to use Ms. Mustafa when Allwell began its operation.

When pressed to explain this, Ms. Abalihi denied knowing Ms. Mustafa, denied ever speaking to Ms. Mustafa, and denied that Ms. Taylor said she would be relying on Ms. Mustafa. According to Ms. Abalihi, “[Ms. Taylor] did not say she would be relying on Ms. Mustafa, no. She said the name came to her when this question was thrown to her. She wasn’t expecting it, but the name came to her.”¹¹³ When asked, however, whether there was a plan in effect to actually have Ms. Mustafa work at the pharmacy, Ms. Abalihi said “not exactly. Jacinta Taylor mentioned her after—you know, after her interview with the DEA she mentioned her to me as a possibility of coverage for her. And I know very well that you can actually get coverage. And I know very well that you can actually get coverage.”¹¹⁴

I am thus presented with two significantly different versions of what was said when Diversion Investigators Boggess and Wald questioned Ms. Abalihi and Ms. Taylor. The Diversion Investigators testified that Ms. Taylor indicated she would leave her job at Sweetwater and join the operation of Allwell only when it started to become profitable—not at its inception. Both investigators testified that Ms. Taylor initially told them she would have a coworker, Ms. Mustafa, serve as the pharmacy’s pharmacist between the time it began its operation and the time when Ms. Taylor joined the store as its pharmacist. Investigator Boggess testified that in furtherance of this representation, Ms. Abalihi committed to providing him with Ms. Mustafa’s contact information—a commitment Ms. Abalihi now denies ever making.

Because the two Diversion Investigators’ testimony is internally consistent, is consistent with the evidence as a whole, is consistent with a common sense understanding of the events being described, and does not appear to be tainted with bias or a motivation to prevaricate, and because I do not find other indicia of unreliability, I give substantial weight to the statements of Investigators Boggess and Wald regarding this exchange.

Further, because I find Ms. Abalihi’s testimony to be internally contradictory, inconsistent with the evidence as a whole, and inconsistent with that of Ms. Taylor’s statements to the investigators and her averments in the affidavit introduced as evidence, and because I find Ms. Abalihi and Ms. Taylor both had a financial interest in claiming that Allwell would have a registered pharmacist on duty in order to obtain a DEA Certificate (even if that was not going to be the case), I do not give substantial weight to Ms. Abalihi’s claim that she never committed to giving the investigators contact information for Ms. Mustafa. From this contradictory account, I find Ms. Abalihi compounded the falsehood Ms. Taylor initiated, by failing to disclose the true lack of involvement of Ms. Mustafa in the planned operation of Allwell Pharmacy; and I find that Ms. Taylor falsely stated to the

⁹³ *Id.* at 129.

⁹⁴ *Id.* at 130.

⁹⁵ *Id.* at 130–31.

⁹⁶ *Id.* at 131.

⁹⁷ *Id.* at 131, 133.

⁹⁸ *Id.* at 134.

⁹⁹ *Id.*

¹⁰⁰ *Id.* at 135.

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ *Id.* at 136.

¹⁰⁴ *Id.* at 144.

¹⁰⁵ *Id.* at 144, 146.

¹⁰⁶ *Id.* at 146.

¹⁰⁷ *Id.*

¹⁰⁸ *Id.* at 156.

¹⁰⁹ *Id.* at 137.

¹¹⁰ *Id.* at 157.

¹¹¹ *Id.*

¹¹² *Id.* at 138.

¹¹³ *Id.* at 138, 161.

¹¹⁴ *Id.* at 139.

investigators that Ms. Mustafa would play a role in the pharmacy when it began its operations.

During her testimony, Ms. Abalihi attempted to minimize the significance of the role Ms. Taylor or Ms. Mustafa would play in the initial stage of Allwell's operation. Ms. Abalihi said that there are agencies (like the one employing her husband) that can cover pharmacies, "so out of the issue of Mustafa as a coverage, a substitute, I don't think it was an issue for running that pharmacy."¹¹⁵ There is, however, no evidence that Ms. Abalihi told the DEA investigators that she intended to start Allwell's operation using temporary agency pharmacists, like the one employing her husband. She recognized, however, that DEA certification was essential to her business plan. She testified that without the DEA Certificate she could not find suppliers or insurers that would work with the pharmacy.¹¹⁶

Ms. Abalihi's husband, Alfred Abalihi, also testified in support of Cove, Inc.'s application. Mr. Abalihi stated that while he would not be part of the business operation, he did have experience in the operation of a pharmacy.¹¹⁷ He holds a license to practice as a pharmacist in Florida, based on an accredited Bachelor of Pharmacy degree from the University of Ife [now Obafemi Awolowo University], in Nigeria.¹¹⁸ He has held the Florida license since 2003, and has never been subject to discipline by any governmental entity with respect to that license, nor has he ever been charged with or convicted of any crime by any governmental entity.¹¹⁹

Mr. Abalihi said he was aware that his wife was attempting to secure a DEA Certificate of Registration that would permit Cove, Inc. to operate the Allwell Pharmacy but said he was never made an owner of that corporation. According to Mr. Abalihi, "[t]o my understanding I've been made to believe that [the] DEA have [sic] blacklisted me based on the temporary work I did at Moon Lake Pharmacy in 2007."¹²⁰

Mr. Abalihi explained that he did not know much about Moon Lake's operation and was working there under contract as assigned by his employer, HealthCare Consultants.¹²¹ He said he worked at Moon Lake only a few days and that this was one of many assignments he had been dispatched to as an employee of HealthCare Consultants.¹²² He said he never interviewed for the job at Moon Lake, knew nothing about who owned the pharmacy, and never spoke with anyone at the pharmacy before starting his work there—adding that the owner worked there as a technician, but spoke only Spanish, which Mr. Abalihi said he neither speaks nor understands.¹²³

Mr. Abalihi said that the DEA agents visited Moon Lake on the last day on this

assignment.¹²⁴ According to Mr. Abalihi, when he asked Investigator Wald whether he was in any kind of trouble, Investigator Wald told him "No, we didn't come here for you. If the pharmacy manager did what we told him to do the last time we came, we wouldn't have been here. So it's not about you."¹²⁵ Mr. Abalihi testified that before working at Moon Lake Pharmacy, he knew nothing about how that pharmacy received its prescriptions—and did not know there was an Internet Web site used as part of the prescribing process.¹²⁶

Prior to the hearing, the parties stipulated that Mr. Abalihi "dispensed controlled substances based on unlawful Internet prescriptions" while working at Moon Lake Pharmacy.¹²⁷ During the hearing, however, Mr. Abalihi said he now could not recall any specific prescriptions he filled during the few days that he was working at Moon Lake, and had no recollection of there being anything wrong with any of the prescriptions he filled there.¹²⁸ He said he knew Moon Lake was compounding hydrocodone into dosage units, but said the compounding was done when he was not present.¹²⁹ He denied, however, ever telling Investigator Wald that what he was doing was legal, saying "I never made any statement like that."¹³⁰ Mr. Abalihi said he worked with two other people at Moon Lake—a husband and wife—both of whom "ran away" and escaped from the pharmacy when the DEA investigators arrived.¹³¹ Mr. Abalihi added that his assignment at Moon Lake was to end on the day the DEA investigators visited the pharmacy, so he did not return, and that he has never been disciplined by the Florida Board of Pharmacy for his work at Moon Lake.¹³²

Mr. Abalihi testified that after this experience, he attempted to open his own pharmacy through Masters Worldwide Ventures, doing business as My Master's Pharmacy.¹³³ He said that his business plan was to operate a community pharmacy and to dispense drugs in some assisted living facilities, apparently pursuing a business plan similar to the one described by his wife with respect to the operation of Allwell Pharmacy.¹³⁴ He said he would have no arrangements with any pain clinics, adding that he did not even know any such clinics.¹³⁵

Mr. Abalihi said he ended this venture at the advice of an attorney, "based on the fact that DEA has told [his lawyer] that they have made up their mind to deny me the license."¹³⁶ He said he personally never spoke to or met with DEA representatives when attempting to secure a Certificate to

operate My Master's Pharmacy, electing instead to have his attorney meet with those agents.¹³⁷ He said he actually tried to operate My Master's Pharmacy without a DEA Certificate of Registration, but found that drug wholesalers would not supply drugs without that Certificate. Further, Mr. Abalihi realized that if he was unable to dispense controlled substances his customers would "quickly go to the other pharmacies that have a controlled [substances] license, leaving me to lose in business."¹³⁸

When asked whether he intends to work at or otherwise operate Allwell Pharmacy once it opens for business, Mr. Abalihi responded "No. I just wanted to stay as—to advise my wife how to do things. But I would have loved to work there, but the DEA wouldn't allow me to."¹³⁹ When asked on cross-examination whether he gave advice to his wife about having her own application for a DEA pharmacy, Mr. Abalihi did not answer directly, but instead responded "I'm her husband. I knew she was going to apply to open a pharmacy."¹⁴⁰

After hearing her husband's testimony, Ms. Abalihi was asked, on cross examination, "what is your understanding why [the] DEA 'blacklisted' Mr. Abalihi", Ms. Abalihi said she cannot answer the question, nor could she answer the Government's question whether it is her belief that her husband violated any DEA laws.¹⁴¹ When she was asked, however, why her husband withdrew his application for a DEA Certificate on behalf of My Master's Pharmacy, she stated the only reason for doing that was the advice given by counsel.¹⁴² When asked whether either Investigator Wald or Investigator Boggess told her that her husband had been blacklisted, Ms. Abalihi stated "[t]hey didn't tell me that."¹⁴³

Analysis

The Administrator is being asked to grant a Certificate of Registration that would permit Cove, Inc., to dispense controlled substances through a pharmacy to be known as Allwell Pharmacy. When presented with such an application, the Administrator is guided by provisions in the United States Code mandating that she determine whether granting such a Certificate "would be inconsistent with the public interest."¹⁴⁴ In determining the public interest, the following factors shall be considered:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

¹²⁴ *Id.* at 100.

¹²⁵ *Id.*

¹²⁶ *Id.* at 103.

¹²⁷ *Id.* at 11–12.

¹²⁸ *Id.* at 103.

¹²⁹ *Id.* at 111.

¹³⁰ *Id.* at 104.

¹³¹ *Id.* at 118–19.

¹³² *Id.* at 104.

¹³³ *Id.* at 106.

¹³⁴ *Id.* at 107.

¹³⁵ *Id.*

¹³⁶ *Id.* at 106.

¹³⁷ *Id.* at 121.

¹³⁸ *Id.* at 107.

¹³⁹ *Id.* at 108.

¹⁴⁰ *Id.* at 122.

¹⁴¹ *Id.* at 153.

¹⁴² *Id.* at 155.

¹⁴³ *Id.* at 163.

¹⁴⁴ 21 U.S.C.A. § 823 (West), current through Public Law 112–283, approved 1–15–13.

¹¹⁵ *Id.* at 139.

¹¹⁶ *Id.* at 138.

¹¹⁷ *Id.* at 108.

¹¹⁸ *Id.* at 97.

¹¹⁹ *Id.*

¹²⁰ *Id.* at 98.

¹²¹ *Id.* at 99.

¹²² *Id.* at 100, 102.

¹²³ *Id.* at 101, 102.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.¹⁴⁵

As correctly noted in the Government's post-hearing brief, an application denial may be based on any one, or any combination, of the five factors cited above.¹⁴⁶ When exercising authority as an impartial adjudicator, the Administrator may properly give each factor whatever weight she deems appropriate in determining whether an application should be rejected.¹⁴⁷ Moreover, the Administrator is "not required to make findings as to all of the factors[.]"¹⁴⁸ The Administrator is not required to discuss each factor in equal detail, or even every factor in any given level of detail.¹⁴⁹ The balancing of the public interest factors "is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest[.]"¹⁵⁰

In this case, the Government does not contend there is a history of professional discipline by a licensing board, nor did it offer evidence of a criminal conviction pertaining to any party, nor did it allege Cove, Inc., or any material party failed to comply with applicable laws relating to controlled substances. Accordingly, Factors One, Three, and Four in 21 U.S.C. 823(f) are not presented as bases for revoking this Certificate.

I would note parenthetically that there is evidence supporting the Respondent's application that neither party directly addresses. There is undisputed evidence that the Respondent obtained the required license from Florida authorities, permitting it to operate a retail pharmacy in Tampa. In a recent DEA adjudication, obtaining such a license was considered by the Administrator as evidence in support of the application under Factor One ("recommendation of the appropriate State licensing board or professional disciplinary authority").¹⁵¹ "Although not dispositive, Respondent's

¹⁴⁵ 21 U.S.C.A. § 823, eff. 4/15/2009, current through Public Law 112-283, approved 1-15-13.

¹⁴⁶ Government's Proposed Findings of Fact, Conclusions of Law, and Argument in Response to "Respondent's Brief" at 3 (citing *Richard J. Lanham, M.D.*, 57 FR 40475-01 (August 27, 1992), *Henry J. Schwartz, Jr., M.D.*, 54 FR 16442-01 (April 24, 1989). Also cited is *Neveille H. Williams, D.D.S.*, 51 FR 17556 (1986), but the entry at that citation corresponds to the matter of *Paul Stepak, M.D.*, 51 FR 17556 (May 13, 1986), and is inapposite here.

¹⁴⁷ *Morall v. DEA*, 412 F.3d 165, 173-74 (D.C. Cir. 2005); *JLB, Inc., d/b/a Boyd Drugs*, 53 FR 43945-02, 43947 (October 31, 1988); see also *David E. Trawick, D.D.S.*, 53 FR 5326-01, 5327 (February 23, 1988).

¹⁴⁸ *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005); see also *Morall v. DEA*, 412 F.3d 165, 173-74 (D.C. Cir. 2005).

¹⁴⁹ *Trawick v. DEA*, 861 F.2d 72, 76 (4th Cir. 1988).

¹⁵⁰ *Jayam Krishna-Iyer, M.D.*, 74 FR 459-01, 462 (January 6, 2009).

¹⁵¹ See *Physicians Pharmacy, L.L.C.*, 77 FR 47096, 47104 (August 7, 2012).

possession of a valid retail pharmacy license . . . weighs against a finding that Respondent's registration would be inconsistent with the public interest."¹⁵² In this case, however, neither party cites to 21 U.S.C. 823(f)(1). Given the focus on Factors Two and Five, it should suffice to note, as the ALJ did in the earlier case, that "[a]lthough not dispositive, Respondent's possession of a valid retail pharmacy license . . . weighs against a finding that Respondent's registration would be inconsistent with the public interest."¹⁵³

In his Order to Show Cause, the Deputy Assistant Administrator, Office of Diversion Control, identified two factors as the bases for denying Cove, Inc.'s application. First, he referred to Factor Two, noting that Ms. Abalihi "had no prior experience with operating or working at a retail pharmacy and had no knowledge of DEA regulations pertaining to handling of controlled substances and related security requirements."¹⁵⁴ Also under Factor Two, the Deputy Assistant Administrator charged that the role Mr. Abalihi played in the operation of Moon Lake Pharmacy and his stated intention to obtain his own Certificate of Registration to operate a pharmacy created a risk to the public interest.¹⁵⁵ The Order also identified Factor Five as a basis for denying the application, stating that "[t]he only pharmacist that Mrs. Abalihi stated would work at Allwell Pharmacy gave DEA investigators evasive and conflicting information about the pharmacy's operation."¹⁵⁶

In hearings regarding the denial of a proposed DEA Certificate of Registration, "the Administration shall have the burden of proving that the requirements for such registration pursuant to section 303 or section 1008(c) and (d) of the Act (21 U.S.C. 823 or 958(c) and (d)) are not satisfied."¹⁵⁷ Accordingly, in order to establish cause to deny Cove, Inc.'s application, the Government must establish by at least a preponderance of the evidence that it would be inconsistent with the public interest to grant this application, given the applicant's experience in dispensing controlled substances (Factor Two), given Mr. Abalihi's past history and present association with the new pharmacy (Factor Two), and given evidence of other conduct which may threaten the public health and safety (Factor Five).

Factor Two Regarding Experience of Cove, Inc., Ms. Abalihi, and Ms. Taylor

The evidence establishes that the applicant did not have personnel with the requisite experience in dispensing controlled substances to support its application. Considering first the experience attributed to

¹⁵² *Id.* (citing *Robert A. Leslie, M.D.*, 68 FR 15,227, 15,230 (March 28, 2003) (state license is a necessary but not a sufficient condition for registration, and therefore, this factor is not dispositive)).

¹⁵³ *Id.*

¹⁵⁴ Order to Show Cause, found in ALJ Exhibit 1, at 1.

¹⁵⁵ *Id.*

¹⁵⁶ *Id.* at 2.

¹⁵⁷ 21 CFR 1301.44, current through April 4, 2013.

Ms. Abalihi, I find the scope of nursing practice does, to some degree, include exposure to regulations pertaining to the distribution of controlled substances. Ms. Abalihi competently testified that in the course of her nursing practice, she has had occasion to deliver controlled substances to persons in her care. Further, there is evidence that as a nurse, Ms. Abalihi has been required to account for controlled substance inventories, and to guard against improper diversion of such inventories.

The scope of this experience, however, leaves material and significant areas of expertise unmet. Pharmacists must conform to the corresponding responsibilities imposed upon them under DEA regulations. These responsibilities are unique to pharmacists, and are not likely to be recognized or met by a person whose sole function is as a Registered Nurse. DEA regulations impose upon pharmacists affirmative obligations regarding the distribution of controlled substances once a prescribing source (such as a doctor or physician's assistant) issues a prescription. Those obligations collectively are referred to as "corresponding responsibilities," as they impose duties on pharmacies and pharmacists that correspond with those of treating sources.¹⁵⁸ There is no corollary set of obligations imposed on Registered Nurses in the course of their professional duties. "The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription."¹⁵⁹

Driving this corresponding responsibility is the standard, also found in DEA regulations, that a prescription for a controlled substance "must be issued for a legitimate medical purpose," and that it be prescribed by "an individual practitioner acting in the usual course of his professional practice."¹⁶⁰ Although the record shows Ms. Abalihi has formal education in the fields of basic and advanced pharmacology, and has experience in administering medications including controlled substances, the record also shows that she has no experience in understanding and applying the corresponding responsibilities imposed on pharmacists who dispense controlled substances under DEA regulations. To the contrary—from her testimony and from her business plan, it is clear Ms. Abalihi disavows having such knowledge, electing to defer all questions on these regulations to her business partner, Ms. Taylor.

Such deference would create a risk of harm to the public in this case. Diversion Investigator Boggess's testimony regarding the experiences of local pharmacists, and their collective concern about drug-seeking activity involving addictive pain killers like Oxycodone, establishes that there is a clear and present danger posed by persons who present themselves to pharmacies in the area, hoping to obtain drugs by questionable

¹⁵⁸ See *Sun & Lake Pharmacy*, 76 FR 24523-02, 24525 (May 2, 2011) (citing 21 CFR 1306.04(a)).

¹⁵⁹ 21 CFR 1306.04(a) (2005), current through February 21, 2013.

¹⁶⁰ *Id.*

prescriptions. Nothing in Ms. Abalihi's training suggests she is familiar with the practices of persons who present questionable prescriptions to pharmacists in the hope of securing controlled substances illegally.

Further, as a corporate entity, Cove, Inc. itself has no history of experience in the distribution of controlled substances. Allwell Pharmacy would be this corporation's first and only venture into such activity, and neither of its shareholders has ever operated a pharmacy before. The evidence calls into question whether Ms. Taylor would actually participate in the operation of Allwell Pharmacy, at least at the beginning of operations. When this application was presented to the DEA, Ms. Taylor was employed at another pharmacy on a full-time basis, during hours that would have made it impossible for her to be present when Allwell was open for business. When asked to describe her intentions in this regard, Ms. Taylor told the DEA investigators that she planned on working at Allwell only once it became profitable—not at the very beginning. Since then, Ms. Taylor has moved to Orlando, and there is no evidence indicating she has any plans to return to Tampa any time soon.

I am mindful that Ms. Abalihi now disputes the DEA investigators' reports regarding when Ms. Taylor would actually begin work. I am persuaded, however, to attribute greater weight to the testimony on this point provided by Investigator Boggess and Investigator Wald, than I attribute to Ms. Abalihi's version of what was said. It is clear from the record that Ms. Taylor had no clear investment in Cove, Inc. nor in Allwell Pharmacy. As a minority shareholder with no proven financial investment in the company, Ms. Taylor was in no way obligated to quit her job at Sweetbay in order to work at Allwell. The record offers no evidence that Ms. Taylor contributed capital or cash in exchange for receiving her ten percent shares in the corporation.

Further, there is no evidence establishing any kind of agreement between Cove, Inc. and Ms. Taylor requiring her to provide professional services. There is, for example, no evidence that Ms. Taylor faced any adverse consequence should she decide not to end her employment at Sweetbay and begin working at Allwell. Ms. Abalihi's claim that Ms. Taylor would quit her job at Sweetbay in order to accept a position at Allwell is not supported by any competent evidence, and is contradicted by what I find to be credible testimony from the two DEA investigators, to the effect that Ms. Taylor was going to take a "wait and see" approach before lending her expertise to this new enterprise—an approach Ms. Abalihi appears to have endorsed.¹⁶¹

This conclusion is buttressed by the evidence regarding the role of Dayla Mustafa. The need for someone to play the role attributed to Ms. Mustafa would arise only upon Ms. Taylor's absence from Allwell during the initial operation of the new pharmacy. The evidence establishes that based on Ms. Taylor's admission that she

would not be present initially, and upon the investigators' query, Ms. Taylor offered Ms. Mustafa as the person who would provide the requisite experience initially. The evidence establishes that this was a falsehood—that in fact Ms. Mustafa never agreed to play such a role, and Ms. Taylor came up with the name only because she felt the need to address concerns being raised by the DEA investigators. Ms. Abalihi tacitly confirmed this false representation and compounded the problem when she offered to provide the investigators with Ms. Mustafa's contact information. Thus, the evidence establishes that no one having the requisite knowledge and experience to operate a pharmacy and to conform to DEA diversion control requirements would be present initially.

I do note the Respondent's complaint regarding the practice, attributed to Investigators Boggess and Wald, of asking applicant's questions regarding their familiarity with DEA diversion control regulations.¹⁶² After stating that "there is no law or regulation supporting this practice," the Respondent avers that "everyone knows that the DEA does not go around interviewing Walgreens or Wal-Mart shareholders or management whenever those pharmacy chains decide to open up a new location in the area."¹⁶³ I cannot endorse this conclusion, as it is not supported by any evidence in the record before me. Further, I am obliged to focus on the application before me. Here, the 90 percent shareholder and sole officer of the corporation that proposes to dispense controlled substances has only limited experience handling controlled substances, and has never operated a pharmacy. Ms. Abalihi recognized the importance of this shortfall, and proposed to fill the gap by taking on a ten percent shareholder, expecting this person to bring with her the experience needed to ensure compliance with DEA diversion control regulations. That shareholder, however, was already committed to a full-time job that prevented her from working at the new pharmacy. When this gap was raised, the ten percent shareholder lied to the DEA investigators, falsely stating a co-worker, Ms. Mustafa, would be filling the gap until the new pharmacy was operational.

Given the evidence before me, I cannot endorse the Respondent's claim that "short of being licensed as a practicing pharmacist, Mrs. Abalihi has about as much experience properly handling controlled substances as anyone is likely to have."¹⁶⁴ From her own testimony, it is clear Ms. Abalihi was unfamiliar with DEA diversion control requirements and was unwilling to answer any questions regarding the regulatory environment in which pharmacies must operate. This was true during the investigation into this application, and it was also true during the evidentiary hearing. Thus, even though Ms. Abalihi has continued her professional development by attending courses that included pharmacology, she continues to lack the knowledge and

experience required to operate a pharmacy that dispenses controlled substances. She has no experience as a pharmacist, professed no knowledge of the standards of care that must be met by registered pharmacists, and proposed no concrete plan to have a pharmacist actually working at the pharmacy, at least until the enterprise was established and operational. Upon this evidence, the Government has established by at least preponderance that issuing a Certificate of Registration to the Respondent would be inconsistent with the public interest, under Factor Two.

Factor Two and the Nexus Between Cove, Inc. and Alfred Abalihi

The Government also offered evidence under Factor Two regarding Ms. Abalihi's husband, Alfred Abalihi. In the Order to Show Cause, the Deputy Assistant Administrator reports that Mr. Abalihi "participated in unlawful dispensing of controlled substances" while employed at a pharmacy in 2007.¹⁶⁵ The Government alleged that Moon Lake Pharmacy had been engaged in illegally dispensing controlled substances based on Internet prescription activity. The general premise in this part of the charge is that Mr. Abalihi told DEA investigators in 2007 that he believed the pharmacy's operations were legal, and that he hoped someday to open his own pharmacy. Further, in its post-hearing brief, the Government calls into question Mr. Abalihi's credibility in his claim that he did not know Moon Lake's operations were illegal. From this, the Government argues that Mr. Abalihi's "negative controlled substance experience" has a "clear nexus with his wife's present experience" warranting a denial of the claim under Factor Two.¹⁶⁶

At the outset, I agree with the Government's skepticism regarding Mr. Abalihi's representation that he did not know Moon Lake's operations were illegal. It may be that current business practices tend to increase reliance on temporary or contract employees, including pharmacists; and that such practices increase the likelihood that the pharmacist will be unaware of the true nature of the pharmacy's operation. It is worth noting that to the extent such a practice exposes the pharmacist to the risk of working in an illegal shop, the pharmacist is not excused from his or her responsibility to act within the law, and must face the consequences of maintaining a blind eye to such an obviously illegal operation. Here, however, I need not rely on any such inference, because I have before me the parties' express stipulation that while at Moon Lake Mr. Abalihi "dispensed controlled substances based on unlawful Internet prescriptions [.]"¹⁶⁷

Given the very small office in which this compounding and dispensing was occurring, I find sufficient credible evidence to conclude Mr. Abalihi was aware that the

¹⁶⁵ Order to Show Cause, at 1.

¹⁶⁶ Government's Proposed Findings of Fact, Conclusions of Law, and Argument in Response to "Respondent's Brief," at 8.

¹⁶⁷ Tr., at 11–12.

¹⁶² Respondent's Post-Hearing Brief, at 12.

¹⁶³ *Id.*

¹⁶⁴ Respondent's Post-Hearing Brief, at 11.

¹⁶¹ See Tr. at 157.

practices in this pharmacy were illegal. Having said that, however, I cannot conclude that this evidence supports the Government's contention that the circumstances arising from Mr. Abalihi's work at Moon Lake Pharmacy establish cause to find Cove, Inc.'s application is inconsistent with the public interest. The evidence establishes that Mr. Abalihi would not directly participate as an officer or owner of Cove, Inc. Thus, I must question whether there is a sufficient link established between Mr. Abalihi's past work at Moon Lake Pharmacy and Cove, Inc.'s proposal to operate Allwell Pharmacy.

In support of its claim that such a nexus exists and must be recognized, the Government offers as guidance the decision in *In Re Matthew D. Graham*.¹⁶⁸ As noted in the Government's brief, *Graham* involved the application for a List 1 Chemical Registration under 21 U.S.C. 823(h) (and not registration under 21 U.S.C. 823(f)). The DEA challenged the application because the applicant's business partner had in the past surrendered a DEA registration after the partner illegally sold pseudoephedrine. In the Final Order, *Graham*'s application was denied, in part by applying language similar to language found in Section 832(f)'s Factor Two, which calls for the "public interest" inquiry to consider "[a]ny past experience of the applicant in the manufacture and distribution of chemicals[.]"¹⁶⁹ While thus not precisely on point, the discussion in *Graham* does highlight those factors that should be considered when determining whether to deny a registration based on the past misconduct of a third party.

The *Graham* opinion explained:

Regarding factor four, the applicant's past experience in the distribution of chemicals, the DEA investigation revealed that *Graham* has no previous experience related to handling or distributing listed chemicals. As set forth previously, however, his business partner Snodell surrendered a DEA registration because a DEA and KBI investigation revealed he was distributing large quantities of List I chemical products having reasonable cause to believe the chemical would be used to manufacture a controlled substance. *Graham* admitted to DEA investigators that Snodell was his source of information concerning the business of distributing listed chemicals. . . . For the above-stated reasons, the Administrator concludes that it would be inconsistent with the public interest to grant the application of *Graham*.¹⁷⁰

The agency thus may attribute to a registrant the prior misconduct of third party. The conditions in *Graham*, however, are not well aligned to those present in Cove, Inc.'s application. In *Graham*, the registrant told the DEA he intended to enter into a wholesale business arrangement with Snodell, with whom he was co-owner of a wholesale business outlet. Thus, unlike the business plan presented by Ms. Abalihi, the

registrant in *Graham* was economically tied to the third party. When it surfaced that Snodell had illegally sold pseudoephedrine a year earlier, and when it became clear that under *Graham*'s business plan Snodell would be responsible for referring List I chemical orders to *Graham*, this nexus served as a basis for denying *Graham*'s application.

In the case presently before the Administrator, on the other hand, Ms. Abalihi presented a business plan that expressly removed Mr. Abalihi from all phases of the proposed pharmacy's operation. The evidence establishes that Mr. Abalihi would not directly participate as an officer or owner of Cove, Inc. While it might be reasonable to be skeptical about the efficacy (or even the existence) of such a line between spouses, the evidence now in the record does not permit me to recognize the kind of nexus that existed in *Graham*.

The Government correctly notes in its brief that Ms. Abalihi has not indicated she would prohibit her husband from working in the pharmacy.¹⁷¹ Ms. Abalihi's statement that she would keep her husband "apart from ownership and management" of the pharmacy, however, effectively distinguishes this case from *Graham*.¹⁷² Equally important, having considered the affidavit of Mr. Abalihi, and having considered the testimony from both Mr. and Ms. Abalihi, I find sufficient credible and un rebutted evidence to conclude Mr. Abalihi does not intend to perform a significant role in the operation of Allwell Pharmacy.

I fully appreciate the Government's concern regarding the events involving Mr. Abalihi during his very short tenure at Moon Lake Pharmacy. I note the skepticism expressed by the investigators, as they recalled the nature of Moon Lake's Internet-based operation. I share their sense that anyone in Mr. Abalihi's position would have had reason to question the legitimacy of the operation, and I share their sense of incredulity that Mr. Abalihi would have failed to recognize the illegal nature of what was going on at Moon Lake, even though his stay there was brief.

The Respondent, however, correctly notes that Mr. Abalihi was not charged with any misconduct arising out of his service at Moon Lake. Mr. Abalihi may have unwisely told the DEA investigators that Moon Lake's operations were legal, but I cannot conclude from that piece of evidence that Mr. Abalihi was knowingly advancing Moon Lake's criminal enterprise when the DEA arrived. Unlike the acknowledged misconduct by *Graham*'s business partner (leading to the partner surrendering his DEA Certificate), here the most we can say for certain is that Mr. Abalihi was the pharmacist who was present when the DEA agents arrived at Moon Lake and brought its operations to an end. While it is true that the parties have stipulated that Mr. Abalihi dispensed controlled substances based on unlawful Internet prescriptions during his short tenure

at Moon Lake, Mr. Abalihi's record since then is unblemished and his plan to avoid direct involvement with Allwell and Cove, Inc. adequately attenuates the link between him and the proposed pharmacy.

Having said that, I must note that a core theme presented in support of the Respondent's application has not been established as fact. In its post-hearing brief, the Respondent states that "[o]nce the decision had been made by the DEA that Mr. Abalihi was banned for the rest of his life from ever having an ownership stake in a pharmacy with a DEA registration, the DEA then set a course of blocking anyone relating to Mr. Abalihi from obtaining a DEA registration."¹⁷³ This record does not support the premise that Mr. Abalihi has been "banned for the rest of his life" from anything.

The record fails to establish why Mr. Abalihi withdrew his request for a DEA Certificate, other than to indicate the action was based on the advice of his attorney. The factual claims on this point appearing in the Order to Show Cause have been supported by substantial evidence, and include the parties' stipulation that Mr. Abalihi improperly dispensed controlled substances while working at Moon Lake Pharmacy. The DEA has in the past recognized the need to evaluate the circumstances that may arise when a husband and wife are involved in a new application for a retail-pharmacy DEA Certificate and when there has been a prior adverse DEA action involving one of the spouses involving another pharmacy.¹⁷⁴ The facts alleged in the Order to Show Cause warranted this measure of scrutiny, but the facts shown here do not establish the kind of ties that link Mr. Abalihi's past brief involvement with Moon Lake's illegal operation to the operation proposed by the Respondent here.

I reject in its entirety, however, the Respondent's assertion that the DEA's "real motivation" in challenging Cove, Inc.'s application, was "Mr. Abalihi's brief employment at Moon Lake Pharmacy."¹⁷⁵ The assertion is based on an unproved premise that Mr. Abalihi has been unfairly "blacklisted" by the DEA, based on what he said and did on the day DEA agents visited Moon Lake Pharmacy.¹⁷⁶ The evidence before me does not establish that Mr. Abalihi is the subject of any bar to obtaining a DEA Certificate of Registration. Instead, the record indicates that Mr. Abalihi's former lawyer met with the DEA while he sought to start his own pharmacy, and was persuaded during that meeting to advise Mr. Abalihi to withdraw his application.

We do not know what was presented to this lawyer during her visits with the DEA, nor do we have the benefit of any documentary evidence supporting her reputed claim that the DEA has deemed Mr. Abalihi ineligible for a Certificate of Registration. We do not, indeed, have documentary evidence that the lawyer said or

¹⁶⁸ Government's Proposed Findings of Fact, Conclusions of Law, and Argument in Response to "Respondent's Brief," at 10, citing *In re Matthew D. Graham*, 67 FR 10229-01 (March 6, 2002).

¹⁶⁹ *Id.* at 10230, quoting 21 U.S.C. 823(h)(4).

¹⁷⁰ *Id.* at 10230.

¹⁷¹ Government's Proposed Findings of Fact, Conclusions of Law, and Argument in Response to "Respondent's Brief," at 10.

¹⁷² *Id.* quoting Affidavit of Ms. Abalihi, attached as Exhibit E to Respondent's Brief, ALJ Exhibit 6.

¹⁷³ Respondent's Post-Hearing Brief, at 11.

¹⁷⁴ See, e.g., *DePietro's Pharmacy*, 56 FR 31675-02 (July 11, 1991).

¹⁷⁵ *Id.* at 14.

¹⁷⁶ *Id.*

did anything that would justify Mr. Abalihi's decision to withdraw his 2007 application. In short, Mr. Abalihi's conclusion that he had been "blacklisted" has not been supported by competent evidence. Instead, I have been told that Mr. Abalihi deferred to his lawyer, electing not to speak with the DEA directly, and apparently withdrew his application solely at his lawyer's suggestion. This does not constitute evidence proving "unfair blacklisting," as alleged by the Respondent.¹⁷⁷

I find insufficient evidence to conclude that Mr. Abalihi's relationship with Cove, Inc., through his marriage to Ms. Abalihi, gives rise to a public threat under Factor Two, although Factor Two does serve as a basis for denying this application, given the absence of sufficient relevant experience by Ms. Abalihi, for the reasons set forth above.

Factor Five

Independent of concerns addressed under Factor Two, the evidence also forces the conclusion that conduct attributed to both Ms. Taylor and Ms. Abalihi would threaten the public health and safety, warranting a denial of the application under Factor Five. Here the evidence establishes that Ms. Taylor misled the DEA investigators when she was asked about arrangements to have a pharmacist present when Allwell began its operations. I find there is competent and credible evidence that when asked who would be working at Allwell initially, Ms. Taylor told the investigators the initial pharmacist would be her coworker, Ms. Mustafa. This was not true, and constitutes a material misrepresentation in the application process. Ms. Taylor elected not to testify (indeed there is no evidence suggesting the Respondent requested her to do so), and nothing in her affidavit¹⁷⁸ compels a more benign interpretation of her conduct.

Further, when the investigators requested contact information from Ms. Abalihi so they could confirm Ms. Mustafa's role, Ms. Abalihi compounded the misrepresentation and offered to get the requested information, rather than disclose that she knew nothing about Ms. Mustafa's role with the pharmacy. If Ms. Abalihi intended on using contract pharmacists at the start of Allwell's operation, she had an affirmative duty to say so when DEA investigators asked her about the role Ms. Mustafa was to play. By her silence, and by promising to provide contact information for Ms. Mustafa, Ms. Abalihi misled the investigators.

Making a material misrepresentation in the course of an investigation into the operation of the proposed pharmacy creates a risk of harm to the public health and safety. The operation of a pharmacy is a highly regulated enterprise, requiring advanced skill and technical expertise unique to the profession. Lying about who would be present with that skill and expertise casts doubt on the ability of both Ms. Abalihi and Ms. Taylor to protect the public, and suggests they will instead act only in their own self-interest. Upon such

evidence, the Government has established by at least preponderance that issuing a Certificate of Registration to the Respondent would be inconsistent with the public interest, under Factor Five.

Where the Government has made out its prima facie case, the burden shifts to the Respondent to show why its continued registration would be consistent with the public interest.¹⁷⁹ Having considered the record as a whole and in particular the claims appearing in the Respondent's post-hearing brief, I find no substantial evidence in rebuttal of the Government's case. Ms. Abalihi continues to take the position that she is fully qualified to operate a pharmacy, based on her experience as a Registered Nurse; and continues to seek a Certificate of Registration to dispense controlled substances out of a retail pharmacy that has no pharmacist on staff.

Findings of Fact

1. On March 3, 2011 and acting on behalf of Cove, Inc., Ogechi E. Abalihi submitted a new application for a DEA retail-pharmacy Certificate of Registration, to operate a pharmacy under the name of Allwell Pharmacy, to be located at 1947 West Dr. Martin Luther King, Jr. Boulevard, Tampa, Florida 33609. This pharmacy is not open for business and has never operated as a business, although it has been issued a community pharmacy license by the state of Florida.

2. Cove, Inc. is owned by its 90 percent shareholder and sole officer, Ogechi E. Abalihi, and its ten percent shareholder, Jacinta Taylor.

3. Ms. Abalihi has no experience working in, managing, or owning a pharmacy; has no direct knowledge of DEA controlled substance regulations; has extensive experience as a Registered Nurse; has worked with controlled substances but only in the context of her service as a Registered Nurse; and has proposed a business plan for Allwell Pharmacy that requires the presence of a pharmacist throughout the pharmacy's operating hours, which were 9:00 a.m. to 6:00 p.m. Mondays through Fridays, and from 9:00 a.m. to 1:00 p.m. on Saturdays.

4. Although the Applicant's business plan called for DEA controlled substance regulations to be implemented by a registered pharmacist on duty throughout the pharmacy's operational hours, there was no provision for having a registered pharmacist present during the initial phase of the pharmacy's operation. Instead, the plan called for Ms. Abalihi to operate the pharmacy until it became profitable, at which time Ms. Taylor planned on quitting her full-time job at another pharmacy and becoming an employee at Allwell Pharmacy. Under this plan, until Ms. Taylor actually began working at Allwell Pharmacy, there would be no one with the experience, knowledge, and training needed to ensure compliance with DEA regulations.

5. During the application process and during interviews with DEA Diversion

Investigators, both Ms. Abalihi and Ms. Taylor acknowledged the need to have a registered pharmacist present whenever the pharmacy was open. Both Ms. Abalihi and Ms. Taylor misled the Investigators by falsely representing that when it opened, Allwell Pharmacy's staff would include Dalya Mustafa, who is a registered pharmacist and was Ms. Taylor's co-worker. The evidence establishes that there would be no pharmacist present when Allwell Pharmacy began its operations, under the business plan created by Ms. Abalihi.

6. Without the active participation of Ms. Taylor or another person experienced in applying DEA regulations, Cove, Inc. lacked the experience required for its application to be consistent with the public interest.

7. The 90 percent owner of Cove, Inc., Ogechi E. Abalihi is married to a registered pharmacist, Alfred Abalihi. Mr. Abalihi is not an officer, shareholder, or employee of either Cove, Inc., or Allwell Pharmacy. There is insufficient evidence establishing that he would have any direct involvement with either Cove, Inc., or Allwell Pharmacy, just as there is insufficient evidence establishing that he would abstain from such involvement, should the pharmacy become operational.

8. Mr. Abalihi was a pharmacist employed in 2007 by HealthCare Consultants. In the course of his employment at HealthCare Consultants, Mr. Abalihi was directed to provide services as a registered pharmacist at Moon Lake Pharmacy. While providing services as a temporary worker through HealthCare Consultants at Moon Lake Pharmacy, Mr. Abalihi dispensed controlled substances based on unlawful Internet prescriptions prior to Moon Lake Pharmacy surrendering its DEA registration on December 17, 2007.

Conclusions of Law

1. When it proposes to deny a new application for a retail-pharmacy DEA Certificate of Registration, the Government is required to establish by at least a preponderance of the evidence that the pharmacy's initial registration is inconsistent with the public interest. 21 U.S.C. 823(f); 21 CFR 1301.44(d).

2. Five factors must be considered when determining the public interest in this case:

(1) The recommendation of the appropriate state licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.

(3) The applicant's conviction record under federal or state laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable state, federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety. 21 U.S.C. 823(f).

3. In order to establish a basis for denying a new application for a retail-pharmacy Certificate of Registration based on the provisions of 21 U.S.C. 823(f)(2) (Factor Two), the Government must present evidence establishing, by at least a preponderance, that

¹⁷⁷ *Id.*

¹⁷⁸ Respondent's Exhibit G, Affidavit of Jacinta Taylor.

¹⁷⁹ See *Theodore Neujahr, D.V.M.* 65 FR 5680-01, 5682 (February 4, 2000) and *Service Pharmacy, Inc.*, 61 FR 10791-01, 10795 (March 15, 1996).

the experience of the applicant in dispensing controlled substances is of such character and quality that registration is not in the public interest. This requires evidence of both the qualitative manner and quantitative volume of the applicant's experience. Where evidence of the applicant's experience, as expressed through its employees and officers, establishes that the business plan provides for the active daily involvement of no one having experience applying DEA controlled substance diversion regulations in a retail pharmacy setting, and provides only for the involvement of an employee familiar with the regulations applicable to Registered Nurses whose duties include dispensing medication, in such an application there is sufficient evidence proving, by at least a preponderance, that granting such an application would be inconsistent with the public interest.

4. When proposing to deny a retail-pharmacy application under Factor Two based on the prior association and dispensing history of a third party, the Government must demonstrate that the third party's past negative experience in dispensing controlled substances warrants a finding that his or her association with the applicant would be inconsistent with the public interest. Where, as here, the third party is the husband of the applicant's majority shareholder but has no clearly demonstrated role in either the corporation (as a shareholder or an officer), or in the retail pharmacy (as an employee or manager), and where there is insufficient evidence demonstrating the third party's past negative experience will have any impact on the operation of the retail pharmacy, the Government has not met its burden of proving a basis to deny the application under Factor Two.

5. In order to establish a basis for denying a new application for a retail-pharmacy Certificate of Registration based on the provisions of 21 U.S.C. 823 (f)(5) (Factor Five), the Government must present evidence establishing, by at least a preponderance, other conduct (*i.e.*, conduct not covered within the scope of Factors One through Four) which may threaten the public health and safety. Where, as here, the evidence establishes that when called upon by DEA investigators to identify the person or persons who would be familiar with DEA diversion control regulations and would be present at the retail pharmacy to ensure compliance with those regulations, the applicant's sole officer and both of its two shareholders made material misrepresentations about having such person or persons present, there is substantial evidence of conduct that may threaten the public health and safety. In such an application there is sufficient evidence proving, by at least a preponderance, that granting such an application would be inconsistent with the public interest.

6. Upon such evidence, the Government has met its burden and has made a *prima facie* case in support of the proposed order denying the Respondent's application for a retail-pharmacy Certificate of Registration.

7. Upon a review of the record as a whole, including all claims made in the Respondent's post-hearing brief, there is

insufficient evidence of remediation. Accordingly, the Government has established cause to deny this application.

Recommendation

As the Government has established its *prima facie* case by at least a preponderance of the evidence, the Respondent's application for a retail-pharmacy DEA Certificate of Registration should be DENIED.

Dated: April 23, 2013.

Christopher B. McNeil,

Administrative Law Judge.

[FR Doc. 2015-12131 Filed 5-19-15; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 13-31]

Farmacia Yani; Decision and Order

On April 10, 2013, the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, issued an Order to Show Cause to Farmacia Yani (Respondent), of San Sebastian, Puerto Rico. ALJ Ex. 1. The Show Cause Order proposed the denial of Respondent's application for a DEA Certificate of Registration as a retail pharmacy, on the ground that its registration "would be inconsistent with the public interest, as that term is defined in 21 U.S.C. 823(f)." *Id.* at 1.

The Show Cause Order specifically alleged that on March 27, 2012, Respondent submitted an application for a registration as a retail pharmacy, seeking authority to dispense controlled substances in schedules II through V, at a location in San Sebastian, Puerto Rico. *Id.* The Order further alleged that Respondent held a registration at the same location, which it "had surrendered for cause on December 2, 2011," and that a DEA investigation found "that from February 2009 through November 2011, [it] filled approximately 218 prescriptions for controlled substances issued by a medical doctor who did not possess a valid DEA registration, in violation of Federal law and regulations." *Id.* (citing 21 U.S.C. 843(a)(2); 21 CFR 1306.04). The Government then alleged that Respondent's "violations of Federal law and regulations render granting its application for a [registration] inconsistent with the public interest." *Id.* (citing 21 U.S.C. 823(f) and 824(a)).

On May 10, 2013, Respondent, through its counsel, requested a hearing on the allegations and the matter was placed on the docket of the Office of Administrative Law Judges. ALJ Ex. 2.

Thereafter, an Administrative Law Judge (ALJ) proceeded to conduct pre-hearing procedures. ALJ Ex. 3.

In its Supplemental Prehearing Statement, the Government provided notice to Respondent that it intended to elicit testimony from an Agency Diversion Investigator (DI) that Respondent had "filled twenty-nine (29) prescriptions for Suboxone that were written by two doctors who did not possess authority to issue these controlled substances," that the "prescriptions were written by Dr. Aguilar-Amieva and Dr. Cesar I. Vargas-Quinones," and that a review of "the DEA registration database . . . found that these two physicians were never registered with DEA as data-waived practitioners, in violation of 21 CFR 1301.28." ALJ Ex. 7, at 3. The Government also provided notice that it intended to question Respondent's owner "about the circumstances of the pharmacy's prior surrender of its . . . registration, and about her failure to note the previous surrender on Respondent's new application for registration." *Id.*

On July 16, 2013, the ALJ conducted an evidentiary hearing in Guaynabo, Puerto Rico.¹ Tr. 27. At the hearing, the

¹ On June 18, 2013, the ALJ had conducted the first day of the hearing, during which he reviewed the parties' proposed stipulations and admitted several documents into the record, while holding the admission of two Government exhibits in abeyance. *See* Tr. 4-14 (June 18, 2013). After Respondent's counsel objected to the admission of some of the Government's exhibits because they contained prescriptions issued by a doctor whose prescriptions were not the basis of what it had previously alleged, the Government announced that it would be filing a supplemental prehearing statement during which it would "outline that the Government discovered some prescriptions by Dr. Cesar Vargas-Quinones." *Id.* at 14. After the ALJ ruled that these exhibits would "be held in abeyance until after we've had the opportunity to see what the Government sets forth in its supplemental prehearing statement," the ALJ explained that the deadline for both parties to file their supplemental prehearing statements would "be simultaneous"; the ALJ also told Respondent's counsel that "you really won't have a chance to reply in your—in your response in the prehearing statement," but that she would be able "to object to these exhibits during the hearing itself." *Id.* at 15-16. Notably, during the June 18 hearing, the Government made no mention of its intent to raise the material falsification issue. Moreover, the ALJ subsequently ordered that the parties file any supplemental prehearing statements with the Office of Administrative Law Judges "not later than 2:00 p.m. on the 9th of July 2013." *Id.* at 18-19.

The same day, the ALJ also issued an Order memorializing these instructions. *See* Order (June 18, 2013). Therein, the ALJ further instructed that "[a]fter this deadline, Prehearing Statements may only be supplemented upon the filing of a motion for extension of time and after a favorable ruling by me. Any new documents identified in a supplemental prehearing statement also need to be exchanged by the parties no later than July 9, 2013." *Id.* at 4.

Government elicited the testimony of a DI and Ms. Yanira Santiago-Soto, Respondent's owner and pharmacist in charge; Respondent also elicited the testimony of Ms. Santiago-Soto. Both parties also introduced documentary evidence into the record. Following the hearing, both parties submitted briefs containing their proposed findings of fact, conclusions of law, and argument.

On September 26, 2013, the ALJ issued his Recommended Decision (hereinafter, cited as R.D.) Therein, the ALJ found that the Government had established a *prima facie* case that granting Respondent's application "would be inconsistent with the public interest." R.D. 36. The ALJ further found that Respondent had "failed to rebut" the Government's case. *Id.* The ALJ thus recommended that Respondent's application be denied.

Respondent filed Exceptions to the Recommended Decision. Having reviewed Respondent's Exceptions along with the entire record, I find that several of them are well taken and that the ALJ committed multiple prejudicial errors. These include:

(1) Barring Respondent from using a document, which, according to Respondent's offer, was from DEA's Web site, to impeach a Government witness, because it was not submitted in advance of the hearing;

(2) barring Respondent from introducing evidence of an email its principal sent to an Agency Investigator the day after she submitted the application, which according to Respondent's offer, memorialized a phone conversation in which she asked if she had correctly answered an application question, also on the ground that it was not submitted in advance of the hearing, notwithstanding that the Government did not even disclose that it was pursuing the material falsification allegation until one week before the hearing; and

(3) finding that Respondent's principal materially falsified its application based on the answer she gave to Question Four when the Government never provided notice that the answer to this question was at issue in the Show Cause Order, its pre-hearing statements, or its opening statement, nor even questioned her about her answer to this question, even though it called her to testify in its case-in-chief.

Because I reject the ALJ's legal conclusions that Respondent's principal materially falsified its application and that Respondent violated its corresponding responsibility under 21 CFR 1306.04(a) when it dispensed prescriptions issued by a physician

whose registration had expired, and these errors solely affect these two allegations, I conclude that a remand is not warranted. While I agree with the ALJ's legal conclusion that Respondent violated federal law when it dispensed Suboxone prescriptions, which were issued to provide maintenance or detoxification treatment and the prescribers lacked the requisite authority to prescribe the drug for this purpose, I do not find that the record as a whole supports the proposed outright denial of the Application. Accordingly, I will order that Respondent be granted a registration subject to conditions set forth in this decision. I make the following findings of fact.

Findings

Respondent's License and Registration Status

Respondent is a corporation which owns a retail pharmacy located at Carretera 109, Kilometer 26.7, Barrio Culebrina, San Sebastian, Puerto Rico. Tr. 9; GX 1. Ms. Yanira Santiago-Soto is the owner of Respondent and its pharmacist-in-charge. Tr. 106.

Respondent is licensed as a pharmacy by the Commonwealth of Puerto Rico Department of Health; this license does not expire until June 26, 2015. RX D1, at 3. Respondent also holds a controlled substance registration, which was also issued by the Commonwealth's Department of Health.² RX E4.

Respondent previously held DEA Certificate of Registration FF1070894, pursuant to which it was authorized to dispense controlled substances in schedules II through V. GX 5, at 1. While this registration was not due to expire until September 30, 2014, on November 30, 2011, Ms. Santiago-Soto surrendered Respondent's registration.³ *Id.*; see also RX I. On March 26, 2012, Ms. Santiago-Soto applied on Respondent's behalf for a new registration. GX 1, at 1–2. It is this

² According to the certificate, the registration was due to expire on September 30, 2013. RX E, at 4.

³ The day before, Ms. Santiago-Soto had been indicted along with thirty-two other defendants, on two felony counts of violating the Controlled Substances Act. The charges were: (1) Conspiring to possess and dispense, with intent to distribute, various controlled substances, in violation of 21 U.S.C. 841(a)(1), 846, and 860; and (2) aiding and abetting each other and "knowingly and intentionally possess[ing] and dispens[ing] with intent to distribute various" schedule II through IV controlled substances, "outside the scope of professional practice and not for a legitimate medical purpose," in violation of 21 U.S.C. 841(a)(1) and 18 U.S.C. 2. RX B, at 1–13. Several months later, the Government moved to dismiss the charges with prejudice, and on March 23, 2012, the District Court entered a Judgment of Dismissal. RX C.

application which is at issue in this proceeding.

On the application, Respondent was required to answer four questions. *Id.* at 1. The second of these asked: "Has the applicant ever surrendered (for cause) or had a federal controlled substance registration revoked, suspended, restricted or denied, or is any such action pending?" GX 1, at 1. Ms. Santiago-Soto answered the question by checking the "no" box. *Id.* The fourth question asked, in relevant part:

If the applicant is a corporation (other than a corporation whose stock is owned and traded by the public), association, partnership, or pharmacy, has any officer, partner, stockholder or proprietor been convicted of a crime in connection with controlled substance(s) under state or federal law, or ever surrendered or had a federal controlled substance registration revoked, suspended, restricted or denied, or ever had a state professional license or controlled substance registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?

Id. Respondent also answered this question, by checking the "no" box. *Id.*

The Investigation of Respondent

Following Ms. Santiago-Soto's submission of Respondent's application, a Diversion Investigator with the Ponce, Puerto Rico DEA Office was assigned to investigate the application. Tr. 40–41. Upon doing so, the DI determined that on November 30, 2011, a search warrant had been executed at Respondent during which various items of evidence, including prescriptions, were seized. *Id.* at 43. Some of the evidence was sent to the DEA digital evidence laboratory for further analysis; according to the DI, the lab extracted various data and sent a CD containing the data to his office. *Id.* at 44. In addition, prescriptions were seized from Respondent and scanned by the Ponce DEA office. *Id.*

Upon reviewing the data provide by the digital evidence lab, the DI determined that "there were two main violations." *Id.* at 46. According to the DI, the first set of violations involved Respondent's having "illegally filled" some "241 prescriptions" which were issued by a Doctor Hector J. Aguilar-Amieva after the latter's registration was retired by DEA on January 31, 2009 and "he was no longer authorized to prescribe any controlled substances. *Id.* at 46–47; see also GX 6 (affidavit of Chief, Registration and Program Support Section, Drug Enforcement Administration, stating that Dr. Aguilar-Amieva's registration expired on June 30, 2008 and was retired from the DEA computer system on January 31, 2009).

As for the second set of violations, the DI stated that they involved

Respondent's having filled twenty-nine prescriptions issued by both Dr. Aguilar-Amieva and Dr. Cesar Vargas-Quinones for Suboxone (buprenorphine). Tr. 47, 49. According to the DI, the prescriptions were unlawful because the doctors "were not authorized to" prescribe Suboxone (buprenorphine) "because they were not DATA-waived⁴ practitioners." *Id.* at 48. The DI further explained that a DATA-waived practitioner is a physician who is approved by "the Center of Substance Abuse" (actually, the Center for Substance Abuse Treatment, a component of the Substance Abuse and Mental Health Services Administration) to prescribe Suboxone (buprenorphine) to treat narcotic addiction and that these physicians are issued "a specific registration that is distinguished with an X number," which "should be on the prescription[s]" they issued for these drugs. *Id.* at 49. However, none of these prescriptions bore an X number (even though seventeen of the twenty-nine prescriptions listed a diagnosis of opiate addiction or dependence). *Id.* at 49–50; *see also* GX 3, at 410–56.

The DI further testified that Respondent's application contained a falsification because in answering "[q]uestion [n]umber 3," Ms. Santiago-Soto failed to disclose that the pharmacy had previously surrendered its registration. Tr. 45. While the DI was not present when Ms. Santiago-Soto surrendered Respondent's registration, he testified that he had read a report that stated that she "voluntarily surrendered the pharmacy's license" and that he had also seen the document that she signed, and that the document said that she "voluntarily surrendered" the registration. *Id.* at 60–61. The DI further explained that based on the inconsistencies between what he read in the report and the answers to the application's questions, he concluded that Ms. Santiago-Soto had falsified the application. *Id.* at 62–63.

Later, on cross-examination, the DI conceded that the criminal charges which were filed against Ms. Santiago-Soto were voluntarily dismissed with prejudice. *Id.* at 72. Moreover, when asked whether Ms. Santiago-Soto had violated any federal law or regulation, the DI answered:

The conclusion, once again, is based on our records, what I see in the records, and it's based on the evidence. Whenever an application is submitted to the DEA, and we are required to analyze this application, and based on the pharmacy's, for example, that

the applicant is dispensing controlled substances.

Id. at 72–73. Respondent's counsel then asked if anyone had found that Ms. Santiago-Soto "has violated any federal law in dispensing those prescriptions that are part of the evidence here today?" *Id.* at 73. The Government objected on the ground that the question "ha[d] been asked and answered" and the ALJ sustained the objection, noting that he knew that the charges were dismissed and that there was no evidence that Ms. Santiago-Soto had been convicted of any federal offense.⁵ *Id.*

Respondent's counsel then asked the DI if there was any official Web site or registry where a pharmacist can verify if a DEA number is active. *Id.* at 74. The DI testified that there is such a registry, that he "believe[d]" that the registry was available in 2009 through 2011 and was located at the DEA Diversion Web site, and that he believed that if a person was registered, they could access the Web site. *Id.* Subsequently, the DI testified that he could confirm that the registry has been available since 2009, but "[t]o [his] knowledge . . . physicians have been informed at least from 2010, [and] that she should have been able to do that." *Id.* at 75–76. However, later in his testimony, Government counsel raised the possibility that this service had been discontinued, when he asked the DI: "But you're not aware of when it started, and when it stopped?" and the DI answered: "That is correct." *Id.* at 92.

Respondent's counsel then asked the DI "why the DEA site, as of today, states that you cannot verify a DEA number online?" *Id.* at 76. The DI replied:

⁵ Contrary to the ALJ's understanding, this was an undue restriction on Respondent's right of cross-examination, especially given that the answer was not responsive.

Later in the proceedings, the Government called Respondent's owner in its case-in-chief. *Id.* at 106. During cross-examination, the Government objected to Ms. Santiago-Soto's testimony (well after the question was asked and well into her answer) regarding a conversation she had in April 2012 with the group supervisor on the ground that it was "[o]utside the scope of the pre-hearing statement" and "[t]here [was] no proffer that they were going to be introducing testimony from DEA agents." Tr. 134. The ALJ sustained the objection on the ground that "it goes beyond the scope of what you informed in the amended pre-hearing statement." *Id.*

Here again, the ALJ erred in sustaining the objection. Even if Respondent's pre-hearing statements did not disclose that Ms. Santiago-Soto would testify regarding this issue, its pre-hearing statement only limited the scope of what she could testify to on direct examination in Respondent's case-in-chief and had no bearing on the appropriate scope of cross-examination given that Ms. Santiago-Soto was still testifying as a Government witness. Moreover, the Government did not argue that the testimony was beyond the scope of its direct examination.

"[t]hat is new to me." *Id.* Respondent's counsel then asked if he could show a document to the DI which, according to the proffer, was from the Agency's Web site and was contrary to the DI's testimony. *Id.* at 76–78. The ALJ barred Respondent's counsel from doing so even for the purpose of impeachment, explaining that his prehearing orders were clear that if documents "were not presented to the Government, in advance of the hearing," he would not "allow it." *Id.* at 77.

Respondent's counsel then asked the DI if, in order to verify a DEA number, one had to pay for a program. *Id.* at 78–79. The DI answered that this was correct but that that "if there are [sic] any reason to verify, you can call our office at any time, and you can ask for a verification." *Id.*; *see also id.* at 92. Next, when asked if "the law requires that any dispensing pharmacist calls the DEA to verify if a physician's license is active," the DI answered "yes." *Id.* at 79. When then asked what statute or agency regulation requires this, the DI could not identify one. *Id.* at 79–80. Moreover, the DI then testified that there is no law or regulation that requires a pharmacy to subscribe to the database provided by the National Technical Information Service. *Id.* at 80.

Still later, when asked if "it is the responsibility of the doctor [to have] a valid DEA license when prescribing a controlled substance," the DI answered: "It is the responsibility of both the doctor and the pharmacist. The pharmacy has the responsibility." *Id.* at 86–87. The DI then acknowledged that the prescriptions in Government Exhibit 3 contained the required information and that he could not identify a prescription that was "suspicious or irregular without knowing that the physician's license has been revoked or expired." *Id.* at 87–88. However, on redirect examination, the DI explained that the Suboxone prescriptions were suspicious because they did not include an X number for the physician. *Id.* at 90–91.

Respondent's counsel then asked whether he had "any evidence" that Ms. Santiago-Soto "ha[d] acted with the intention or knowledge" in dispensing either Dr. Aguilar's or Dr. Vargas' prescriptions. *Id.* at 88. The DI answered that he did not "base [his] evaluations on intentions" but "on the documents" that he had "seen." *Id.*

Also on redirect, the DI was asked whether part of the process of granting the applications of pharmacies involves "explaining to the pharmacies that they have the burden to verify all prescriptions." *Id.* at 91. The DI answered "that is correct," and agreed

⁴ *See* Drug Addiction Treatment Act of 2000, Pub. L. 106–310, Div. B, Title XXXV, § 3502(a), 114 Stat. 1222 (2000) (codified at 21 U.S.C. 823(g)(2)).

that this is a requirement for maintaining a DEA registration “under the code of regulations.” *Id.*

Still later in his testimony, when no question was pending, the DI proceeded to state that even aside from the Suboxone prescriptions, the 241 prescriptions at issue were suspicious because they were for oxycodone and alprazolam, which are highly abused drugs. *Id.* at 95–96. The DI then explained that “if physicians regularly prescribe those drugs only, those should be of concern to any pharmacist who is . . . trying to ensure the public health and safety.” *Id.* at 96. The Government did not produce any evidence, however, to show that these were the only drugs which were being prescribed by Dr. Aguilar-Amieva and being filled by Respondent.

The Government also called Ms. Santiago-Soto as a witness. Tr. 105. Ms. Santiago-Soto acknowledged that she has been Respondent’s owner and pharmacist-in-charge since she opened the pharmacy.⁶ *Id.* at 106. Asked by the Government whether the pharmacy had filled “241 prescriptions for Dr. Aguilar-Amieva from February 2009 to October 2009,” Ms. Santiago-Soto answered “yes.” *Id.* However, when asked whether she knew “that his registration had been revoked in January of 2009,” Ms. Santiago-Soto answered that she “didn’t know” at the time.⁷ *Id.* at 106–07.

Next, the Government asked Ms. Santiago-Soto whether she “believe[d] that it’s your duty to verify all prescriptions”; she replied: “That’s what I do all the time.” *Id.* at 107. The Government then asked Ms. Santiago-Soto why she had filled Dr. Aguilar-Amieva’s prescriptions “if that’s what you do all the time?” *Id.* Ms. Santiago-Soto replied:

Well to start with, I’m a pharmacist. And I revise [sic] prescriptions, and I make sure

⁶ Ms. Santiago-Soto testified that she had worked at four other pharmacies prior to opening Respondent. Tr. 139–40. She also testified that Respondent had been inspected by the Commonwealth’s Health Department and the AMSCA, which is the Commonwealth agency that regulates controlled substances, and that she held the licenses required by the Commonwealth. Tr. 141–42. She further testified that Respondent had been inspected twice by DEA and had provided the DIs with both prescriptions and a list of various controlled medications that it had dispensed; according to Ms. Santiago-Soto, she was never notified that her pharmacy had engaged in any wrongdoing. *Id.* at 143.

⁷ The Government’s evidence does not establish that Dr. Aguilar-Amieva’s registration had been revoked, in which case a Decision and Order would have been published in the *Federal Register*. See GX 6. Rather, the Government’s evidence shows that Dr. Aguilar-Amieva’s registration expired on June 30, 2008 and was retired from the DEA computer system on January 31, 2009. See *id.*

that the indications are correct, are the adequate ones, that they meet all standards and legal requirement [sic], whether they be federal or state laws.

Once all those standards are met, and there is no question surrounding the prescription that might prompt me to call the physician for whatever reasons, then we proceed to dispense it.

Id. at 107–8.

Ms. Santiago-Soto then acknowledged that Respondent filled the twenty-nine Suboxone prescriptions issued by Drs. Aguilar-Amieva and Vargas-Quinones and that she was not aware that neither doctor was a DATA-waiver physician. *Id.* at 108. When asked whether Respondent had ever contacted the two doctors to verify the purpose of these prescriptions, Ms. Santiago-Soto answered:

I verified the exhibit that you . . . gave me. . . . And if you take a look at the Suboxone prescriptions, in their majority, they have a diagnosis that is related to the abuse of opioids, or opiates.

Therefore, it was my understanding that these physicians had their license current, including some prescriptions that were invoiced to health insurance plans, and they were paid by these, even after they were reviewed.

So, supposedly, that if the health insurance plan hires a physician, all the credentials should be up to date. And if they didn’t come to notice this, and with them being the health insurance plan, when they are usually up to date on everything, then it was my understanding that the prescriptions were okay.

Id. at 109. When then asked what her understanding was of who could prescribe Suboxone to treat substance-abuse patients, Ms. Santiago-Soto answered that she “was aware of the use given to the medication” and that “[i]f you go prescription by prescription . . . the amounts are not such that would raise my suspicions that something is running amok.” *Id.* at 109–10. She then reiterated that, at the time, she “was not aware of the X DEA number” that is required to prescribe Suboxone and buprenorphine to treat narcotic-dependent patients. *Id.* at 110.

Upon questioning by the Government, Ms. Santiago-Soto acknowledged that a DATA-waiver physician must meet certain requirements and that “not all physicians may prescribe” Suboxone, and that a physician who prescribes Suboxone for this purpose must have an X-number. *Id.* The Government then asked Ms. Santiago-Soto why she did not know this when she “became accredited as a pharmacist?” *Id.* Ms. Santiago-Soto explained that she graduated in 1995, that the DATA was enacted in 2000, and that Suboxone and buprenorphine were not approved for

this purpose until 2002. *Id.* She then contended that “the DEA in Puerto Rico never has provided any guidance to her whether through an orientation or conference, online guidance, or by letters.” *Id.* She further asserted that in none of the continuing education classes that she was required to take to maintain her pharmacist license was there any training offered by DEA on the DATA’s requirements. *Id.* at 111.

Ms. Santiago-Soto testified that she did not become aware of the DATA’s requirements until Respondent was audited by a health insurance plan and the buprenorphine prescriptions were discussed with her.⁸ *Id.* at 112. However, she acknowledged that she should have learned of these requirements earlier. *Id.* at 114. After describing what she was taught at pharmacy school about spotting diversion, *id.* at 114–16, the Government asked Ms. Santiago-Soto whether she found “anything suspicious with Dr. Aguilar-Amieva’s prescriptions?” *Id.* at 116. She replied:

The prescriptions met all legal parameters. The patients would come over to the drug store, and the ones that I did dispense, their reputation wasn’t in doubt, in my judgment, because many of them would also bring me prescriptions of their medications that they took for continuous use.

Id.

The Government then asked Ms. Santiago-Soto whether she analyzed the prescribing practices of a physician for signs of diversion when filling a prescription. *Id.* at 117. Ms. Santiago-Soto replied:

I don’t speak with the doctors. There is a confidentiality law between doctor and patient. I review that the prescription meets the law and that it shouldn’t raise the least suspicion possible in me, that this medication is not intended, particularly intended for this patient, for medical use.

Id. at 117. When then asked whether she “went through [Respondent’s] computer system looking for patterns,” Ms. Santiago-Soto answered that she “kept a manual inventory and . . . from it I couldn’t necessarily discern that something was out of place.” *Id.* at 119. She then explained that in 2009, she dispensed a total of 30,000 prescriptions (including 27,000 for non-controlled drugs), of which 66 had been written by

⁸ Ms. Santiago-Soto denied that she had not learned about the DATA’s requirements until after being served with the Show Cause Order. Tr. 112. Ms. Santiago-Soto testified that the insurance plan audit occurred several months before the search warrant was executed at her pharmacy. *Id.* at 113. It is noted that the Government’s evidence shows that Respondent did not dispense any Suboxone prescriptions after July 3, 2011. GX 4, at 23–24.

Dr. Aguilar-Amieva.⁹ *Id.* She further stated that Dr. Aguilar-Amieva's prescriptions did not raise any suspicion. *Id.* at 122.

Turning to the application, Ms. Santiago-Soto acknowledged that she understood both questions two and three.¹⁰ *Id.* at 123–24. When then asked whether she had surrendered her DEA registration for cause in November 2011, Ms. Santiago-Soto replied: “In my judgment, I surrendered the license, but not with cause.” *Id.* at 124. She then explained that:

. . . . In my judgment, this is simple. When I surrendered my license, it was in a situation where I was under arrest, and I had no other choice but to sign the document that was placed in front of me.

Moreover, at the moment of having to sign the document, an agent came out speaking or yelling, “was her rights read to Yanira Santiago, was her Miranda rights”—and just before I signed that paper that said “surrender,” I had my Miranda rights read. And I was practically signing simultaneously.

Agent [P.N.], from the Ponce DEA, explained to me that I had to sign that surrender because of the criminal charges against me. And not because of what I'm being told of here.

* * * * *

I'm handcuffed, and I had to sign a document that they demand from me to sign because I had no other option. Because, according to what they were saying, I was part of a scheme.

When I proceed to answer this questions [sic] that is posed in the new application and quote/unquote, it puts the words “with cause.”

It's my understanding, as of this day, that I surrendered the license without cause, because it was taken away from me because of my criminal case [an]d not because of what I'm being told here.

Id. at 124–26. *See also id.* at 132 (“I signed the document, because he told me that I had to surrender the license because of a criminal charge against me.”).

Ms. Santiago-Soto then explained that when she filled out the application “that question raised doubts in my mind.” *Id.* at 126. Accordingly, the next day, she called “the regional director for

the DEA in Ponce¹¹ . . . and . . . told her . . . that I was unsure if I had answered the question correctly” and that she had “answered ‘no,’ because, quote/unquote, it said ‘with cause.’” *Id.* Ms. Santiago-Soto further testified that the official said “that she would look into it and verify if that was answered correctly, because she didn't know. And she also told me that, since I had informed her about it, eventually, if any situation came up, she could appear as a witness and say that I had that doubt, and I had asked her about it, and that she had answered me.” *Id.* at 126–27. Ms. Santiago-Soto testified that she memorialized the conversation in an email. *Id.* at 127. However, as of the date of the hearing, the official had not replied to the email. *Id.* at 136.

The Government then asked Ms. Santiago-Soto “if you had to fill this application out again today, what would you put for the Question No. 3?” *Id.* at 128. Ms. Santiago-Soto replied:

I would answer it the same way. I would answer the same thing. Because of the statement “with cause,” if that statement wouldn't have been there, I would have no reason to answer “no.” I would've answered “yes.” Because I surrendered.

But since it stated, in parentheses, “with cause,” that's not my issue. Because I surrendered my DEA license because of the criminal case against me. Not because of this intervention right now, that we're having today.

Id.

Throughout her testimony, Ms. Santiago-Soto maintained that she did not voluntarily surrender Respondent's registration, but rather was coerced into surrendering it. *Id.* at 132. She also testified that the various prescriptions which form the basis of the allegations regarding the dispensing violations were taken from Respondent on the date she was arrested. *Id.* at 135–36.

Upon the conclusion of Respondent's cross-examination of Ms. Santiago-Soto, Respondent's counsel attempted to move into evidence a copy of the email which she had sent to the group supervisor and explained that he had shown a copy of the email to the Government. *Id.* at 137. The ALJ denied the motion, explaining: “That may be true, Counsel, but I don't have it. It's not evidence before me. I don't have any reason to understand why it wasn't presented ahead of time, so I could evaluate it.” *Id.* at 137–38.

As found above, the email appears to have been relevant to the issue of whether Ms. Santiago-Soto falsified Respondent's application. And contrary

to the ALJ's on the record explanation for denying the motion, there was ample reason for why the document was not “presented ahead of time.” Specifically, the ALJ ignored that the Government did not provide any notice that it intended to litigate the issue of material falsification until its supplemental pre-hearing statement, which it filed one week before the hearing, and on which date Respondent was also required to file its supplemental pre-hearing statement. Moreover, the ALJ's June 18 order did not address what procedure Respondent was required to follow in the event the Government raised an entirely new allegation at this stage of the proceeding. *See* ALJ Ex. 7. Finally, the document was not included with the transmitted record as a rejected exhibit as it should have been. *See* 21 CFR 1316.60.

Ms. Santiago-Soto also testified in Respondent's case-in-chief. Ms. Santiago-Soto testified that prior to her arrest on November 30, 2011, she had been inspected twice by DEA. Tr. 142–43. The first of these inspections occurred on September 2, 2010; the second on September 7, 2011. RXs G & H. While Agency Investigators apparently reviewed the controlled-substance prescriptions and her dispensing records, they never notified her of “any findings or wrongdoings on” the part of Respondent. Tr. 143. Nor did they advise that Dr. Aguilar-Amieva or any other doctor was under investigation. *Id.* at 144.

Ms. Santiago-Soto further testified that there is a “question and answer section” on the DEA diversion Web site which includes a question regarding whether the Agency can verify a DEA registration. *Id.* at 145–46. According to Ms. Santiago-Soto, “the answer that the DEA gives . . . is ‘no’” and that she has to buy a program from the National Technical Information Service “to be able to have access on several occasions to that registry.” *Id.* at 146. Ms. Santiago-Soto further testified that it “costs over \$2,000 on an annual basis . . . for one user.” *Id.* However, she then explained that she would buy the program if she is issued a registration. *Id.* at 146–47. Still later, she testified that the NTIS is “costly for a drugstore that's just starting out” and that she did not “know of any small community pharmacy that has purchased” a subscription to the NTIS database, “because the law does not require that it be purchased.” *Id.* at 149. However, she reiterated that she would purchase the database. *Id.*; *see also id.* at 154–55. Moreover, Ms. Santiago-Soto testified that if she was granted a registration, she would be willing to consider any

⁹In Respondent's case in chief, Ms. Santiago-Soto testified that Respondent dispensed 104 prescriptions in 2010 and 63 prescriptions in 2011 which were issued by Dr. Aguilar-Amieva. Tr. 151.

¹⁰Question three asks whether “the applicant [has] ever surrendered (for cause) or had a state professional license or controlled substances registration revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?” GX 1, at 1. There is no evidence, however, that the Commonwealth took any of these actions against Respondent's (or Ms. Santiago-Soto's) professional license or controlled substance registration. Thus, it is unclear why Ms. Santiago-Soto was asked about this question rather than question four.

¹¹I have taken official notice that the official is actually a group supervisor.

recommendations made by the Agency. *Id.* at 155.

Regarding the allegation that she dispensed prescriptions written by Dr. Aguilar-Amieva, whose registration had expired, Ms. Santiago-Soto explained that she had reviewed the DEA Pharmacist's Manual, and that while the Manual contains extensive information as to what must be provided on a prescription, "[n]owhere in the law am I told that I have to be checking each one of the licenses at every moment." *Id.* at 148. She also testified that during the period at issue, she "would check the list of those physicians that had been criminally charged because of their prescriptions," *id.*, and that if the name of a doctor was not on the list, she "proceeded to dispense the prescription." *Id.* at 161.

However, neither Dr. Aguilar-Amieva nor Dr. Vargas-Quinones appeared on the various lists for the years 2008 through 2013.¹² *Id.* at 148–49. Finally, Ms. Santiago-Soto denied that she had ever knowingly dispensed a prescription which had not been lawfully issued. *Id.* at 154.

Following the conclusion of Ms. Santiago-Soto's testimony, Respondent's counsel requested that the ALJ take official notice of various documents, including the Web page containing various questions and answers which Respondent's counsel had previously sought to use to impeach the testimony of the DI to the effect that Ms. Santiago-Soto could have verified whether the physicians were registered by calling DEA. Tr. 162–67. After the ALJ asserted that the document's "relationship to the narrative . . . attributed to" Respondent should have been clear to its counsel when she filed its amended pre-hearing statements, Respondent's counsel again argued that it had no "knowledge that the witness for the DEA would provide testimony . . . under oath, that contradicts the information the DEA provided on that Web page." *Id.* at 167.

¹² On cross-examination by the Government, Ms. Santiago-Soto acknowledged that these lists may actually have been of those physicians who were subjected to administrative proceedings. Tr. 158. When the Government suggested that her review of these lists was inadequate because they were lists of final agency actions and would not "contain the names of doctors that voluntarily surrendered" their registrations, Ms. Santiago-Soto replied that "I can't make any supposition, as you've been telling me. You're asking me to suppose something, and I'm not here to suppose anything. I'm here with facts. I'm being shown facts. So I have to answer with facts." *Id.*

However, upon questioning by the ALJ, Ms. Santiago-Soto admitted that if a doctor who voluntarily surrendered his registration was not identified on the Web site, she "wouldn't know" that the doctor did not have the requisite authority. *Id.* at 161–62.

However, the ALJ again rejected Respondent's request. *Id.*

Discussion

Section 303(f) of the Controlled Substances Act (CSA) provides that an application for a practitioner's registration may be denied upon a determination "that the issuance of such registration would be inconsistent with the public interest." 21 U.S.C. 823(f). In making the public interest determination, the CSA requires the consideration of the following factors:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The applicant's experience in dispensing . . . controlled substances.

(3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

Id.

"These factors are . . . considered in the disjunctive." *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). I "may rely on any one or a combination of factors, and may give each factor the weight [I] deem[] appropriate in determining whether . . . an application for registration [should be] denied." *Id.* Moreover, I am not required to make findings as to all of the factors.¹³ *Volkman v. DEA*, 567 F.3d 215, 222 (6th Cir. 2009); *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005).

Under Section 304(a)(1), a registration may be revoked or suspended "upon a

¹³ I have considered Respondent's evidence that it is currently licensed by the Commonwealth of Puerto Rico as a pharmacy and holds a registration from the Commonwealth which authorizes it to dispense controlled substances. I have also considered Respondent's evidence that the Pharmaceutical Board took no action against Ms. Santiago-Soto's pharmacist's license. However, none of these documents constitute a recommendation from the state licensing board as to whether DEA should grant the application, *see* 21 U.S.C. 823(f)(1), and while Respondent clearly possesses authority to dispense controlled substances under the laws of the Commonwealth and thus meets a prerequisite for obtaining a registration, this finding is not dispositive of the public interest inquiry.

So too, I acknowledge that neither Respondent, nor Ms. Santiago-Soto, has been convicted of an offense under either federal or Puerto Rico law "relating to the manufacture, distribution or dispensing of controlled substances." 21 U.S.C. 823(f)(3). However, while the charges against Ms. Santiago-Soto were dismissed, this finding is not dispositive of the allegations that Respondent filled unlawful prescriptions because this proceeding involves different allegations than those brought in the criminal proceeding and is subject to a lower standard of proof (the preponderance standard) than that applied in a criminal proceeding.

finding that the registrant . . . has materially falsified any application filed pursuant to or required by this subchapter." 21 U.S.C. 824(a)(1). Under agency precedent, the various grounds for revocation or suspension of an existing registration that Congress enumerated in section 304(a), 21 U.S.C. 824(a), are also properly considered in deciding whether to grant or deny an application under section 303. *See The Lawsons, Inc.*, 72 FR 74334, 74337 (2007); *Anthony D. Funches*, 64 FR 14267, 14268 (1999); *Alan R. Schankman*, 63 FR 45260 (1998); *Kuen H. Chen*, 58 FR 65401, 65402 (1993). Thus, the allegation that Respondent materially falsified its application is properly considered in this proceeding. *See The Lawsons*, 72 FR at 74337; *Samuel S. Jackson*, 72 FR 23848, 23852 (2007). Moreover, just as materially falsifying an application provides a basis for revoking an existing registration without proof of any other misconduct, *see* 21 U.S.C. 824(a)(1), it also provides an independent and adequate ground for denying an application. *The Lawsons*, 72 FR at 74338; *cf. Bobby Watts, M.D.*, 58 FR 46995 (1993).

In this matter, the Government alleged that Ms. Santiago-Soto materially falsified Respondent's application for registration by failing to disclose that it had previously surrendered its prior registration for cause. Gov. Post-Hearing Br., at 6–9. It also alleged that Respondent's registration is inconsistent with the public interest because it violated 21 U.S.C. 843(a)(2), as well as 21 CFR 1306.04 and 1306.06, when: (1) Between February 2009 and October 2009, it filled 241 prescriptions which were issued by Dr. Aguilar-Amieva, whose registration had been retired by the Agency; and (2) it filled Suboxone prescriptions issued by Dr. Aguilar-Amieva and Dr. Vargas-Quinones to treat narcotic addiction, when neither doctor was authorized under Federal law to do so. *See* Gov. Post-Hearing Br., at 11–12.

The Material Falsification Allegation

The Government argues that Ms. Santiago-Soto materially falsified Respondent's application for registration because she failed to disclose the November 30, 2011 surrender of its registration. More specifically, the Government contends that Ms. Santiago-Soto materially falsified the application, when she provided a "no" answer to question two, which asked: "Has the applicant ever surrendered (for cause) or had a federal controlled substances registration revoked, suspended,

restricted or denied, or is any such action pending?" Gov. Br. at 7 (citing GX 1, at 1). Moreover, in its post-hearing brief, the Government contends—for the first time in the proceeding—that Ms. Santiago-Soto also materially falsified the application when she provided a "no" answer to question four, which asked: "If the applicant is a corporation . . . or pharmacy . . . has any officer, partner, stockholder or proprietor . . . ever surrendered or had a federal controlled substances registration revoked, suspended, restricted, or denied" *Id.* at 8. I reject the allegations.

One of the fundamental tenets of Due Process is that an Agency must provide a Respondent with notice of those acts which the Agency intends to rely on in seeking the revocation of its registration so as to provide a full and fair opportunity to challenge the factual and legal basis for the Agency's action. See *NLRB v. I.W.G., Inc.* 144 F.3d 685, 688–89 (10th Cir. 1998); *Pergament United Sales, Inc. v. NLRB*, 920 F.2d 130, 134 (2d Cir. 1990). Because the Government did not allege in the Order to Show Cause that Respondent had materially falsified its application, before proceeding to address whether the evidence supports the Government's contention, it is necessary determine whether the Government otherwise provided adequate notice of its intent to litigate the issue. See 5 U.S.C. 554(b) ("Persons entitled to notice of an agency hearing shall be timely informed of . . . the matters of fact and law asserted.").

"Pleadings in administrative proceedings are not judged by the standards applied to an indictment at common law." *Aloha Airlines v. Civil Aeronautics Bd.*, 598 F.2d 250, 262 (D.C. Cir. 1979) (quoted in *CBS Wholesale Distributors*, 74 FR 36746, 36749 (2009)); *accord Citizens State Bank of Marshfield v. FDIC*, 751 F.2d 209, 213 (8th Cir. 1984). Accordingly, "the failure of the Government to disclose an allegation in the Order to Show Cause is not dispositive and an issue can be litigated if the Government otherwise timely notifies a [r]espondent of its intent to litigate the issue." *CBS Wholesale*, 74 FR at 36570. Thus, while the Agency has held that "the parameters of the hearing are determined by the prehearing statements," consistent with numerous court decisions, it has also recognized that even where an allegation was not raised in either the Show Cause Order or the pre-hearing statements, the parties may nonetheless litigate an issue by consent. *Pergament United Sales*, 920 F.2d at 135–37; see also *Duane v. Department of Defense*, 275 F.3d 988,

995 (10th Cir. 2002) (discussing *Facet Enterprises, Inc. v. NLRB*, 907 F.2d 963, 974 (10th Cir. 1990); "we held that defendant had constructive notice of an alternate theory of liability not described in the formal charge when the agency detailed that theory during its opening argument and at other points during the hearing and when the defendant's conduct revealed that it understood and attempted to defend against that theory").¹⁴

"The primary function of notice is to afford [a] respondent an opportunity to prepare a defense by investigating the basis of the complaint and fashioning an explanation that refutes the charge of unlawful behavior." *Pergament United Sales*, 920 F.2d at 135 (citation omitted). While the issue of whether an allegation "has been fully and fairly litigated [by consent] is so peculiarly fact-bound as to make every case unique," *id.* at 136, "the simple presentation of evidence important to an alternative [allegation] does not satisfy the requirement" that a respondent be afforded with a full and fair opportunity to litigate the alternative allegation. *I.W.G.*, 144 F.3d at 688 (quoting *NLRB v. Quality C.A.T.V., Inc.*, 824 F.2d 542, 547 (7th Cir. 1987) (other citation omitted)).

"An agency may not base its decision upon an issue the parties tried inadvertently. Implied consent is not established merely because one party introduced evidence relevant to an unpleaded issue and the opposing party failed to object to its introduction. It must appear that the parties understood the evidence to be aimed at the unpleaded issue." *Yellow Freight System, Inc. v. Martin*, 954 F.2d 353, 358 (6th Cir. 1992) (citation omitted). Accordingly, where the Government's case "focus[es] on another issue and [the] evidence of [an] uncharged violation [is] 'at most incidental,'" the Government has not satisfied its constitutional obligation to provide a full and fair opportunity to litigate the issue and it cannot rely on the incidental issue as the basis for imposing a sanction. *Pergament*, 920 F.2d at 136 (quoting *NLRB v. Majestic Weaving Co.*, 355 F.2d 854, 861–62 (2d Cir. 1966)).

¹⁴ See also *Grider Drug #1 & Grider Drug #2*, 77 FR 44070, 44077 n.23 (2012) (holding that while the Government did not provide adequate notice of its intent to litigate an allegation in either the Show Cause Order or its pre-hearing statements, where respondents "did not object that the allegation was beyond the scope of the proceeding and that they were denied adequate notice of it" and "fully litigated the issue," the allegation was litigated by consent) (citing *Citizens State Bank*, 751 F.2d at 213; *Kuhn v. Civil Aeronautics Bd.*, 183 F.2d 839, 841–42 (D.C. Cir. 1950); and *Yellow Freight System, Inc. v. Martin*, 954 F.2d 353, 358 (6th Cir. 1992)).

In its initial Pre-Hearing Statement, the Government again failed to allege that the application was materially false. Nor, in summarizing the testimony of its proposed witnesses therein, did the Government provide notice that it intended to put forward any evidence which would lead Respondent to conclude that the material falsification of its application was an issue in the case.

Instead, the Government did not provide notice that it intended to litigate the issue of whether the application contained a material falsification until its Supplemental Pre-Hearing Statement, which was not filed until one week before the evidence-taking phase of the proceeding convened. Even then, the Supplemental Pre-Hearing Statement did not identify which specific statements on the applications were allegedly false. Rather, the Supplemental Pre-Hearing Statement merely stated that "Ms. Soto will be asked about the circumstances of the pharmacy's prior surrender of its DEA certificate of registration, and about her failure to note the previous surrender on Respondent's new application for registration." ALJ Ex. 7, at 3. Because the Government's Supplemental Pre-Hearing Statement did not specifically identify which of the various application statements it was alleging to be materially false, only those issues which the record shows were litigated by consent can support a finding (if proved by substantial evidence) that Ms. Santiago-Soto materially falsified the application and the imposition of a sanction.

Notably, while at the evidentiary phase of the hearing the Government made an opening statement, here again, it did not identify the specific statements which were allegedly false. Rather, it confined its opening statement to the following: "Your Honor, the Government seeks a recommendation of a denial of application based on Sections 823 and 824 of the Controlled Substances Act, on the basis of a material falsification on the application, and the fact that Respondent's registration would be inconsistent with the public interest." Tr. 39.

Moreover, in questioning both the DI and Ms. Santiago-Soto, the Government did not elicit any testimony regarding Question Four. Rather, it focused entirely on the answers Ms. Santiago-Soto had given to Question Two, and, notwithstanding that there was no evidence that the Commonwealth of Puerto Rico had taken any action against either Respondent or Ms. Santiago-Soto, Question Three. See Tr. 45 (testimony of DI that Respondent's application

contained a falsification at “Question Number 3”); *id.* at 123–24 (Government’s questioning of Ms. Santiago-Soto regarding Questions Two and Three). Indeed, it was not until its post-hearing brief that the Government finally argued that Ms. Santiago-Soto had provided a materially false answer to Question Four. This, however, is simply too late in the day to provide a meaningful opportunity to refute the allegation. *See Pergament United Sales*, 920 F.2d at 135.¹⁵

Thus, I hold that the Government provided adequate notice to support a finding that the parties litigated by consent the issue of whether Ms. Santiago-Soto’s answer to Question Two was materially false. However, I further hold that the record does not support a finding that the parties litigated by consent whether her answer to Question Four was also materially false.

Turning to the merits of the allegation pertaining to Question Two, the evidence showed that on November 29, 2011, Ms. Santiago-Soto was indicted (along with thirty-two other persons) on two felony counts of violating the Controlled Substance Act, including: (1) By conspiring to possess and dispense, with intent to distribute, various controlled substances, in violation of 21 U.S.C. 841(a)(1), 846, and 860; and (2) by aiding and abetting each other and “knowingly and intentionally possess[ing] and dispens[ing] with intent to distribute various” schedule II through IV controlled substances, “outside the scope of professional practice and not for a legitimate medical purpose,” in violation of 21 U.S.C. 841(a)(1) and 18 U.S.C. 2. RX B, at 1–13.

On November 30, 2011, Ms. Santiago-Soto was arrested early in the morning and taken to her pharmacy where, after receiving the Miranda warnings, she was told by P.N., a DI,¹⁶ that she had to surrender her registration “because of the criminal charges against” her and that she “had no other options” because she was “part of a scheme.” Tr. 125–26. The evidence further showed that Ms. Santiago-Soto executed a Voluntary Surrender form, which was witnessed by P.N. (as well as another DI). RX I. This form stated that she had been “fully advised of my rights, and

underst[ood] that I am not required to surrender my controlled substance privileges,” and that “[i]n view of my alleged failure to comply with the Federal requirements pertaining to controlled substances, and as an indication of my good faith in desiring to remedy any incorrect or unlawful practices on my part” she was “voluntarily surrender[ing] my . . . Certificate of Registration.” *Id.*

As found above, the DI who testified for the Government did not personally participate in the arrest of Ms. Santiago-Soto and did not witness the events surrounding her execution of the Voluntary Surrender form. Tr. 60–61. Nor did the Government call as a witness any other person who witnessed the execution of the surrender form. Thus, there is no evidence that, at the time she surrendered Respondent’s registration, Ms. Santiago-Soto was confronted with any allegations of misconduct aside from those which comprised the criminal case.

Subsequently, the U.S. Attorney moved to dismiss *with prejudice* both of the charges against Ms. Santiago-Soto. RX C. On March 23, 2012, the District Court granted the Government’s motion and entered a Judgment of Dismissal and discharged her. *Id.* The consequence of this was that the charges could not be refiled against her.

The Government nonetheless argues that Ms. Santiago-Soto “could not under any reasonable circumstances have answered the relevant liability questions . . . in the negative” and that she “placed undue emphasis on the words ‘for cause’ in liability question #2.” Gov. Post-Hrng. Br., at 7. The Government further notes Ms. Santiago-Soto’s claim that she signed the surrender form “under duress.” *Id.*

I need not decide whether surrendering a registration under duress constitutes a valid defense to a charge of material falsification of Question Two or whether the facts here would support such a defense.¹⁷ This is so because I find unpersuasive the Government’s contentions that Ms. Santiago-Soto could not have reasonably answered Question Two in the negative and that

she “placed undue emphasis on the words ‘for cause.’”

As for the latter contention, Ms. Santiago-Soto was only required to answer Question Two as it was written on the application and not as it otherwise could have been written (such as without those words). Indeed, the Government does not explain how Ms. Santiago-Soto could have “placed undue emphasis on the words ‘for cause,’” when those words were part of the question and the application contains no explanation of what the term “surrender for cause” means.

There is no Agency regulation which defines the term “for cause” as it is applied in the context of an application for registration. However, two regulations do define the term in the context of imposing requirements on practitioners in the employment of persons who handle or have access to controlled substances, *see* 21 CFR 1301.76(a), as well as on manufacturers and distributors (among others) in the employment of persons who will have access to listed chemicals. *See* 21 CFR 1309.72(a). Under these provisions, “the term ‘for cause’ means a surrender in lieu of, or as a consequence of, any Federal or State administrative, civil or criminal actions resulting from an investigation of the handling of controlled substances or listed chemicals.” 21 CFR 1301.76(a); *id.* at 1309.72(a).

However, even if this definition was applied to Respondent’s application, it would offer no support to the Government. Here, there is no evidence that Ms. Santiago-Soto was advised that if she did not surrender the registration, Respondent would face an Order to Show Cause. Thus, she did not surrender the registration “in lieu of” a hearing. Moreover, while she had been indicted prior to the surrender, there is no evidence that she surrendered the registration in lieu of facing the criminal charges, which were not dismissed until several months later.¹⁸

Notably, Ms. Santiago-Soto’s testimony that she was told that she had to surrender her registration because of her involvement in a criminal scheme stands unrefuted, and there is no evidence that, at the time of the surrender, she was told by Agency personnel that the Agency was alleging additional violations of the CSA or DEA

¹⁵ Indeed, even if an allegation could be refuted without further factual development because it involves a matter of law, because DEA proceedings customarily require the parties to file their post-hearing briefs simultaneously (as was done here), there is no meaningful opportunity to respond prior to the issuance of an ALJ’s recommended decision.

¹⁶ In her testimony, Ms. Santiago-Soto referred to this person as an Agent; however, on the Voluntary Surrender form, this person signed as a witness and listed his title as “Diversion Investigator.” RX I.

¹⁷ Of consequence, Question Two did not ask whether Respondent had “ever voluntarily surrendered (for cause)” but only if it had “ever surrendered (for cause)” its registration. GX 1, at 1. Moreover, notwithstanding that Ms. Santiago-Soto was under arrest at the time she surrendered Respondent’s registration, in signing the Voluntary Form, she acknowledged that she had been “fully advised of [her] rights” and understood that she was “not required to surrender my controlled substances privileges”; she then acknowledged that she was “freely execut[ing]” the form and “choos[ing] to” voluntarily surrender her registration. RX I.

¹⁸ Nor does the evidence support a finding that she surrendered the registration as a consequence of the criminal action. Ms. Santiago-Soto did not surrender the registration as part of a pre-trial diversion agreement, a plea agreement, or as part of a sentence imposed by a court. Rather, the criminal case against Ms. Santiago-Soto was dismissed with prejudice.

regulations beyond the offenses for which she was indicted.¹⁹ Moreover, the consequence of the district court's dismissal of the charges "with prejudice," on motion of the Government (and apparently before trial), was that she could be not recharged for the same offenses. Under these circumstances, a layperson could, in good faith, conclude that there was no basis for both the charges and the DI's demand that she surrender her registration, and given the absence of any definition of the limiting term, a layperson could also, in good faith, conclude that she had not surrendered her registration "for cause."²⁰

Even had I concluded otherwise, I would hold that there are mitigating circumstances that substantially diminish the egregiousness of the alleged misconduct. Ms. Santiago-Soto testified that the day after she submitted the application, she contacted the Diversion Group Supervisor and explained to her that she answered the question "no" and "was unsure if [she] had answered the question correctly" because the question used the words "with cause." Tr. 126. Ms. Santiago-Soto also testified that the Group Supervisor told her that she did not know, but that she would look into it and get back to her. *Id.* at 126–27. Ms. Santiago-Soto further testified that she had memorialized the conversation in an email to the Group Supervisor. *Id.* at 127. However, the Group Supervisor did not respond to her. *Id.* Notably, all of this testimony was unrefuted by the Government.

While the ALJ acknowledged this testimony in his summary of the testimony, *see* R.D. at 5–6, in his discussion of whether Ms. Santiago-Soto had materially falsified the application, he entirely ignored it and offered no explanation for why he apparently rejected it even as a mitigating circumstance. *Id.* at 27–28. However, in concluding that Ms. Santiago-Soto had materially falsified the application, the

ALJ repeatedly noted that Santiago-Soto had also provided a "no" answer to Question Four, which does not use the words "for cause" to modify the scope of surrenders which must be disclosed. *Id.* at 27–29. Moreover, in his earlier summary of the testimony, the ALJ noted that "[t]here is no evidence indicating that Ms. Santiago-Soto also inquired about Question Four during her conversation with" the Group Supervisor, *id.* at 5, and that in her testimony, she did not address her answer to Question Four. He also explained that the Group Supervisor "did not testify at the hearing, and [that] neither party sought such testimony." *Id.* The ALJ further observed that "the record before me does not include a copy of" the email which Ms. Santiago-Soto testified she had sent to the Group Supervisor. *Id.* at 6.

Thus, it appears that the ALJ rejected Santiago-Soto's testimony regarding the phone call and email to the Group Supervisor because she did not claim to have asked about Question Four. However, to the extent this is an accurate discernment of the ALJ's unexplained reasoning, it not surprising that there is no evidence as to why Ms. Santiago-Soto answered Question Four as she did. This is so because the Government never asked her why she did, nor otherwise adequately put her on notice that her answer to this question was at issue in the proceeding.²¹

This, however, is not the only problematic aspect of the ALJ's failure to adequately explain why he gave no weight to Ms. Santiago-Soto's testimony regarding the phone call she made to the Group Supervisor. As explained above, the ALJ's decision also suggests that he gave no weight to her testimony because the Group Supervisor was not called to testify and the email was not part of the record.

As for the failure to obtain the Group Supervisor's testimony, Respondent was not required to call the Group Supervisor in order to establish that her testimony was credible. As for the ALJ's

observation that the email is not part of the record, it should have been (indeed, notwithstanding the Agency's regulation, which requires that an ALJ forward a rejected exhibit to the Administrator's Office, it was not). As found above, the ALJ allowed the Government to delay filing its supplemental prehearing statement until one week before the hearing and imposed the same deadline on Respondent. Moreover, the ALJ failed to provide any direction to Respondent as to what steps it must take in the event the Government raised an entirely new allegation at this state of the proceeding and wished to present evidence to refute the allegation.

As for the ALJ's on-the-record explanation that the email had to be presented "ahead of time, so [he] could evaluate it," Tr. 138, this begs the question: Evaluate it for what? Even in jury trials (where there is a manifest need to protect the factfinder from being misled or confused), judges routinely rule from the bench on the admissibility of evidence. And here, where there is no jury, the ALJ could have evaluated this evidence at the same time he evaluated the testimony. Finally, the Government offered no objection to the email; nor could it reasonably claim prejudice given that it waited until one week before the hearing to finally make the allegation. Under these circumstances, I conclude that the ALJ's refusal to admit the email was arbitrary and capricious.

I further reject the ALJ's findings that Ms. Santiago-Soto materially falsified Respondent's application when she provided a "no" answer to Question Two and Four. R.D. at 29, 30–31. I further reject the ALJ's Conclusions of Law with respect to this issue. *See id.* at 35.

Factors Two and Four—The Applicant's Experience in Dispensing Controlled Substances and Compliance With Applicable Laws Related to Controlled Substances

With respect to Factors Two and Four, the Government made two allegations. First, it alleged that "from February 2009 to October 2009," Respondent "filled approximately 241 prescriptions" which were issued by Dr. Aguilar-Amieva, after his registration had been retired by the Agency. Gov. Post-Hrng. Br., at 11. The Government alleged that this "conduct violated 21 U.S.C. 843(a)(2), 21 CFR 1306.04 and 1306.06." *Id.* Second, it alleged that Respondent filled twenty-nine Suboxone prescriptions, which were issued by both Dr. Aguilar-Amieva and Dr. Vargas-Quinones, neither of whom were authorized to prescribe this drug to

¹⁹ It is acknowledged that on the Voluntary Surrender form the box was checked which indicates that Ms. Santiago-Soto surrendered Respondent's registration "[i]n view of my alleged failure to comply with the Federal requirements pertaining to controlled substances." RX I. However, the Voluntary Surrender form did not list (nor is there a space to list) what those alleged failures were. *See id.* Given the absence of any evidence that at the time the surrender occurred, Ms. Santiago-Soto was told of additional allegations against her, the Voluntary Surrender form does not refute her testimony that because the criminal case was dismissed, she did not believe that she had surrendered for cause.

²⁰ The Government does not argue that the mere fact that she was indicted was sufficient to place her on notice that she had surrendered her registration for cause.

²¹ For this reason, in testifying regarding the phone call, Ms. Santiago-Soto had no obligation to address whether she had also discussed her answer to Question Four with the Group Supervisor.

In its Post-Hearing Brief, the Government asserts that Ms. Santiago-Soto's "failure to testify on this question supports an adverse inference that she knew the statement was false." Gov. Post-Hrng. Br., at 8. The Government ignores that it called Ms. Santiago-Soto to testify in its case in chief and could have—but failed to—ask her about her answer to Question Four. Nor did the Government, at any time prior to filing its Post-Hearing Brief, provide notice to Santiago-Soto that her answer to Question Four was at issue. I therefore hold that the Government is not entitled to an adverse inference regarding her answer to Question Four.

treat narcotic addiction. *See id.* at 11–12. The Government alleged that this conduct also violated 21 U.S.C. 843(a)(2), 21 CFR 1306.04 and 1306.06.

Allegation One—Respondent's Filling of Prescriptions Issued By A Physician Who Was No Longer Registered

As found above, the evidence showed that Dr. Hector J. Aguilar-Amieva's registration expired on June 30, 2008 and was retired from the DEA computer system on January 31, 2009. GX 6. The evidence, which was not objected to, further showed that Respondent filled more than two hundred controlled-substance prescriptions which were issued by Dr. Aguilar-Amieva from February 2, 2009 through August 8, 2011.²² GX 4.

Except for in limited circumstances which are not implicated here, the Controlled Substances Act requires that “[e]very person who dispenses . . . any controlled substance [] shall obtain from the Attorney General a registration issued in accordance with the rules and regulations promulgated by him.” 21 U.S.C. 822(a)(2).²³ Moreover, under a DEA regulation, “[a] prescription for a controlled substance may be issued only by an individual practitioner who is: (1) [a]uthorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession and (2) [e]ither registered or exempted from registration pursuant to 1301.22(c) and 1301.23 of this chapter.” 21 CFR 1306.03(a). Also, it is “unlawful for any person knowingly or intentionally . . . to use in the course of the . . . dispensing of a controlled substance . . . a registration number which is fictitious, revoked, suspended, expired, or issued to another person.” 21 U.S.C. 843(a)(2). Thus, it is clear (and undisputed) that Dr. Aguilar-Amieva repeatedly violated the CSA by issuing controlled-substance prescriptions using his expired registration number.

The issue in this matter, however, is whether liability can be imposed on Respondent because its principal filled Dr. Aguilar-Amieva's prescriptions. As explained above, the Government

contends that Respondent's conduct violated section 843(a)(2); the Agency's corresponding responsibility rule, *see* 21 CFR 1306.04(a); as well as a further regulation, 21 CFR 1304.06. Contrary to the Government's understanding, its evidence does not support a finding that Respondent violated any of the three provisions in dispensing these prescriptions.

As explained above, section 843(a)(2) imposes criminal liability on any person who uses, in the course of dispensing a controlled substance, an expired registration number. While no case has been cited by the Government where a pharmacist has been convicted of violating this provision because it filled prescriptions issued by a physician whose registration had expired, given that a prescription provides the lawful authority for a pharmacist to dispense a controlled substance, *see* 21 U.S.C. 829(a) & (b), it is clear that a pharmacist can held liable for dispensing a controlled substance prescription issued by a physician who no longer holds a registration. However, the statute imposes liability only where a pharmacist does so knowingly or intentionally. *See* 21 U.S.C. 843(a)(2).

As for 21 CFR 1306.04(a), it requires that a controlled substance prescription “be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice” and imposes “a corresponding responsibility” on the pharmacist who fills a prescription which was not issued “in the usual course of professional treatment.” However, here again, the regulation imposes liability only on a “person knowingly filling such a purported prescription.” *Id.* (emphasis added).

While the plain language of both of these provisions requires proof that a pharmacist dispensed a prescription knowing that the issuer lacked the requisite authority, the Government produced no evidence that Ms. Santiago-Soto knew (or was even willfully blind) to the fact that Dr. Aguilar-Amieva did not hold a DEA registration. Indeed, while in its brief the Government argues that Ms. Santiago-Soto admitted that Respondent had filled the prescriptions, Ms. Santiago-Soto expressly denied that she knew that Aguilar-Amieva's registration “had been revoked in January 2009.” Tr. 106–07.²⁴ Thus, although it is true that

Ms. Santiago-Soto admitted that Respondent had filled the prescriptions, her admission satisfies the Government's evidentiary burden only with respect to showing that the dispensings occurred. Moreover, when asked whether he had any evidence that Ms. Santiago-Soto had “acted with the intention or knowledge [of] illegal activity when dispensing Dr. Aguilar's . . . prescriptions,” the DI gave an unresponsive answer, stating that he did not “base [his] evaluations on intentions,” and when asked a follow-up question, the ALJ interjected (without the DI even answering the question): “I'll take it as a no.” Thus, I hold that the Government did not prove that Ms. Santiago-Soto acted with the requisite knowledge to sustain a violation of either 21 U.S.C. 843(a)(2) or 21 CFR 1306.04(a), with respect to this allegation.

The Government also alleged that Respondent's filling of the 241 prescriptions violated 21 CFR 1306.06. In relevant part, this regulation provides that “[a] prescription for a controlled substance may only be filled by a pharmacist, acting in the usual course of his professional practice.” 21 CFR 1306.06. Thus, on its face, this regulation does not require proof of knowledge to sustain a violation.

However, the regulation does require that the Government establish what the standards of pharmacy practice require, through either expert testimony or by reference to federal or state laws, pharmacy board or Agency regulations, or decisional law (whether of administrative bodies or the courts). Here, while the Government's evidence establishes that Respondent dispensed some 241 controlled substance prescriptions over a period of approximately thirty months, which were written by a physician who was not registered, the Government did not put on any expert testimony establishing that pharmacists have a duty to verify the registration status of the prescribers whose prescriptions they fill. Nor did the Government cite to any other rule or decision imposing such a duty.

Notwithstanding that the Government neither produced any evidence establishing that the usual course of professional practice requires that a pharmacist verify the registration status of prescribers, nor cited any law, regulation, or other authority, which imposes such a requirement, the ALJ found that when “she filled these prescriptions[,] Ms. Santiago-Soto failed

order doing so would have been published in the **Federal Register** and on the Agency's Web site.

²² At the hearing, Respondent did not challenge the admission of this evidence on the ground of lack of foundation. Nor did it raise such a challenge in its Exceptions. Notably, the only Government witness to testify did not participate in the execution of the search warrant and did not specifically identify the prescriptions submitted by the Government as those which were seized when the warrant was issued. Moreover, the prescription labels (which were apparently affixed to the back of the prescriptions), do not identify Respondent as the dispensing pharmacy. Nor did the Government submit any documentary evidence tending to establish that the prescriptions were those which were seized from Respondent.

²³ *See* 21 U.S.C. 822(c); 21 CFR 1301.22.

²⁴ The quotation is from the Government's question. The Government's evidence did not establish that the Agency had revoked Dr. Aguilar-Amieva's registration, but only that Aguilar-Amieva let his registration expire after which his number was retired from the DEA registrant database. Had Aguilar-Amieva's registration been revoked, an

to conform to regulations relating to the distribution of controlled substances and failed to act in the usual course of professional pharmacy practice.” R.D. at 34. Apparently, this was based on the ALJ’s earlier conclusion that “[o]ne way or another, pharmacists *must ensure* that they are filling only those controlled substance prescriptions that have been written by persons registered with the DEA. A pharmacy applicant who fails to appreciate the need to verify DEA credentials of prescribing doctors (either by contacting the DEA²⁵ or subscribing to a private verification service) demonstrates a lack of experience material to the application.” *Id.* at 23 (emphasis added). Thus, the ALJ applied a standard of strict liability in concluding that Ms. Santiago-Soto had “failed to act in the usual course of professional pharmacy practice.” *Id.* at 34.

Contrary to the ALJ’s understanding, no Agency regulation requires that a pharmacist ascertain that each prescription presented to him/her has been issued by a practitioner who possesses a valid DEA registration and the Agency expressly disclaimed the existence of such a duty in 2010, when it promulgated its Interim Final Rule on Electronic Prescriptions for Controlled Substances. *See* 75 FR 16236, 16266 (2010). Therein, the Agency noted that it had proposed requiring pharmacies “to confirm that the [prescriber’s] DEA registration . . . was valid at the time” the prescription was signed. *Id.*

²⁵ Based on the testimony of the DI, the ALJ found that “[i]n order to determine whether a medical provider is authorized by the DEA to prescribe controlled substances, a pharmacist may contact the DEA by telephone and inquire.” R.D. 31 (FoF #13); *see also id.* at 23 (“Although it might be a cumbersome and time-consuming verification process, the DEA does permit a pharmacist to call into a field office to confirm the status of a given prescribing source.”). However, as found above, the ALJ barred Respondent from using a Question and Answer printout from the DEA Web page to impeach the DI’s testimony to this effect, reasoning that the Respondent was required to disclose this document in advance of the hearing. Tr. 164.

It is true that under the Agency’s rule, a party is generally required to provide a copy of any proposed exhibit which is being offered as substantive evidence in the matter. However, contrary to the ALJ’s understanding, a party is not required to disclose, in advance of the hearing, a document which is being used to impeach a witness. I therefore reject this finding.

As for the NTIS database, the ALJ acknowledged that subscribing to this service is expensive. However, he then opined that “[i]t is no answer to complain that the NTIS program costs a lot of money; nor is it a sufficient legal response to argue that DEA regulations do not require pharmacists to purchase the program.” R.D. at 23. To the extent this comment might be understood as creating an obligation on all pharmacies to subscribe to this service, it is rejected. While it was not fully developed on the record of this proceeding, DEA provides a web tool which allows a registrant to verify the registration of another person or entity.

However, several commenters objected “that pharmacies are not required to check DEA registrations for paper prescriptions unless they suspect something is wrong with a prescription.” *Id.*

In its response (which appears to be missing pertinent text), the Agency stated that it “agrees with those commenters that expressed the view that, when filling a paper prescription, it is not necessary for a pharmacist who receives an electronic prescription for a controlled substance to check the CSA database in every instance to confirm that the prescribing practitioner is properly registered with DEA.” *Id.* The Agency thus removed the requirement from the Interim Final Rule, but “made clear that a pharmacist continues to have a corresponding responsibility to fill only those prescriptions that conform in all respects with the requirements of the [CSA] and DEA regulations, including the requirement that the prescribing practitioner be properly registered.” *Id.* However, as explained above, the corresponding responsibility does not impose strict liability on pharmacists but rather requires proof that a pharmacist filled a controlled-substance prescription either knowing that it was unlawful or with willful blindness or deliberate ignorance of the fact that the prescription was unlawful.²⁶

²⁶ Notwithstanding the Agency’s pronouncement in the Interim Rule, the Agency’s corresponding responsibility rule is not the only potential basis for finding a violation where a pharmacist dispenses a controlled substance prescription issued by a practitioner who does not hold the requisite authority. Upon a showing that such conduct is outside of “the usual course of professional practice,” 21 CFR 1306.06, a pharmacist may be held to have violated DEA regulations and to have committed acts which render her pharmacy’s registration inconsistent with the public interest.

Moreover, in *Medicine Shoppe—Jonesborough*, 73 FR 364, 381 (2008), the ALJ found that a pharmacist had filled a large number of controlled-substance prescriptions which were issued by a veterinarian who did not hold either a state license or DEA registration. The ALJ further found that this conduct constituted such other conduct which may threaten public health and safety, reasoning, in part, that a pharmacy has a duty to periodically verify whether a prescriber retains authority to practice medicine and dispense controlled substances. I found a violation of 21 CFR 1306.04(a), based on the evidence that the prescriptions were being presented on a daily basis by the veterinarian’s brother and were for drugs that were toxic for certain animals. However, in dictum, I noted that “[a] pharmacy has a duty to periodically check to see that a practitioner retains the authority to practice medicine and dispense a controlled substance.” *Id.* at n.45. I also noted my agreement with the ALJ’s reasoning that failing “to do so could threaten public health and safety because there is usually a good reason for why a practitioner has lost his or her state license and DEA registration.” *Id.*

The Government does not rely on this theory and no case (until recently) has presented the question of how frequently a pharmacy must re-verify the

Accordingly, I reject the ALJ’s reasoning as contrary to the published guidance of the Agency. And because the Government failed to put forward either: (1) any evidence to show that Ms. Santiago-Soto either knew or was willfully blind to the fact that Dr. Aguilar-Amieva was no longer registered, or (2) any evidence or legal authority establishing that Ms. Santiago-Soto acted outside of the usual course of professional practice, I reject the Government’s contention that Respondent violated federal law and DEA regulations in filling these prescriptions.

Allegation Two—Respondent’s Filling of Suboxone Prescriptions

Regarding this allegation, the evidence shows that Respondent filled twenty-nine Suboxone prescriptions, which were issued by Dr. Aguilar-Amieva and Dr. Vargas-Quinones, *see* GX 4, at 23–24; and Ms. Santiago-Soto admitted that a majority of the prescriptions (17 of the 29) listed “a diagnosis that is related to the abuse of opioids[] or opiates.” Tr. 108. It was undisputed that neither Dr. Aguilar-Amieva nor Dr. Vargas-Quinones was qualified to prescribe Suboxone to treat narcotic addiction. *See* GX 6, at 1 & 5.

A physician who seeks to prescribe Suboxone (or other schedule III through V drugs approved by FDA) for maintenance or detoxification treatment must meet certain conditions (including that the physician either holds various certifications or has training or experience in the management of opiate-dependent patients) and must provide a notification (which includes various certifications) to the Secretary of the Department of Health and Human Services, who must then determine (within 45 days from the date of receipt of the notification) whether the physician meets the requirements for a waiver under 21 U.S.C. 823(g)(2)(B). 21 CFR 1301.28(a)–(d). If the practitioner holds “the appropriate registration” and the Secretary either makes “a positive determination” or fails to act within the 45 day period, DEA issues an identification number, which is otherwise known as an X-number to the practitioner. *Id.* § 1301.28(d)(1); *see also* Tr. 48–49.

Moreover, under DEA’s regulation:

A prescription may not be issued for “detoxification treatment” or “maintenance treatment,” unless the prescription is for a

credentials of prescribers. Nor has the Agency published any guidance to the regulated community setting forth the parameters of this duty. What is clear, however, is that a pharmacy is not required to verify the credentials of the prescriber for every prescription it fills.

Schedule III, IV, or V narcotic drug approved by the Food and Drug Administration specifically for use in maintenance or detoxification treatment and the practitioner is in compliance with requirements in § 1301.28 of this chapter.

21 CFR 1306.04(c) (emphasis added).

So too, pursuant to 21 CFR 1306.05(b), “[a] prescription for a Schedule III, IV, or V narcotic drug approved by FDA specifically for ‘detoxification treatment’ or ‘maintenance treatment’ must include the identification number issued by the Administrator under 1301.28(d) of this chapter or a written notice stating that the practitioner is acting under the good faith exception of [21 CFR] 1301.28(e).”²⁷ (emphasis added). This information is in addition to the prescriber’s DEA registration number. See 21 CFR 1306.05(a). Also, under 21 CFR 1306.05(f), “[a] corresponding liability rests upon the pharmacist . . . who fills a prescription not prepared in the form prescribed by DEA regulations.” However, none of the Suboxone prescriptions issued by either Dr. Aguilar-Amieva or Dr. Vargas-Quinones bore either an X number or a statement that the physician was “acting under the good faith exception.” See GX 3, at 410–456.

The Government contends that Respondent violated, *inter alia*, 21 CFR 1306.04 and 1306.06, because it “does not contest that [it] acted outside the usual course of professional practice” when it dispensed the Suboxone prescriptions. Gov. Post-Hrng. Br., at 12. Contrary to the Government’s understanding, Ms. Santiago-Soto made no such admission and the Government put forward no evidence as to what the usual course of professional practice requires of a pharmacist who is presented with prescriptions that are clearly marked as being issued for the purpose of providing maintenance or detoxification treatment for narcotic-dependent patients and yet are missing the requisite X number or good faith statement.

However, the evidence does establish that Ms. Santiago-Soto violated 21 CFR 1306.05(f) when she filled at least seventeen of these prescriptions.²⁸ With

²⁷ The good faith exception applies only during the period before the practitioner receives his X-number from the Agency and only if “[t]he Secretary has not notified the registrant that he/she is not qualified” to provide such treatment. 21 CFR 1301.28(e).

²⁸ While the Government alleged that Respondent violated 21 CFR 1306.04 in filling the Suboxone prescriptions, it did not identify the specific subsection which it alleges was violated. See Gov. Post-Hrng. Br. at 12. Notably, in contrast to subsection a of this regulation, which imposes a corresponding responsibility on a pharmacist to not

respect to the seventeen Suboxone prescriptions which contained a notation by the doctor that he had diagnosed the patient as being opioid dependent, Ms. Santiago-Soto knew that the prescriptions were issued to provide either maintenance or detoxification treatment.²⁹ Moreover, notwithstanding the clear requirement that the prescriptions include (in addition to the prescriber’s DEA number), either his DATA-waiver identification number or the practitioner’s statement that he was “acting under the good faith exception of § 1301.28(e),” none of the prescriptions contained either an X-number or the good faith statement.

In her testimony, Ms. Santiago-Soto maintained that she “was not aware” that the X number had to be on the prescription “for that medication in particular,” Tr. 110, and that she “was not aware that buprenorphine [the generic name for Suboxone] fell among the medications that required the X DEA number.” *Id.* at 112. However, Ms. Santiago-Soto did know that the purpose of most of the Suboxone prescriptions was to treat narcotic addiction. And as explained above, under the Agency’s regulation, a prescription could not be issued for a Schedule III through V controlled substance such as Suboxone for this purpose unless the drug was approved by FDA for this purpose and the practitioner met the requirements for prescribing for this purpose.

Accordingly, her testimony does not establish that she made a mistake of fact but rather that she was ignorant of the regulations. This, of course is not a defense. See *United States v. International Minerals & Chem. Corp.*, 402 U.S. 558, 563 (1971) (“The principle

knowingly fill a prescription that is issued outside of the usual course of professional practice and which lacks a legitimate medical purpose, subsection c impose duties only on the issuer of the prescription which has been issued to provide maintenance or detoxification treatment. See 21 U.S.C. 1306.04(c). However, as explained above, 21 CFR 1306.05(f), imposes “[a] corresponding liability . . . upon the pharmacist . . . who fills a prescription not prepared in the form prescribed by DEA regulations.”

²⁹ I do not find any violations with respect to those prescriptions which did not contain a diagnosis of narcotic dependence. Under federal law, a doctor may prescribe a drug for a legitimate off-label use and absent evidence that the prescriptions, which lacked a diagnosis of narcotic dependence, were actually being issued for this purpose, I do not find a violation proved. The Government offers no argument to the effect that a doctor cannot prescribe Suboxone for any legitimate medical purpose unless they have X-number. Nor did it offer evidence that when a pharmacist is presented with a Suboxone prescription that does not list a diagnosis and lacks an X number, the standards of professional practice require the pharmacist to call the physician and determine the purpose of the prescription.

that ignorance of the law is no defense applies whether the law be a statute or a duly promulgated and published regulation.”).

Indeed, Ms. Santiago-Soto’s testimony regarding the allegation was most unpersuasive. More specifically, Ms. Santiago-Soto testified that she had graduated from pharmacy school in 1995, and that the DATA law was passed in 2000, but after 2002, when Suboxone was approved by FDA for the purpose of treating narcotic addiction, “the DEA in Puerto Rico never has provided any orientation or guidance online, or by way of a conference, or through continuing education, or by letters, letting me know, or providing me these kinds of guidelines.” Tr. 110.³⁰

However, in 2003, the Agency published in the **Federal Register** a notice of proposed rulemaking, and in 2005, the Agency published its final rule, which promulgated the various provisions set forth above, including 21 CFR 1301.28 (requirements for obtaining an X-number and the good faith exception), 21 CFR 1306.04(c) (prohibiting a prescription for maintenance or detoxification treatment unless the drug has been approved by FDA for this purpose and the practitioner is in compliance with 1301.28), 21 CFR 1306.05(a) (requiring that such prescription include either the prescriber’s X number or a good faith statement), and 21 CFR 1306.07 (allowing a practitioner to administer, dispense or prescribe a Schedule III through V drug specifically approved by FDA for use in maintenance or detoxification treatment if the practitioner complies with 1301.28). See DEA, *Authority for Practitioners to Dispense or Prescribe Approved Narcotic Controlled Substances for Maintenance or Detoxification Treatment*, 70 FR 36338 (2005); see also DEA, *Authority for Practitioners to Dispense or Prescribe Approved Narcotic Controlled Substances for Maintenance or Detoxification Treatment*, 68 FR 37429 (2003) (Notice of Proposed Rulemaking). Indeed, prior to the 2005 issuance of the final rule, no narcotic controlled substance *could be prescribed* by a physician (including those authorized to conduct a narcotic treatment program under 21 U.S.C. 823(g)(1)) to treat narcotic addiction and no pharmacy could have lawfully

³⁰ The Government offered no evidence regarding the contents of the package insert for Suboxone and whether it contained any special instructions regarding the prescribing and dispensing of Suboxone following the FDA’s approval of the drug for use in providing maintenance or detoxification treatment.

dispensed such a prescription. *See id.* at 37429.

As the 2003 Notice of Proposed Rulemaking explained:

[t]he Controlled Substances Act (CSA) and current regulations requires that practitioners who want to conduct maintenance or detoxification treatment using narcotic (opioid) controlled drugs be registered with DEA as narcotic treatment programs (NTPs) in addition to the practitioners' personal registrations. The separate NTP registrations authorize the practitioners to dispense or administer, but not prescribe narcotic (opioid) controlled drugs.

Id. The Notice also observed that “[o]n October 8, 2002, FDA approved two products containing buprenorphine, [S]ubutex and [S]uboxone, Schedule III controlled drugs, for use in maintenance and detoxification treatment,” and that the proposed rule would “[p]ermit pharmacies to fill prescriptions for Schedule III, IV, and V narcotic (opioid) controlled drugs approved by FDA specifically for use in maintenance or detoxification treatment.” *Id.* at 37430.

The dispensing of controlled substances is a highly regulated industry, and as a participant in this industry, Ms. Santiago-Soto is properly charged with knowledge of the applicable regulations, including: (1) The requirement that a Suboxone prescription, which has been issued to provide treatment for opiate addiction, can only be issued by a person who meets the requirements of 21 CFR 1301.28; as well as (2) that the prescription must bear either the prescriber's X-number or the good faith statement. *See International Minerals*, 402 U.S. at 565 (where “dangerous or deleterious . . . products . . . are involved, the probability of regulation is so great that anyone who is aware that he is in possession of them or dealing with them must be presumed to be aware of the regulation”); *United States v. Southern Union Co.*, 630 F.3d 17, 31 (1st Cir. 2010) (“[T]hose who manage companies in highly regulated industries are not unsophisticated. It is part of [their] business to keep abreast of government regulation.”) (citing *United States v. Lachman*, 387 F.3d 42, 56–57 (1st Cir. 2004)), *rev'd on other grounds*, 132 S.Ct. 2344 (2012).

I therefore find that Ms. Santiago-Soto knowingly dispensed the seventeen Suboxone prescriptions which were issued for maintenance or detoxification purposes in violation of federal law by the respective physicians and thus also violated federal law in doing so. 21 CFR 1306.04(c); *see also* 21 U.S.C. 841(a)(1). While it is true, as Ms. Santiago-Soto testified, that the amounts of most of the prescriptions were limited (most being

for ten tablets or less), there were also two prescriptions for sixty tablets issued to the same patient, which contained a diagnosis of opiate dependence. Thus, I am not persuaded by her testimony “that the amounts are not such that would raise my suspicions that something is running amok.” Tr. 109–10.

However, Ms. Santiago-Soto testified that she had become aware of the DATA of 2000 during an audit by a health insurance plan, which occurred months before she was arrested and surrendered her registration, and that she then went online and familiarized herself with the statute's requirements. Tr. 112. Most significantly, the Government's own evidence shows that Respondent dispensed the last Suboxone prescription on July 3, 2011, nearly five months before Ms. Santiago-Soto was arrested and surrendered its registration.³¹ *See* GX 4, at 23–24. Finally, in her testimony, Ms. Santiago-Soto demonstrated some degree of knowledge of the requirements pertaining to the prescribing of Suboxone to identify those prescriptions which do not comply with the DATA requirements and should not be dispensed. Tr. 110.

Thus, while I conclude that the Government has proved that Respondent committed acts which are “inconsistent with the public interest,” 21 U.S.C. § 823(f), I also find that there are several factors which mitigate the violations.

Sanction

Under Agency precedent, where, as here, “the Government has proved that a registrant has committed acts inconsistent with the public interest, a registrant must “‘present sufficient mitigating evidence to assure the Administrator that it can be entrusted with the responsibility carried by such a registration.’”” *Medicine Shoppe-Jonesborough*, 73 FR 364, 387 (2008) (quoting *Samuel S. Jackson*, 72 FR 23848, 23853 (2007) (quoting *Leo R. Miller*, 53 FR 21931, 21932 (1988))). “Moreover, because ‘past performance is the best predictor of future performance,’ *ALRA Labs, Inc. v. DEA*, 54 F.3d 450, 452 (7th Cir.1995), [DEA] has repeatedly held that where a registrant has committed acts

inconsistent with the public interest, the registrant must accept responsibility for its actions and demonstrate that it will not engage in future misconduct.” *Medicine Shoppe*, 73 FR at 387; *see also Jackson*, 72 FR at 23853; *John H. Kennedy*, 71 FR 35705, 35709 (2006); *Prince George Daniels*, 60 FR 62884, 62887 (1995). *See also Hoxie v. DEA*, 419 F.3d at 483 (“admitting fault” is “properly consider[ed]” by DEA to be an “important factor[]” in the public interest determination).

While a registrant must accept responsibility and demonstrate that it will not engage in future misconduct in order to establish that its registration is consistent with the public interest, DEA has repeatedly held these are not the only factors that are relevant in determining the appropriate sanction. *See, e.g., Joseph Gaudio*, 74 FR 10083, 10094 (2009); *Southwood Pharmaceuticals, Inc.*, 72 FR 36487, 36504 (2007). Obviously, the egregiousness and extent of a registrant's misconduct are significant factors in determining the appropriate sanction. *See Jacobo Dreszer*, 76 FR 19386, 19387–88 (2011) (explaining that a respondent can “argue that even though the Government has made out a *prima facie* case, his conduct was not so egregious as to warrant revocation”); *Paul H. Volkman*, 73 FR 30630, 30644 (2008); *see also Paul Weir Battershell*, 76 FR 44359, 44369 (2010) (imposing six-month suspension, noting that the evidence was not limited to security and recordkeeping violations found at first inspection and “manifested a disturbing pattern of indifference on the part of [r]espondent to his obligations as a registrant”); *Gregory D. Owens*, 74 FR 36751, 36757 n.22 (2009). So too, the Agency can consider the need to deter similar acts, both with respect to the respondent in a particular case and the community of registrants. *See Gaudio*, 74 FR at 10095 (quoting *Southwood*, 71 FR at 36503). *Cf. McCarthy v. SEC*, 406 F.3d 179, 188–89 (2d Cir. 2005) (upholding SEC's express adoptions of “deterrence, both specific and general, as a component in analyzing the remedial efficacy of sanctions”).

As found above, the only allegation sustainable on the record is that Respondent filled seventeen Suboxone prescriptions that were issued to provide maintenance or detoxification treatment by two physicians who were not DATA-waived physicians. As explained above, I find that Ms. Santiago knowingly violated federal law by dispensing these prescriptions because the purpose of the prescriptions was clearly identified on them and none of the prescriptions had the physician's

³¹ It is also noted that Respondent had stopped dispensing these prescriptions two months before a DEA inspection which occurred on September 7, 2011. *See* RX H. While DEA had also inspected Respondent on September 2, 2010, *see* RX G, as of that date, Respondent had dispensed but a single prescription (only three days earlier) for fourteen tablets. GX 4, at 23–24. No evidence was put forward by the Government as to whether this prescription was discussed with Ms. Santiago-Soto.

identification number or the requisite good faith statement. Moreover, the Government's interest in deterring pharmacists from dispensing Suboxone prescriptions, which have been issued to treat narcotic-dependent patients by physicians, who lack the requisite qualifications to treat such patients, is manifest.

Regarding these violations, Respondent's evidence of its acceptance of responsibility was less than unequivocal. While Ms. Santiago-Soto admitted that she was aware that the prescriptions were issued to treat substance abuse patients and that she should have learned about the requirements applicable to the prescribing of Suboxone for this purpose earlier than she did, she also attempted to minimize her misconduct by attributing it to the failure of the DEA office in Puerto Rico to provide any guidance to her regarding the requirements. DEA did, however, publish, in the **Federal Register**, both a Notice of Proposed Rulemaking and a Final Rule, which provided legally sufficient notice that Suboxone could only be prescribed for maintenance or detoxification purposes by a qualified physician, and that such a physician was required to either list his identification number or provide a good faith statement on the prescriptions.

Yet, while Ms. Santiago-Soto is presumed to have knowledge of the applicable regulations and thus violated federal law in dispensing those Suboxone prescriptions which bore a diagnosis indicating that they were issued to treat narcotic addiction, the egregiousness of her misconduct is diminished by two factors. First, the violations were limited in scope, as the total amount of the unlawful dispensings was 224 tablets. Second, Ms. Santiago-Soto had determined, prior to the Agency's bringing it to her attention, that the Suboxone prescriptions were illegal, and at the time she surrendered Respondent's registration, had long since ceased the offending practice.³²

³² In rejecting Respondent's evidence of remediation, the ALJ faulted Ms. Santiago-Soto for testifying that DEA "maintained information on its Web site that is contradictory to what the Diversion Investigator said during the hearing." R.D. at 29. Given that the ALJ improperly precluded Respondent from using a printout from the Agency's Web site to impeach the DI, there is no basis for this finding.

The ALJ further found that there is "scant evidence that Ms. Santiago-Soto has engaged in a course of conduct that would ensure that she remains properly informed about changes in DEA controlled substance regulations." *Id.* at 30. Continuing, he explained that "[t]here was no suggestion that she would accept responsibility for keeping up with changes in the DATA-waived list

In its Exceptions, Respondent argues that the ALJ's recommended sanction of denial "is drastic and overly broad." Exceptions at 15. It argues, *inter alia*, that the Agency "could grant a license with a monetary sanction or provide in its determination that it can be issued after a determined period of additional time"; it also argues that it "is willing to undertake and place into action any diverse measures the DEA requires as a condition for approving the" application. *Id.* at 16.

"Proceedings under sections 303 and 304 of the CSA are . . . non-punitive." *Samuel S. Jackson*, 72 FR 23848, 23853 (2007) (citing *Leo R. Miller*, 53 FR 21931, 21932 (1988)). As the Agency previously recognized, "this proceeding 'is a remedial measure, based upon the public interest and the [need] to protect the public from those individuals who have misused their' registrations and 'who have not presented sufficient mitigating evidence to assure the Administrator that they can be entrusted with the responsibility' attendant with holding a registration. *Id.* (quoting *Miller*, 53 FR at 21932).

I agree with Respondent that the outright denial of its application is not supported by the record and that its application can be granted "after a determined period of additional time," subject to Respondent meeting various conditions. First, while I acknowledge Ms. Santiago-Soto's testimony as to the steps she took to familiarize herself with the requirements pertaining to the prescribing of Suboxone, she also testified that while she reviews a prescription to ensure that it meets legal requirements and is not suspicious, she does not "speak with the doctors" because "[t]here is a confidentiality law

in the future, for example." *Id.* There is, however, no evidence in the record that a DATA-waived list exists, whether maintained by DEA or any other agency.

It may be that the ALJ actually meant to say that he does not believe that Ms. Santiago-Soto will properly verify that the issuers of Suboxone prescriptions for addiction treatment will have the requisite qualifications. If this was the ALJ's intent, it is refuted by his acknowledgment—one page earlier in his decision—of Ms. Santiago-Soto's testimony that she would subscribe to the NTIS service and that "[t]his would appear to be an effective remedial step [which] possibly could lessen the risk of filling prescriptions for Suboxone if the prescribing provider was not a DATA-waived" physician. *Id.* at 29. (Indeed, I have taken official notice that the DEA registration validation web-tool provides this information. See 21 CFR 1316.59(e)). Moreover, the ALJ entirely ignored Ms. Santiago-Soto's testimony (which is corroborated by the Government's evidence), that following the audit by a health plan, she reviewed the requirements applicable to prescribing Suboxone to treat narcotic addiction, and the evidence that she had ceased dispensing the Suboxone prescriptions long before DEA raised this as an issue with her. See R.D. at 29–30.

between doctor and patient." Tr. 117. While the Government did not address the validity of this statement in its post-hearing brief, it is flatly inconsistent with long-standing authority setting forth the scope of a pharmacist's corresponding responsibility under the Controlled Substances Act. See, e.g., *United States v. Hayes*, 595 F.2d 258, 260 (5th Cir. 1979); see also *Medicine Shoppe—Jonesborough v. DEA*, 300 Fed. App'x 409, 412 (6th Cir. 2008) (quoting *Ralph J. Bertolino*, 55 FR 4729, 4730 (1990) (" 'When [pharmacists'] suspicions are aroused as reasonable professionals,' they must at least verify the prescription's propriety, and if not satisfied by the answer they must 'refuse to dispense.' ")). Accordingly, I will order that Ms. Santiago-Soto take a course on controlled substance dispensing and the corresponding responsibility of a pharmacist under federal law. Said course must be completed and a certificate of such completion must be presented to the Agency prior to the granting of Respondent's application.

I will further order that Respondent's application be held in abeyance for six months from the date of this order (not the date of publication) at which time, its application shall be granted provided Respondent has provided evidence to DEA that Ms. Santiago-Soto has completed the above-described course and commits no violation of federal or commonwealth controlled substance laws. If, however, Ms. Santiago-Soto fails to provide evidence that she has completed such course within the six-month period, Respondent's application shall be denied.

Upon the granting of the registration, Respondent shall be placed on probation for a period of three years. During the period of the probation, Respondent and its principal shall agree to consent to unannounced inspections by DEA personnel and shall waive its right to require DEA personnel to obtain an Administrative Inspection Warrant prior to conducting an inspection. Ms. Santiago-Soto shall provide a letter to DEA manifesting Respondent's consent to unannounced inspections by DEA and waiving its right to require DEA personnel to obtain an Administrative Inspection Warrant prior to the issuance of its registration.

Respondent shall provide a copy of its controlled substance dispensing log on a quarterly basis to the DEA Ponce Office. Said quarters shall end on March 31st, June 30th, September 30th, and December 31st of each year, and the log shall be provided to the DEA Ponce Office no later than ten (10) calendar

days following the last day of each quarter.

Respondent and Ms. Santiago-Soto shall notify the DEA Ponce Office of any disciplinary action undertaken against its pharmacy license and Puerto Rico controlled substance registration, as well as any action taken against Ms. Santiago-Soto's pharmacist license, including the initiation of any proceeding by the Commonwealth's authorities to suspend or revoke any of the licenses or registration. Such notification shall occur no later than three business days following service on Respondent or Ms. Santiago-Soto of any document initiating such a proceeding, any interim or emergency order of suspension, and any final order.

The above conditions shall terminate upon Respondent's completion of the period of probation, provided Respondent fully complies with each term of its probation. Any violation of these conditions shall constitute an act inconsistent with the public interest and grounds for the suspension or revocation of Respondent's registration.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f), as well as 28 CFR 0.100(b), I order that the Application of Farmacia Yani be, and it hereby is, held in abeyance for a period of six months to begin on the date of this ORDER. I further order that upon the conclusion of the six-month period, the Application of Farmacia Yani shall be granted or denied as set forth above. I also order that in the event that Ms. Santiago-Soto complies with the condition that she complete a course in controlled substance dispensing and the corresponding responsibility, Farmacia Yani's Application shall be granted subject to the probationary conditions set forth above. This ORDER is effective immediately.

Dated: May 12, 2015.

Michele M. Leonhart,
Administrator.

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BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 12-62]

Jana Marjenhoff, D.O.; Decision and Order

On June 24, 2014, Chief Administrative Law Judge (ALJ) John J. Mulrooney, Jr., issued the attached

Recommended Decision.¹ Respondent filed Exceptions to the Decision.

Having reviewed the entire record, including Respondent's Exceptions, I have decided to adopt the ALJ's findings of fact,² conclusions of law, and

¹ All citations to the Recommended Decision (hereinafter, cited as R.D.) are to the slip opinion as issued by the ALJ.

² I do not adopt the ALJ's findings that hydrocodone combined with acetaminophen is a schedule III controlled substance. *See, e.g.*, R.D. at 5 n.12; *id.* at 20 n.42. While that was correct at the time of the underlying events, as well as on the date of the issuance of the Recommended Decision, this drug has since been placed in schedule II of the Controlled Substances Act. *See Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II*, 79 FR 49661 (2014).

I also do not adopt the ALJ's finding that the dispensing event which occurred on March 15, 2011 was based on a hard copy prescription which was dated March 11, 2011, or that the March 11 prescription was presented to different pharmacies on three occasions. *See* R.D. at 22-25. Rather, I find that the March 15 prescription was based on a telephone prescription which was dated March 15, 2014. *See* GX 6, at 3; GX 8, at 5. As for the hard copy prescription which the ALJ cited as the evidence to support this finding, I find the date to be illegible. However, this finding does not alter the disposition of this matter because I adopt the ALJ's finding that PA Francis, whose prescribing authority was used to obtain the prescriptions, credibly denied having issued Respondent any controlled substance prescriptions after the initial controlled substance prescription she issued on February 14, 2011. *See* R.D. at 55.

While I adopt the ALJ's finding that the testimony of Malana Diminovich, who testified that the PA had issued the controlled substance prescriptions, was not credible, as explained in my discussion of Respondent's fourth exception, I do not rely on his reasoning to the extent it is based on the suggested inconsistency between Diminovich's testimony that "Respondent was never observed to be under the influence of controlled substances during the time the two worked together" and "that she was aware that . . . Respondent was receiving controlled substance prescriptions from PA Francis." *Id.* at 30-31.

In his decision, the ALJ found that "the only evidence received on the issue supports the Respondent's claim that she had an objective medical basis that could arguably have supported the prescribing of controlled substances." *Id.* at 62. Given the ALJ's findings, it is notable that the record is devoid of evidence as to whether patients who are taking narcotics for legitimate pain would necessarily manifest symptoms consistent with abuse or intoxication.

In any event, the Government's case primarily focused on Respondent's obtaining of controlled substances through fraud or misrepresentation such as by presenting forged prescriptions. Thus, resolution of the allegations does not require proof that Respondent was abusing the controlled substances.

Also, I do not adopt the ALJ's findings related to the dates of the phone call in which Dr. Edmonds confronted Respondent as to whether she was forging prescriptions which were purportedly authorized by PA Francis. In the decision, the ALJ referred to this phone call as occurring in July 2011, following Respondent's positive urinalysis for opiates. *See* R.D. at 39. The evidence is clear, however, that this conversation did not occur in response to the July 2011 drug test, but in September 2011, after a pharmacist had notified PA Francis about the prescriptions and the latter had presented a printout from the State Prescription Monitoring Program to the clinic's Human

recommended order, except as discussed below. A discussion of Respondent's Exceptions follows.

Exception One—Whether Respondent Was Denied Adequate Notice Because the ALJ Relied on Matters That Were Not Raised in the Order To Show Cause

Respondent argues that her rights under the Due Process Clause and the Administrative Procedure Act were violated because in the Show Cause Order, the Government alleged only that Respondent forged eight prescriptions and the ALJ proceeded to rely on "other matters of fact to support" his recommendation. Exceptions, at 2. Respondent does not, however, identify the specific facts of which she believes she was denied adequate notice, but rather, simply asserts that "the matters determined by the ALJ to support findings against Respondent as to factors four and five were not previously raised in the Order to Show Cause." *Id.* at 3.

To the extent Respondent takes issue with the ALJ's decision because the Show Cause Order alleged only eight instances of forgery rather than the ten instances that the ALJ found proved (as well as the instance in which Respondent filled the first prescription a second time at a second pharmacy), her argument is not well taken. However, to the extent Respondent takes issue with the ALJ's finding that Respondent engaged in conduct actionable under factor five because she attempted to obstruct the pharmacist who questioned her prescription from contacting PA Francis, her argument is well taken.

One of the fundamental tenets of Due Process is that an Agency must provide a Respondent with notice of those acts which the Agency intends to rely on in seeking the revocation of its registration so as to provide a full and fair opportunity to challenge the factual and legal basis for the Agency's action. *See NLRB v. I.W.G., Inc.*, 144 F.3d 685, 688-89 (10th Cir. 1998); *Pergament United Sales, Inc. v. NLRB*, 920 F.2d 130, 134 (2d Cir. 1990); *see also* 5 U.S.C. 554(b) ("Persons entitled to notice of an agency hearing shall be timely informed of . . . the matters of fact and law asserted.") (emphasis added).

However, "[p]leadings in administrative proceedings are not judged by the standards applied to an indictment at common law." *Aloha Airlines v. Civil Aeronautics Bd.*, 598 F.2d 250, 262 (D.C. Cir. 1979) (quoted in *CBS Wholesale Distributors*, 74 FR

Resources Manager, who raised it with Dr. Edmonds. *See* Tr. 195-202; 368; 831-32.

36746, 36749 (2009)); *accord Citizens State Bank of Marshfield v. FDIC*, 751 F.2d 209, 213 (8th Cir. 1984). Accordingly, “the failure of the Government to disclose an allegation in the Order to Show Cause is not dispositive and an issue can be litigated if the Government otherwise timely notifies a [r]espondent of its intent to litigate the issue.” *CBS Wholesale*, 74 FR at 36750. Thus, while the Agency has held that “the parameters of the hearing are determined by the prehearing statements,” consistent with numerous court decisions, the Agency has also recognized that even where an allegation was not raised in either the Show Cause Order or the pre-hearing statements, the parties may nonetheless litigate an issue by consent. *See Clair L. Pettinger*, 78 FR 61592, 61596 (2013) (citing *Pergament United Sales, Inc. v. NLRB*, 920 F.2d 130, 135–37 (2d Cir. 1990)); *see also Duane v. Department of Defense*, 275 F.3d 988, 995 (10th Cir. 2002) (discussing *Facet Enterprises, Inc., v. NLRB*, 907 F.2d 963, 974 (10th Cir. 1990); “we held that defendant had constructive notice of an alternate theory of liability not described in the formal charge when the agency detailed that theory during its opening argument and at other points during the hearing and when the defendant’s conduct revealed that it understood and attempted to defend against that theory”).³

“The primary function of notice is to afford [a] respondent an opportunity to prepare a defense by investigating the basis of the complaint and fashioning an explanation that refutes the charge of unlawful behavior.” *Pergament United Sales*, 920 F.2d at 135 (citation omitted). While the issue of whether an allegation “has been fully and fairly litigated [by consent] is so peculiarly fact-bound as to make every case unique,” *id.* at 136, “the simple presentation of evidence important to an alternative [allegation] does not satisfy the requirement” that a respondent be afforded with a full and fair opportunity to litigate the alternative allegation. *I.W.G.*, 144 F.3d at 688 (quoting *NLRB v. Quality C.A.T.V., Inc.*, 824 F.2d 542, 547 (7th Cir. 1987) (other citation omitted)).

³ *See also Grider Drug #1 & Grider Drug #2*, 77 FR 44070, 44077 n.23 (2012) (holding that while the Government did not provide adequate notice of its intent to litigate an allegation in either the Show Cause Order or its pre-hearing statements, where respondents “did not object that the allegation was beyond the scope of the proceeding and that they were denied adequate notice of it” and “fully litigated the issue,” the allegation was litigated by consent) (citing *Citizens State Bank*, 751 F.2d at 213; *Kuhn v. Civil Aeronautics Bd.*, 183 F.2d 839, 841–42 (D.C. Cir. 1950); and *Yellow Freight System, Inc. v. Martin*, 954 F.2d 353, 358 (6th Cir. 1992)).

“An agency may not base its decision upon an issue the parties tried inadvertently. Implied consent is not established merely because one party introduced evidence relevant to an unpleaded issue and the opposing party failed to object to its introduction. It must appear that the parties understood the evidence to be aimed at the unpleaded issue.” *Yellow Freight System, Inc. v. Martin*, 954 F.2d 353, 358 (6th Cir. 1992) (citation omitted). Accordingly, where the Government’s case “focus[es] on another issue and [the] evidence of [an] uncharged violation [is] ‘at most incidental,’” the Government has not satisfied its constitutional obligation to provide a full and fair opportunity to litigate the issue and it cannot rely on the incidental issue as the basis for imposing a sanction. *Pergament*, 920 F.2d at 136 (quoting *NLRB v. Majestic Weaving Co.*, 355 F.2d 854, 861–62 (2d Cir. 1966)).

Here, in the Government’s initial prehearing statement, Respondent had notice that the Government intended to prove that all of the “prescriptions purportedly issued by PA Francis . . . after February 14, 2011 were not authorized by” her. ALJ Ex. 4, a 4. Moreover, in advance of the hearing, the Government provided Respondent with both the prescriptions it alleged were fraudulent as well as the search results from the New Mexico Prescription Monitoring Program, which listed each of the prescriptions which were purportedly issued by PA Francis to Respondent. ALJ Ex. 7, at 2. Furthermore, prior to the hearing, the parties engaged in extensive litigation over the admissibility of Government Exhibit 4, the exhibit containing the alleged fraudulent prescriptions, as well as over the PMP report. Finally, at the hearing, each of the prescriptions was offered into evidence and was the subject of testimony by witnesses for both parties, including Respondent who testified that each of the prescriptions had been authorized by PA Francis.

Thus, Respondent clearly had fair notice that the Government was alleging that she had obtained controlled substances on eleven occasions by presenting the first prescription (which was authorized by PA Francis) for filling at a second pharmacy, and by forging ten other prescriptions which were presented and filled by multiple pharmacies. Nor can Respondent claim that she lacked notice as to the legal basis for the allegations, as the Government alleged and argued that her conduct violated 21 U.S.C. 843(a)(3). *See* ALJ Ex. 1, at 1–2 (Show Cause Order ¶ 3); ALJ Ex. 59, at 24–25 (Govt’s

Proposed Findings of Fact and Conclusions of Law, hereinafter, Gov. Post-Hrng. Br.).

As noted above, Respondent also took exception to the ALJ’s discussion at pages 62–64 of his decision. Therein, the ALJ concluded that Respondent had engaged in actionable misconduct which may threaten public health and safety, *see* 21 U.S.C. 823(f)(5), based on his finding that “Respondent engaged in significant, intentional efforts to circumvent the efforts of [a pharmacist] in his attempt to execute his corresponding responsibility under the DEA regulations.” R.D. at 62.

Review of the Government’s Prehearing Statement clearly shows that the Government provided Respondent with notice that it intended to elicit testimony from the pharmacist that he had received a faxed hydrocodone prescription for Respondent but that upon submitting the prescription information to Respondent’s insurer, the pharmacy “received an insurance rejection message of ‘refill too soon’” and that a pharmacy technician had reported to the pharmacist “that the same prescription had been filled the day” before at another pharmacy. ALJ Ex. 4, at 3–4. The Government also provided notice that it intended to elicit testimony from the pharmacist that he “attempted to call PA Francis to verify the prescription, but the call was intercepted by the Respondent,” who told the pharmacist that she did not know the prescription had been sent to the other pharmacy and asked him to cancel the prescription. *Id.* at 4. The Government further provided notice that it intended to elicit testimony from the pharmacist that he had contacted the pharmacy which had already filled the prescription and determined that Respondent had picked up the prescription the day before. *Id.* At the hearing, both parties elicited testimony regarding this incident and the ALJ found the pharmacist’s account credible.

Thus, Respondent clearly had notice that her conduct related to this incident would be at issue in the proceeding. Moreover, this conduct is clearly probative of the allegation that Respondent engaged in obtaining controlled substances through fraud, and the Government relied on the pharmacist’s testimony in support of its contention that Respondent forged the prescriptions issued under the PA’s registration. Gov. Post-Hrng. Br. at 26.

However, at no point in the proceeding did the Government contend that this conduct provided an independent basis to support a finding under factor five. Indeed, while in its

post-hearing brief, the Government argues that Respondent's "testimony demonstrated a lack of candor and should weigh against granting Respondent's application," it did not argue that Respondent's acts in intercepting the pharmacist's phone calls and making a false statement to the pharmacist was separately actionable as misconduct under factor five. *See id.* at 30.

While I agree with the ALJ that engaging in intentional and significant acts to obstruct a pharmacist who is attempting to verify the validity of a prescription constitutes "conduct which may threaten public health and safety," the Government never advanced this theory in the proceeding. Thus, Respondent was never provided with the opportunity to argue as to why her conduct did not rise to the level of intentional and significant acts such as to warrant sanction under factor five. *See Duane*, 275 F.3d at 995. Accordingly, I hold that Respondent was not provided with fair notice that this conduct would also be considered under factor five.

However, in light of the extensive evidence that Respondent obtained controlled substances by fraud or deception on eleven occasions and the ALJ's finding that she has not accepted responsibility for her misconduct, *see* R.D. at 66, my rejection of his conclusion that Respondent engaged in actionable misconduct under factor five when she attempted to circumvent the pharmacist's effort to verify the prescription does not alter the ultimate disposition of this matter.⁴

Exception Two—The ALJ Erred When He Found That Twelve Dispensing Events Had Occurred

Respondent also takes exception to the ALJ's findings that the prescriptions had resulted in the occurrence of twelve dispensing events, "each signif[ying] an episode wherein Respondent actually obtained prescription narcotics." Exceptions, at 3 (citing R.D. at 20–28). According to Respondent, this finding is not supported by the record because "there was *no* evidence as to [the] actual 'dispensing' of any prescriptions." *Id.* In support of this contention, Respondent

⁴ I do not adopt the ALJ's finding that the explanation Respondent provided on her DEA application lacked candor because she failed to include various information. R.D. at 68. At no point in this proceeding has the Government alleged that her explanation on the application was at issue in the proceeding, and at no point has it argued that her explanation lacked candor. In short, there is no basis for concluding that Respondent had fair notice that her explanation on the application would be at issue. Nor is there any basis for concluding that the parties consented to the litigation of the issue.

further notes that "a clear distinction was made during testimony between *filling* a prescription (*i.e.*, processing it for dispensing to a patient) and actually *dispensing* it to an individual" and that the Government never presented the evidence necessary to show that the prescriptions were actually dispensed, *i.e.*, the signature logs maintained by the pharmacy. *Id.*

This argument is not persuasive. While it is true that a pharmacy's creation of a dispensing label for a filled prescription, as well as its inputting of data which was then submitted to the State's Prescription Monitoring Program, does not establish that the prescription was actually dispensed, Respondent testified that either she or members of her family picked up at least ten of the prescriptions before she attempted to change her story. Tr. 901–03, 921. Moreover, when asked by her counsel if she knew whether "there are some prescriptions waiting for you at some place," she answered: "No, I don't think so, but." *Id.* at 920. Respondent's testimony on this issue seems to go well beyond that of a faulty recollection induced by the passage of time and into the realm of being intentionally misleading.

Indeed, her attempt to deny that the prescriptions were picked up defies logic, given that at the hearing she maintained that all of the prescriptions had been authorized by the PA (Tr. 822, 899, 910) and were issued to treat a legitimate medical condition (Tr. 903, 922). Nor does it make sense that having previously presented a prescription, she would, in the absence of having been told that the pharmacy had declined to fill it, then present a further prescription to another pharmacy without first picking up the already filled prescription.

In any event, even if Respondent (or her family) did not actually pick up any of the prescriptions, the evidence would still support a finding that she violated federal law. Here, the ALJ found that Respondent forged the PA's signature on the prescriptions and both the dispensing labels and the PMP report establish that the prescriptions were presented to the pharmacies. Thus, even if Respondent or her family members never picked up any of filled prescriptions, her conduct is still actionable as an attempt to obtain controlled substances by fraud or deception. *See* 21 U.S.C. 843(a)(3) & 846.

Exception Three—The ALJ Failed To Consider Evidence That Another Person Committed the Acts

Respondent argues that the ALJ abused his discretion because he failed to consider evidence that two persons "had access to the necessary process and information to perform the alleged acts in [her] name without her knowledge and/or agreement." Exceptions, at 9, 11. Respondent identifies these two persons as her husband, who was also taking hydrocodone, and Ms. Diminovich, Respondent's medical assistant at the clinic. *Id.* at 9–10.⁵

I reject the exception. Even ignoring the fundamental inconsistency between Respondent's contention and her testimony that the prescriptions were lawfully prescribed to her by PA Francis, the exception is unsupported by anything bordering on substantial evidence.

As for whether Respondent's husband was actually forging the prescriptions, even assuming that he had received hydrocodone prescriptions from PA Francis, no evidence was put forward that he had access to either the electronic medical records system (which included software for creating and printing a prescription) or to PA Francis's prescription pads. Thus, Respondent's theory is pure conjecture.

As for whether Ms. Diminovich was forging the prescriptions, it is true that she had access to the clinic's electronic medical records system. Moreover, it seems possible that she could have had access to the PA's prescription pad. However, while Respondent called Ms. Diminovich as a witness, Diminovich was never asked if she had forged any of the prescriptions; nor was any other evidence put forward that Diminovich was forging prescriptions and using Respondent's name as the patient. Indeed, consistent with her theory that the prescriptions were authorized by PA Francis, Respondent elicited testimony from Ms. Diminovich that PA Francis "would fill out the script for [Respondent] personally" and either hand it to Respondent or leave it on her desk. Tr. 732. Respondent's theory that Ms. Diminovich was forging and filling the prescriptions and filling them in the former's name is thus not supported by anything more than the evidence that she had access to the clinic's prescribing

⁵ Respondent also maintains that PA Francis had prescribed hydrocodone to her husband. Exceptions, at 10. PA Francis testified that while she had written prescriptions for Respondent's husband, which possibly included pain medication, she did not recall if these included narcotics. Tr. 249.

software.⁶ Accordingly, I reject the exception.⁷

Exception Four—The ALJ's Credibility Determinations Were Arbitrary

Finally, Respondent argues that the ALJ arbitrarily discounted the testimony of Ms. Diminovich and that he ignored "the context" of her testimony. Exceptions, at 11. Respondent also contends that the Government's witnesses, who had "the exact same 'issues' in their testimony, were called completely credible by the ALJ provided they blamed" her. *Id.*

Respondent does not, however, take exception to the ALJ's findings as to her own testimony. Of note, the ALJ found that "Respondent's testimony throughout this hearing was punctuated by internal inconsistencies, implausibility, and chronic equivocation." R.D. at 46. The ALJ further found that "there were several times where her answers seemed to evolve with objective evidence and dates she was confronted with." *Id.*

As for Respondent's contention that the ALJ arbitrarily discounted Ms. Diminovich's testimony, the argument is based largely on her testimony that she observed animosity between Respondent and Dr. Edmond (the co-owner of the clinic), PA Francis, and the clinic's human resources manager. Exceptions, at 11–12. To be sure, in explaining why he gave less weight to Ms. Diminovich's testimony, the ALJ relied on her failure to testify as to whether the animosity pre-dated or post-dated the discovery of the prescriptions at issue. *See* R.D. at 30. Nor was this the only reason the ALJ gave for giving less weight to her testimony. *See id.* at 30–31 (discussing Ms. Diminovich's testimony that she

never observed Respondent being under the influence of controlled substances).⁸

However, I need not decide whether these two reasons provide a sufficient basis to support the ALJ's credibility determination because the ALJ also explained that "much of Ms. Diminovich's testimony was too vague and lacking in detail to stand up against other record evidence." R.D. at 31. As the ALJ further explained, while Ms. Diminovich testified that "she saw PA Francis prescribe controlled substances to the Respondent and hand the scripts over, [she] never sa[id] when or how often, and [did] not provide details about a single such event she recalls." *Id.* at 31. So too, based on Ms. Diminovich's testimony that she had left the clinic after five years because she had been accused by a clinic employee of forging some undisclosed document, the ALJ concluded that she could not be viewed "as a completely impartial witness." *Id.*

In short, to resolve the factual dispute as to whether PA Francis had authorized the prescriptions or Respondent was forging them, the ALJ was required to make credibility determinations with respect to the testimony presented by the witnesses for the Government and those for Respondent. Notably, with regard to the testimony of the Government's witnesses, Respondent makes only the conclusory assertion that their testimony raised "the exact same issues" as her witnesses, Exceptions at 11, and fails to cite to any specific portions of their testimony which she asserts lacked credibility. The ALJ was, however, in the best position to observe the demeanor of the witnesses, and having considered the "consistency and inherent probability of the testimony," I find no reason to reject the ALJ's credibility determinations and findings of fact. *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 496 (1951).

Accordingly, I reject the exception. I further adopt the ALJ's findings of fact and legal conclusions that with the exception of the February 14, 2011 prescription (which she filled that same day), Respondent violated 21 U.S.C. 843(a)(3) on eleven separate occasions by presenting the already-dispensed February 14, 2011 prescription to a

second pharmacy for filling, as well as by forging the ten other prescriptions (or presenting the forged prescription to a second pharmacy). *See* R.D. at 52–55 (citing 21 U.S.C. 843(a)(3); 21 CFR 1306.04(a)). Moreover, while I adopt the ALJ's factual finding and legal conclusions that Respondent unlawfully obtained controlled substances pursuant to the aforesaid prescriptions, *see* R.D. at 55, even if Respondent did not obtain possession of the controlled substances in each instance, her misconduct is still actionable as an attempt to obtain controlled substances by fraud or misrepresentation. *See* 21 U.S.C. 846. So too, I adopt the ALJ's legal conclusions with respect to the findings of the Iowa Board. *See* R.D. at 59–60.

I therefore adopt the ALJ's conclusion of law that the Government has established a *prima facie* case to deny Respondent's application.⁹ R.D. at 65. Finally, because I agree with the ALJ's findings and conclusion of law that Respondent has not acknowledged her misconduct nor demonstrated that she had undertaken sufficient remedial steps to rebut the Government's *prima facie* case, as well as his finding that Respondent's actions were especially egregious, I will adopt his recommendation that I deny her application.

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f), as well as by 28 CFR 0.100(b), I order that the application of Jana Marjenhoff, D.O., for a DEA Certificate of Registration as a practitioner, be, and it hereby is, denied. This Order is effective immediately.

Dated: May 6, 2015.

Michele M. Leonhart,
Administrator.

Anthony S. Yim, Esq., for the
Government

Billy R. Blackburn, Esq., for the
Respondent

⁶ While Ms. Diminovich testified that she had left the clinic after she was accused of forging a document, the record does not establish the nature of the document she allegedly forged. As for her testimony that PA Francis had written the prescriptions, as discussed under Exception Four, the ALJ did not find Ms. Diminovich's testimony credible when considered against the testimony of the Government's witnesses.

⁷ The Government notes the testimony of the pharmacist who questioned Respondent's prescription to the effect that "in order to pick up a controlled substance prescription, an individual would need to provide picture identification, which is then recorded in the pharmacy computer system." Gov. Response to Respondent's Exceptions, at 9. While the Government attempted to introduce various documents which it represented as being pharmacy pick-up logs, it did not succeed. Moreover, the Executive Director of the New Mexico Pharmacy Board testified that while a "person picking up the controlled substance prescription must be identified with a government-issued photo ID," the person need not be the actual patient. Tr. 446–7.

⁸ I acknowledge that it is plausible that Ms. Diminovich may never have observed Respondent being under the influence of narcotics while at the clinic. Respondent may have developed tolerance to the medication or she may have been diverting the narcotics to others. However, I need not adopt each of the ALJ's reasons for giving less weight to her testimony to adopt the ALJ's factual findings, which give no weight to her testimony that PA Francis wrote narcotic prescriptions for Respondent on "multiple" occasions. Tr. 733.

⁹ I do not adopt the ALJ's discussion of factor two to the extent it states that the factor manifests Congress's "acknowledgement that the . . . quantitative volume in which an applicant has engaged in the dispensing of controlled substances may be [a] significant factor[] to be evaluated in" the public interest determination. R.D. at 51. So too, I decline to publish the ALJ's discussion of the substantial evidence test, the degree of deference owed the ALJ's findings, and the scope of the Agency's discretion. *See Michael A. White*, 79 FR 62957, 62957 n.2 (2014). It suffices to say that the Agency adheres to the principles set forth in *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 496 (1951).

RECOMMENDED RULINGS, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION OF THE ADMINISTRATIVE LAW JUDGE

Chief Administrative Law Judge John J. Mulrooney, II. On July 13, 2012, the Deputy-Assistant Administrator of the Drug Enforcement Administration (DEA) issued an Order to Show Cause (OSC) proposing to deny the application¹ of Jana Marjenhoff, D.O. (Respondent), for a DEA Certificate of Registration (COR). In its OSC, the Government avers that the Respondent's application should be denied because the granting of a COR to the Respondent would be inconsistent with the public interest as that term is defined under the Controlled Substances Act (CSA). 21 U.S.C. 823(f) (2012). On August 20, 2012, the Respondent, representing herself *pro se*, filed a timely request for a hearing.²

A hearing was originally conducted in this matter on February 5, 2013, in Arlington, Virginia (First Hearing). However, because the Administrative Law Judge presiding over that hearing unexpectedly retired before issuing a recommended decision, this case was reassigned to another Administrative Law Judge (Second Administrative Law Judge), who conducted a supplemental hearing on April 10, 2013, in Albuquerque, New Mexico (Supplemental Hearing). The Second Administrative Law Judge certified the record and forwarded a recommended decision to the Administrator.

The Administrator reviewed, reversed, and remanded the recommended decision issued by the Second Administrative Law Judge. In an order dated December 12, 2013 (Remand Order), the Administrator remanded the case for a new hearing to be conducted by another Administrative Law Judge,³

¹ A printed copy of the Respondent's on-line application was received into the record. Gov't Ex. 1.

² In her brief, the Respondent points to the Agency's "extreme delay" in issuing an OSC almost a year and a half after her application for a DEA COR. ALJ Ex. 60, at 1. In this regard, it is worthy of note that the charges of misconduct that constitute the body of the Government's allegations in this matter relative to the Respondent's time practicing in New Mexico commenced a month after she submitted this application to receive a COR in New Mexico.

³ The Administrative Law Judge presiding at the Supplemental Hearing found that the Respondent's exit from the hearing room, based on a medical emergency that resulted in her departure from the courthouse via ambulance and an attendant hospital stay, constituted an implied waiver of her right to be present at her hearing. Consequently, the Supplemental Hearing was conducted entirely *in absentia*. The (unarguably regrettable) decision by the Second Administrative Law Judge to proceed *in absentia* (not surprisingly) formed a significant basis (although clearly not the only basis) for the

and I designated myself to preside at the remanded proceedings.

At a January 14, 2014 on-the-record status hearing conducted in Albuquerque, New Mexico, the Respondent, representing herself *pro se*,⁴ signaled her intent to proceed with a new hearing. Current counsel filed a notice of appearance on February 10, 2014, and a request on his part for additional time to prepare was granted. ALJ Ex. 37, at 1 n.1. On April 22–23, 2014, a hearing was conducted in this matter in Albuquerque, New Mexico (Hearing on Remand).

The issue ultimately to be adjudicated by the Administrator in these remanded proceedings, with the assistance of this recommended decision, is whether the record as a whole establishes by substantial evidence that the Respondent's application for registration with the DEA should be denied on the grounds alleged by the Government.

After carefully considering the testimony elicited at the Hearing on Remand, the admitted exhibits, the arguments of the parties,⁵ and the record as a whole, I have set forth my recommended findings of fact and conclusions of law below.⁶

Administrator's decision to remand the case for a new hearing (ALJ Ex. 9, slip op. at 6) by a different Administrative Law Judge and, unfortunately, resulted in a significant additional delay in the adjudication of this matter. On the positive side, as a result of the Administrator's Remand Order, the Respondent, who represented herself at the First and Second Hearings, was the beneficiary of skilled, diligent counsel at the Hearing on Remand, where any perceived due process issues ascribed to the hearing *in absentia* could be and were addressed and cured.

⁴ From the outset and repeatedly throughout the course of these protracted proceedings, the Respondent was advised of her right to procure counsel. 21 CFR 1316.50 (2013). While she did retain counsel for a short period of time during the prehearing procedures prior to the First Hearing, that counsel withdrew from the case, and she opted to represent herself *pro se* for a relatively large swath of time during the pendency of the proceedings. The Respondent's fluctuating representation status also resulted in additional adjudication delays. During the course of the Supplemental Hearing, the Respondent initially sought to be represented by her (non-attorney) spouse under the theory that he falls within the regulatory definition of her employee within the meaning of 21 CFR 1316.50. The Administrator's Remand Order cites an absence of required findings associated with the Second Administrative Law Judge's denial of this request as an additional basis to justify remanding the case. ALJ Ex. 9, slip op. 5. During the course of the remanded proceedings, the Respondent withdrew her request to be represented by her husband at an on-the-record Status Hearing conducted on January 14, 2014, and, during the time afforded to her to do so, procured the representation of a qualified attorney.

⁵ The due date that was set for the submission of closing briefs incorporated additional time that was requested by the Government. Tr. 976–79.

⁶ Because the December 12, 2013 Remand Order directed that a "new hearing" be conducted in this

The Allegations

In its OSC and subsequent prehearing statements, the Government alleges that the COR application filed by the Respondent should be denied as inconsistent with the public interest. In support of the denial it seeks based on the public interest, the Government avers that the Respondent, "from February 2011 through January 2012, . . . forged approximately eight prescriptions for [herself] by using another individual's DEA registration number . . . without that person's knowledge, permission, or consent" in order to obtain controlled substances.⁷ The Government alleged that the Respondent did so in violation of 21 U.S.C. 843(a)(3), 21 CFR 1306.04 (2013), and N.M. Stat. Ann. § 30–31–23 (West 2013).⁸

The Stipulations of Fact

The Government and the Respondent have entered into stipulations regarding the following matters:

(1) Respondent's prior DEA Certificate of Registration was BM1443681. In the absence of any renewal application, it expired by its own terms on January 31, 2006.

(2) Respondent does not currently possess a DEA Certificate of Registration.

(3) On January 17, 2011,⁹ the Respondent applied for a DEA Certificate of Registration in Schedules II through V.

(4) Respondent is licensed as an osteopathic physician in the State of New Mexico pursuant to license number A–1590–10. This license is active.¹⁰

(5) All medications described in Government Exhibit 6 as being

matter (ALJ Ex. 9, slip. op. 7), the testimony and evidence gathered in the previous hearings in this case, to the extent they were not re-introduced and received into the record, were not considered for purposes of deciding on the merits on remand. ALJ Ex. 29, at 4. Both parties were given the opportunity to file supplemental prehearing statements and to present evidence at the Hearing on Remand. *Id.* at 3–4. The testimony from the previous hearings (ALJ Ex. 8) was made available to the parties for purposes of cross-examination. ALJ Ex. 29, at 4.

⁷ ALJ Ex. 1, at 1.

⁸ *Id.* at 2.

⁹ While the parties stipulated to an application date of January 17, 2011, the record evidence reflects an application date of January 14, 2011. Tr. 631–32; Gov't Ex. 1, at 1; Gov't Ex. 2, at 1. The 3-day variance regarding the application date presents no impediment to an adjudication of this matter on the merits.

¹⁰ Although this stipulation by the parties originally contained the additional phrase "and set to expire by its own terms on July 1, 2013," the fact that this date expired well before the commencement of the Hearing on Remand renders the relevance of this portion of the stipulation obsolete.

prescribed to the Respondent are Schedule III controlled substances.¹¹

The Evidence

The Government's Evidence

The Government's Witnesses

The Government's case-in-chief rested on the testimony of five witnesses:

Physician's Assistant Raphaela Francis, John Alvis, the pharmacist-in-charge (PIC) of a Walmart Pharmacy located in Edgewood, New Mexico, Dr. Jeremy Edmonds, D.O., New Mexico Pharmacy Board (NM Pharmacy Board) Executive Director (Exec. Dir.) Larry Loring, and DEA Diversion Investigator (DI) Randall Bencomo.

Raphaela Francis testified that she is a physician's assistant (PA) who is currently licensed and practicing in New Britain, Connecticut, but that she had previously worked as a PA at the McLeod Medical Center (McLeod Medical) in Moriarty, New Mexico from 2008 until August 2012. Tr. 173–74, 215–16. PA Francis testified that, while working at McLeod Medical, she maintained a DEA COR, and she knew and worked with the Respondent. Tr. 174.

PA Francis stated that her working relationship with the Respondent at the time they worked together at McLeod was a good one, that the Respondent, who "had lots more medical experience," was a mentor to her, and that Francis never observed behavior that she would classify as drug-seeking, impaired, or erratic from the Respondent at work. Tr. 219, 261.

According to PA Francis, on February 14, 2011, the Respondent approached her at work and asked to be placed on her schedule for chronic neck pain. Tr. 175. The Respondent told Francis that she had made arrangements to see a pain management specialist in Albuquerque, but because the pain specialist, Dr. Pamela Black, could not see her for several weeks, she needed a single prescription for pain medication to tide her over for one month. Tr. 175–77, 182–84, 221–22. PA Francis testified that, consistent with McLeod Medical procedures, before she saw the Respondent as a patient, Leilani, the medical assistant assigned to Francis, took an initial medical history on a patient questionnaire, and that the Respondent, who had brought her own x-rays, was added onto Francis's patient schedule for the end of the day. Tr. 178–81, 219. Equipped with the completed patient questionnaire, PA Francis took her own history from the Respondent

and reviewed the x-ray films. Tr. 181. Francis testified that she recalled that the x-ray imaging showed that the Respondent's neck had signs of prior surgery. Tr. 181–82, 220. She also remembered that the Respondent was complaining of headaches. Tr. 182. Francis recalled that, in response to her inquiry, the Respondent told her that hydrocodone had been effective for her in the past. Tr. 184. PA Francis's opinion was that, under the circumstances, the hydrocodone requested by the Respondent was appropriate as a short-term (not long-term) measure, so she prepared a prescription and handed it to the Respondent.¹² Tr. 184–85, 188, 227; Gov't Ex. 3. Francis was initially unambiguous in stating that this scrip was "the one and only prescription" she wrote for the Respondent. Tr. 185; *accord* Tr. 202, 240. When pressed, however, she recalled that she may have also treated the Respondent on another occasion for nausea with a non-controlled substance administered by injection in the office. Tr. 241, 243–44.

According to PA Francis, the Respondent called off work two days after Francis saw her as a patient, telling Dr. Edmonds, the office supervising doctor/facility co-owner, that she had been to a hospital emergency room experiencing abdominal pain that was likely a reaction to the hydrocodone prescribed by Francis. Tr. 189–90, 193. Shortly after his conversation with the Respondent, Dr. Edmonds questioned PA Francis about the prescription and told her that, from that point forward, McLeod Medical employees were no longer permitted to write narcotic prescriptions for other employees. Tr. 192, 239. PA Francis testified that she complied with the new policy from the time it was conveyed to her. Tr. 194.

PA Francis had no more cause to consider her prescription to the Respondent until September 2, 2011, when she received a call from a pharmacist in Moriarty, New Mexico, informing her that a Walmart pharmacist named John Alvis needed to speak with her. Tr. 195–96. When Francis returned the call, Alvis told her he came upon some scrips purportedly written by Francis for the Respondent that he felt were likely forgeries. Tr. 197–99. Alvis went on to say that he was forced to utilize an intermediary pharmacist to contact Francis because multiple telephonic attempts to do so had been intercepted by the

Respondent, and he advised Francis to secure a state prescription monitoring program (PMP) report on the Respondent and to contact the NM Pharmacy Board. Tr. 199–200, 202. When Francis queried the PMP system, she was surprised to learn that, although she had written only one controlled substance prescription for the Respondent, the system reflected that twelve had been dispensed. Tr. 200–02.

PA Francis testified that she brought the PMP report to the McLeod Medical human resources (HR) director who, in turn, notified Dr. Edmonds. Tr. 202–03.

Upon reviewing copies of the scrips listed in the PMP report and issued over her name and COR number after the single February 14, 2011 scrip she did write, PA Francis testified that not a single one bore her true signature and that all were forgeries. Tr. 205–06, 261. The witness indicated that she did not personally see anyone create these scrips, but she did know that they were not signed by her. Tr. 261.

Francis explained that, during the time she worked at McLeod Medical, scrips could be generated by handwriting them on scrip pads or by producing them electronically (e-scrip) from the system that maintained the office medical records. Tr. 207. The e-scrip would be printed out on blue security paper loaded into a printer designated for that purpose and hand-signed by the prescriber. Tr. 207, 211, 226. Through the use of a drop-down list, the medical record system allowed any McLeod Medical employee with prescriber access to create an e-scrip for any patient in the practice over the name of any authorized prescriber in the practice who has seen that patient. Tr. 208, 215, 253–57, 260. Access to the system for prescribing controlled substances is password-protected, but as a McLeod Medical provider, the Respondent had complete access to the system, as did Francis, Dr. Edmonds, and a part-time nurse practitioner named Linda Agnes. Tr. 208–13, 217. The controlled substance scrip can be hand-carried by the patient, faxed to a pharmacy by a McLeod staff member,¹³ or a staff member can even phone in a prescription to a pharmacy so long as there is a hard-copy follow-up scrip. Tr. 228–30.

There is no indication that PA Francis has anything to gain or lose by the outcome of this adjudication. In light of

¹¹ The parties reached this stipulation during the course of the hearing in this matter. Tr. 747–48.

¹² During her testimony, PA Francis mistakenly characterized this medication as being listed under Schedule II (Tr. 230), when, in fact, it is a Schedule III controlled substance. Stipulation 5.

¹³ Francis testified that McLeod Medical office policy on the disposition of hard copies of faxed prescriptions was inconsistent. When a scrip was faxed, sometimes the hard copy would also be handed to the patient, sometimes it would be shredded, and other times it would be retained in the patient's chart. Tr. 233–35.

the fact that Francis currently works for a different employer in a different state and no longer answers to Dr. Edmonds or McLeod Medical, the Respondent's argument that her credibility was suspect because she was somehow "in fear of her career" because she had been reprimanded¹⁴ for writing a controlled substance prescription for the Respondent, and/or continued to do so after being directed not to is not supported in the record by anything beyond conjecture, and is simply unpersuasive. Her hearing testimony, much of which was corroborated by other witnesses, was sufficiently objective, detailed, plausible, and internally consistent to be considered fully credible in this recommended decision.

The Government also elicited the testimony of John Alvis, the pharmacist-in-charge (PIC) at the Walmart Pharmacy in Edgewood, New Mexico (Walmart Pharmacy Edgewood), where he has worked as a pharmacist for the last twenty-nine years. Tr. 264–65. PIC Alvis testified that he was familiar with the Respondent because she was a local practitioner with whom he had professional contact, and because she and her family had been customers of his pharmacy. Tr. 265–67. In the early afternoon of August 31, 2011, PIC Alvis received a phone call from the Respondent who stated that her daughters were coming by the pharmacy to pick up prescriptions for themselves, and that she hoped to have them also pick up a prescription for her during the same visit. Tr. 266–67. The Respondent explained to Alvis that she would contact PA Francis to "get that [prescription] faxed in right away." Tr. 267. Alvis also recalled that the Respondent told him that she was having trouble with her insurance and requested that the pharmacy bill her for the prescription in cash, without submitting a claim through her insurance carrier. Tr. 268–69. PIC Alvis testified that, while a request to have several medications picked up at once was not particularly out of the ordinary, a request to refrain from processing a scrip through a customer's insurance company where Medicare billing was not involved was not typical. Tr. 268–70. Alvis described such a request, even regarding Medicare billing, as "fairly rare." Tr. 270.

Although Alvis apparently voiced no objection to the Respondent's request to

process the scrip for cash, owing to the work volume of the day and the speed at which the faxed prescription reached the pharmacy, a staff member allowed the prescription to be electronically submitted as a claim to the Respondent's insurance company. Tr. 270–71. The Respondent's insurance company rejected the claim after determining that the refill was too early, based on medication that had already been dispensed to the patient. Tr. 270, 272. PIC Alvis testified that once he learned from the insurance company notice that the Respondent was attempting to fill a prescription for the same controlled substance too early, he had an obligation to investigate the issue. Tr. 279–80. At PIC Alvis's direction, the pharmacy staff member contacted¹⁵ the Respondent's insurance company and was informed that the coverage rejection was based on the fact that the same medication had been dispensed to the Respondent at May Pharmacy the previous day. Tr. 275–76. Based on the information he had at that moment, PIC Alvis directed his staff member to reach out to PA Francis at McLeod Medical, the prescriber depicted on the scrip. Tr. 281. A McLeod Medical staff member indicated that Francis was unavailable and took a message to have Francis return the call to the pharmacy. Tr. 281–82.

Shortly after the phone message was left at McLeod Medical for Francis, the

¹⁵ The pharmacy employee was clearly an individual with no interest in these proceedings. PIC Alvis (a 29-year veteran pharmacist) testified that he was present and listening to his employee as she conducted these telephone inquiries at his direction, that he could hear her responses as the phone call was proceeding, that it is "standard practice" to rely upon this type of communication in the pharmacy setting, and that the employee who took the call had a duty to receive and convey this type of information accurately. Tr. 272–76. In short, even over the Respondent's timely objection, there was ample support in the record to find this hearsay evidence sufficiently reliable to rely upon it to a support substantial evidence determination in these administrative proceedings. 5 U.S.C. 556(d). See *Richardson v. Perales*, 402 U.S. 389, 402 (1971) (holding that signed reports prepared by licensed physicians were correctly admitted at Social Security disability hearing); *Echostar Comm's Corp. v. F.T.C.*, 292 F.3d 749, 753 (D.C. Cir. 2002) (holding hearsay admissible at administrative hearing so long as it bears satisfactory indicia of reliability); *Bennett v. NTSB*, 66 F. 3d 1130, 1137 (10th Cir. 1995) (holding hearsay admissible at administrative hearing to the extent it is reliable and probative); *Hoska v. Dep't of the Army*, 677 F.2d 131, 138–39 (D.C. Cir. 1982) (holding hearsay admissible at administrative hearing where witness is disinterested, statements are consistent, and access is provided prior to hearing); *Mark P. Koch, D.O.*, 79 FR 18714, 18717 (2014) (finding an affidavit sufficiently reliable to be considered as substantial evidence at a DEA administrative hearing); *Fred Samimi, M.D.*, 79 FR 18698, 18712 (2014) (holding hearsay statements are admissible at DEA administrative proceedings and can constitute substantial evidence so long as they bear sufficient indicia of reliability).

Respondent's daughters (whom Alvis recognized as established customers) arrived at Walmart Pharmacy Edgewood to pick up the Respondent's medication and some other medication. Tr. 282–83. Alvis told the daughters that he needed to check with the prescriber on their mother's prescription, and they left the pharmacy. Tr. 282–84. "Almost immediately" after the Marjenhoff daughters exited the pharmacy, PIC Alvis received a call from the Respondent, who informed Alvis that she understood he was trying to contact Dr. Black about her prescription. Tr. 284. PIC Alvis clarified that he was trying to reach PA Francis and that he had not yet heard back from her. Tr. 284. The Respondent explained to Alvis that there was some "confusion" because the prescription he was inquiring about was also sent to May Pharmacy without her knowledge, and that Alvis should "just disregard this prescription." Tr. 284–85.

Following Alvis's conversation with the Respondent, a pharmacy staff member received a return call from someone at McLeod Medical, asking if the pharmacy still needed to speak with PA Francis.¹⁶ Tr. 285. When the pharmacy technician told the McLeod Medical staff member that she still needed to speak with Francis, the call was placed on hold, and the Respondent picked up the line and identified herself. Tr. 825. The technician informed the Respondent that she was holding to speak with PA Francis, not with the Respondent. The Respondent told the technician, "I know it's concerning my prescription. I've already spoken to John [Alvis]. There's some confusion with that. I've told John [Alvis] to cancel that prescription, and so we're good," and unilaterally ended the call by hanging up the phone. Tr. 286–88.

PIC Alvis testified that this development deepened his level of concern about the prescription. Tr. 288. Additionally, Alvis compared the faxed scrip with prior, reliable examples on file and concluded that the purported signature of PA Francis on the scrip at issue was not consistent with the signatures found on the prior scrips. Tr. 302–04. The next morning, Alvis telephoned Kenny Romp, the pharmacist at May Pharmacy, who at one time worked for Alvis. Tr. 290–93. Pharmacist Romp indicated that he specifically recalled the prescription in question. He told Alvis that he remembered that the Respondent,

¹⁶ Alvis testified that he was present for the conversation and could even overhear the voice on the phone from McLeod Medical. Tr. 287.

¹⁴ ALJ Ex. 60, at 6, 8, 15. Furthermore, the position that PA Francis was reprimanded at all flies in the face of the Respondent's testimony that no policy regarding the prescribing of controlled substance to other employees was ever put in place at McLeod. Tr. 721, 824.

herself, picked up the medication, and that he also recalled it was a partial fill because May Pharmacy did not have the entire amount called for by the prescription in stock. Tr. 293–95. This revelation that the Respondent actually picked up the medication the day before her phone calls to Alvis flew in the face of the Respondent's representations on the phone that she did not know that her prescription had been filled at May Pharmacy, and her assertion that the early refill insurance notification was the result of some sort of an inadvertent mix-up. Tr. 295–96. The fact that the Respondent picked up her medication at May Pharmacy the day before she told Alvis she did not know it had been dropped off there left little doubt that there was more afoot than an innocent mix-up.

Alvis then devised a plan wherein he enlisted the help of a third local pharmacist, Reid Rowe, to reach out to PA Francis and relay a message that Alvis needed to speak to her privately and directly. Tr. 296–97. Alvis's plan was successful, and, the following day, he finally received a call from PA Francis. Tr. 298–99. Francis apologized for not calling back, and related to Alvis that she had actually been standing next to the Respondent when the pharmacy technician called. Francis explained to Alvis that based on what she heard of the call, she assumed that the matter had been resolved as a benign insurance issue. Tr. 301. When PIC Alvis conveyed the details of the current prescription and asked Francis to verify it and indicate whether he had her authorization to dispense, Francis informed him that she had not written a controlled substance prescription for any McLeod Medical employee since February 14, 2011. Tr. 301–02. When PIC Alvis let Francis know that his pharmacy was in possession of other scrips purportedly authorized by her on behalf of the Respondent and that he questioned the validity of the signatures, PA Francis asked him to provide copies. Tr. 304. Alvis faxed copies of some scrips that had been filled by his pharmacy on the Respondent's behalf over PA Francis's purported signature to the McLeod Medical HR manager. Tr. 305–09. The HR manager, in turn, sent PIC Alvis a copy of a corresponding complaint filed by PA Francis with the NM Board of Osteopathic Medical Examiners regarding the incident, which Alvis forwarded through his internal, corporate channels and to the NM Pharmacy Board. Tr. 309–11, 316. The prescription was then deactivated at

Walmart Pharmacy Edgewood and not dispensed. Tr. 335.

PIC Alvis is a witness with no stake in the outcome of the case.¹⁷ His testimony, which was largely corroborated by other sources in the record, was enhanced by the professionalism with which he executed his corresponding responsibilities as a pharmacist, and sufficiently objective, detailed, plausible, and internally consistent to be fully credited in this recommended decision.

The Government also presented the testimony of Dr. Jeremy Edmonds, D.O. Although Dr. Edmonds testified that is currently employed at Presbyterian Healthcare Services in Albuquerque, during all times relevant in these proceedings, he served as the medical director and co-owner of McLeod Medical and supervised the Respondent and all other staff members at McLeod. Tr. 358–60. Dr. Edmonds also testified that he is on the New Mexico Board of Osteopathic Medicine. Tr. 387.

Dr. Edmonds recalled that, when the Respondent was hired by McLeod Medical, she did not possess a COR. Tr. 382. According to Edmonds, the work-around for this issue was that the Respondent would see patients and “draft up” a controlled substance prescription over her name when necessary, but that Dr. Edmonds or PA Francis would co-sign the scrip and manually fill in their respective COR numbers. Tr. 382–85. Edmonds testified that all providers (including the Respondent) were “practicing primary care [medicine and] all treated very similar problems.” Tr. 386. Consistent with the testimony of PA Francis, Dr.

¹⁷ In her brief, the Respondent argues that she and PIC Alvis “had previously been in strong disagreements . . . in regards to his lack of competence.” ALJ Ex. 60, at 4. However, the record is unresponsive. The Respondent testified that she “switched pharmacies, mainly over to May's [Pharmacy] because [she] had a problems with [Alvis], in that on a couple of occasions he prescribed the wrong medication to [her] patients, and [she] reprimanded him.” Tr. 935. Apart from the reality that pharmacists do not “prescribe” medication, the objective evidence of record is that, notwithstanding the multiple pharmacy options available to (and used by) the Respondent, she continued to patronize the Walmart Pharmacy Edgewood that Alvis managed. Additionally, the record demonstrates that the Respondent was not only sufficiently satisfied with Alvis that she selected his pharmacy on one of the occasions where she illegitimately utilized the February 14, 2011 prescription from PA Francis (Gov't Ex. 3, at 1), but she was sufficiently comfortable with her relationship with Alvis to call him on August 31, 2011 to request that his pharmacy refrain from submitting the prescription to her insurance company, and, once again, when Alvis declined to dispense the medication to her daughters. Tr. 268–69, 282. Indeed, the PMP/Marjenhoff Report reflects as many dispensing events through Walmart Pharmacy Edgewood as occurred at May Pharmacy. Gov't Ex. 6, at 2–3, 13–14.

Edmonds explained that prescriptions in the office could be generated by writing on a pad or through the e-scrip system, and that, while all employees had a sign-in password, only providers had the e-scrip access required to produce controlled substance scrips off the system. Tr. 415–21. Non-controlled prescriptions could be electronically signed and forwarded to pharmacies for filling, but controlled substance e-scrips required a manual signature by an authorized prescriber.¹⁸ Tr. 424–28.

Dr. Edmonds, who (like PA Francis) characterized his working relationship with the Respondent as “good,”¹⁹ recalled that, in February 2011, the Respondent called off work for one or two days, explaining to Edmonds on the phone that she had an adverse reaction to hydrocodone. Tr. 361. When the Respondent told Edmonds that PA Francis had supplied her with the hydrocodone prescription, Dr. Edmonds sat both Francis and the Respondent down and unambiguously informed them, in a conversation that he characterized as “stern . . . very direct,”²⁰ that “prescribing potentially habit-forming medications to a colleague or staff member” at McLeod Medical “is not tolerated and should not persist.” Tr. 361–62. Dr. Edmonds was precise and forceful in the manner in which he recalled the details of the meeting. In his words:

[T]he discussion really went as follows. I walked into the room, and Dr. Marjenhoff and Raphaela Francis were both there. And I basically said that—I sat them both down, and I said that, you know, I understand that, Raphaela, you prescribed controlled substance to Dr. Marjenhoff, and I believe it was hydrocodone. And you had an adverse reaction to that. And I said, I want you to know that this is not good practice. I don't want this to continue. Don't let it happen again, and just don't do it. Those were my exact words. Just don't do it.

Tr. 955–56. According to Dr. Edmonds, although his tone at the outset of the meeting was “one of collegiality,” he stated that, “at the end, it was very stern in the tone.” Tr. 956.

Edmonds clarified that this directive, which applied to all controlled substances, was “mandatory” and not optional, and it was disseminated throughout the McLeod Medical staff by the HR manager and was subsequently reduced to writing in the McLeod Medical employee handbook. Tr. 363–64, 393–99, 956–57. Dr. Edmonds

¹⁸ At another point during the proceedings, NM Pharmacy Board Executive Director Larry Loring confirmed that all controlled substance scrips must bear a hard signature to be effective. Tr. 458–61.

¹⁹ Tr. 359.

²⁰ Tr. 392, 956.

further recalled that, at the time, he encouraged the Respondent to seek out the consultation of a pain and spine physician. Tr. 362.

Dr. Edmonds also testified that, about five months later, on July 21, 2011, he was notified that a random urinalysis sample collected from the Respondent two days earlier registered positive for an opiate. Tr. 364–66, 400. Edmonds recalled that on the day of the urinalysis, when the preliminary, in-office screen-test results indicated the presence of opiates, the Respondent approached him and said she felt she was “being singled out.” Tr. 971. Several days later, after receiving the lab confirmation that the Respondent had opiates in her system, Dr. Edmonds sought her out for an explanation. Tr. 963–64, 971. It was at that point (and not before) that the Respondent told Edmonds that she was receiving pain medication from a Dr. Pamela Black, a pain treatment specialist. Tr. 365, 391–92, 963–64, 971. When, in response to Edmonds’s request to see the prescription, the Respondent brought him a bottle of morphine with a prescription label dated July 25, 2011 (six days after the urinalysis sample was collected),²¹ Dr. Edmonds did not push the matter, extending what he euphemistically characterized as “professional courtesy.” Tr. 363–67, 400–01. He extended this courtesy, even in light of the fact that the portion of the form completed by the Respondent at the time she provided the urine sample that could have reflected that she was taking medications did not. Tr. 958, 964, 966–70. Thus, Dr. Edmonds knew that the Respondent could have indicated on the form that she was on controlled substances at the time she provided the sample, and could have told him that she was seeing Dr. Black when the in-office screen test popped positive (instead of indicating that she was being singled out), but did not avail herself of either opportunity.

Two months after the positive urinalysis result, Dr. Edmonds was informed by the McLeod HR manager that personnel at Walmart Pharmacy Edgewood had advised her that the Respondent had attempted to fill, and may have filled, multiple illegitimate narcotic medication prescriptions over PA Francis’s name and DEA COR number. Tr. 368–69. After a meeting with PA Francis and the HR manager where the three consulted a PMP report,²² Edmonds set about attempting

to contact officials at the local DEA office. A day or so later, Edmonds telephoned the Respondent at home. Tr. 369–70. In his testimony, Dr. Edmonds was clear that he asked the Respondent three questions: First, did she have a problem with drugs? Second, did she have an addiction problem? And, third, did she forge the prescriptions that Edmonds was inquiring about? Tr. 370, 959. According to Edmonds, the Respondent’s answer to the first two inquiries was “no,” but, regarding the forgery question, the Respondent replied that she only did that (forged prescriptions) twice. Tr. 370, 959. Edmonds recalled that the Respondent’s exact words were “I only did that twice.” Tr. 370, 408–09, 959. Although, in her hearing testimony, the Respondent indicated that she replied “twice” when asked how many times Francis prescribed controlled substances to her, Dr. Edmonds was clear, persuasive, and credible in relating his detailed recollection that he had no reason to ask the Respondent about the number of times Francis prescribed controlled substances to her, and that he did not ask that question. Tr. 959. Indeed, in the face of the six to eight scripts that Francis presented to Edmonds at that time as forged,²³ it would have made little sense for Edmonds to ask the Respondent such a question, and less sense for the Respondent (who claims that Francis was regularly and appropriately prescribing controlled substances to her) to answer “twice.” Additionally, to the extent that the Respondent believed that Dr. Edmonds’s meeting on employee-to-employee controlled substance prescribing yielded only optional guidance, the answer “twice” and even the question would have made little sense. In this regard, Dr. Edmonds’s recollection of events is more plausible and will be credited in this recommended decision.

Dr. Edmonds put the Respondent on administrative leave and placed two conditions on the Respondent’s continued employment at McLeod Medical. First, she was to enroll in the New Mexico Monitored Treatment Program (MTP), a drug treatment monitoring program designed to evaluate, treat, and monitor physicians and healthcare providers.²⁴ Second, the Respondent was required to “mend the relationship that she had broken with [PA] Francis.” Tr. 370, 409–11. According to Dr. Edmonds, he discussed these conditions both orally and in writing with the Respondent, and she

agreed to both. Tr. 371–72. It took a few weeks for the Respondent to affiliate with MTP,²⁵ but after she was in the program, MTP notified Edmonds that a treatment plan had been developed and that, at least in MTP’s view, she could return to a work environment. Tr. 372–73. Shortly thereafter, however, Dr. Edmonds terminated her based on his determination she was not sufficiently committed to repairing her professional relationship with PA Francis. In Dr. Edmonds’s words:

I fired [the Respondent] because she created a hostile work environment and eroded the trust between herself and her subordinate, Physician’s Assistant Raphaela Francis.

Tr. 962. According to Dr. Edmonds, the Respondent’s sole effort directed at relationship repair was an email she sent to Francis, wherein the former explained to the latter that she was sorry she chose her as her provider. Tr. 373–77, 414. Apparently, the tenor of the Respondent’s email was just not what Edmonds was looking for in the repair of a professional relationship torn atwain by one coworker forging another coworker’s name on controlled substance prescriptions, and, on October 24, 2011, approximately six weeks after she was placed on administrative leave, the Respondent was let go. Tr. 378–79, 415.

Dr. Edmonds is no longer associated with McLeod Medical. It is clear that he has no stake in the outcome of these proceedings, and his testimony presented as clear, certain, and unequivocal. In this case, the testimony presented by Dr. Edmonds, much of which was corroborated by other testimony in the record, was sufficiently objective, detailed, plausible, and internally consistent to be deemed fully credible in this recommended decision.

NM Pharmacy Board Executive Director (Exec. Dir.) Larry Loring also testified on behalf of the Government at the hearing. Loring testified that, prior to his appointment as the executive director, he had served for twenty-two years as a NM Pharmacy Board inspector. Tr. 440–41. As executive director, his responsibilities at the NM Pharmacy Board include the supervision of the Board’s administrative and inspector personnel, as well as the assignment of cases to the inspection staff. Tr. 430–31. Additionally, Exec. Dir. Loring testified that he has been in charge of the New Mexico Prescription Monitoring Program (PMP) since its inception in 2005 until last year, when he hired a

²¹ Dr. Edmonds could not recall whether the bottle label reflected an original prescription or a refill. Tr. 366.

²² Tr. 402.

²³ Tr. 369.

²⁴ Tr. 374–76, 388–90, 410.

²⁵ Tr. 378.

manager to administer the program. Tr. 431. Loring explained that the PMP is a computer database maintained by the NM Pharmacy Board that is the repository for information on all controlled substances dispensed in New Mexico. Tr. 432, 434. Information is inputted into the PMP exclusively by the pharmacies across the state. Tr. 433. The pharmacies bear a legal obligation to accurately report dispensing data to the PMP,²⁶ and, at the time of these events, could do so at upload increments of up to seven days. Tr. 433–34, 444–45.

Exec. Dir. Loring testified that he opened an investigation concerning the Respondent based on a phone call he received from PIC Alvis. Tr. 441, 450. When Alvis advised him that he believed he had identified a forged prescription made out on behalf of the Respondent, Loring ran a PMP report querying all controlled substance prescriptions issued by PA Francis where the Respondent is reflected as a patient for a two-year period commencing on October 12, 2010 (PMP/Marjenhoff Report),²⁷ and he used this report as a framework to contact pharmacies in furtherance of his investigation. Tr. 441–43, 447–48; Gov't Ex. 6. Exec. Dir. Loring testified that he went to each pharmacy listed on the PMP/Marjenhoff Report and obtained documents related to the transactions listed therein by supplying the prescription transaction numbers from the Report.²⁸ Tr. 443, 660; Gov't Ex. 8. According to Loring, he eventually turned over the documents he procured from the pharmacies to DEA DI Bencomo. Tr. 443, 661; Gov't Ex. 8.

On the issue of the PMP/Marjenhoff Report, Exec. Dir. Loring did not know why there was no indication of a controlled substance prescription dispensed at May Pharmacy on August 30, 2011 (the day May Pharmacy

partially dispensed the same medication the Respondent was seeking to procure from Walmart Pharmacy Edgewood on August 31, 2011).²⁹ Tr. 455–56, 465–66.

Exec. Dir. Loring presented as a thorough, impartial, methodical state regulator.³⁰ He has no stake in the outcome of the proceedings, and his testimony was sufficiently objective, detailed, plausible, and internally consistent to be fully credited in this recommended decision.

The Government also presented the testimony of its lead investigator in this matter, Diversion Investigator (DI) Randall Bencomo, a fifteen-year DEA investigator and retired Air Force veteran. Tr. 474. DI Bencomo testified that his contact with this case began with a referral from his supervisor to investigate the Respondent's COR application due to an affirmative response on an application liability question. Tr. 475–77, 632. During the course of his investigation, Bencomo learned that the Respondent had a history of disciplinary action with the Board of Medical Examiners of the State of Iowa (Iowa Medical Board). Tr. 475, 477–78. In August of 2011, DI Bencomo telephonically contacted the Iowa Medical Board and was referred to its Web site (*medicalboard.iowa.gov*) where he located, printed out, and supplied this tribunal with a document styled "Settlement Agreement and Final Order" (Iowa Board Order/Settlement Agreement or IBO/SA), which related to an administrative action regarding the Respondent's Iowa medical license, and a corresponding document entitled "Statement of Charges" (Iowa Board Charging Document or IBCD), which provides the charges resolved in the IBO/SA. Gov't Ex. 9; Tr. 484, 552–59, 619–22.

²⁹ However, it is worthy of note that the Prescriber Rx History Report (Gov't Ex. 6, at 2–12) of the PMP/Marjenhoff Report admitted into evidence only queried prescriptions issued by PA Francis, not those issued by Dr. Pamela Black, the pain specialist the Respondent indicated she was seeing for pain medication, the prescriber she mentioned to PA Francis during their February 14, 2011 appointment, and the prescriber she asked PIC Alvis about when they spoke on the phone regarding her insurance-rejected prescription. See Tr. 183, 221–22, 366, 652–53, 810, 819, 836–40, 924–28, 947–49, 964–66, 973.

³⁰ Notwithstanding the Government's curious assertion to the contrary (ALJ Ex. 59, at 11), Exec. Dir. Loring was never offered, qualified, or recognized as an expert in these proceedings. In fact, during the course of an extremely limited inquiry regarding whether particular scrip signatures were handwritten or machine generated, the Respondent's counsel decisively declined the opportunity to do so during the hearing, and made it clear that any mention of this witness as an expert "was just in jest." Tr. 706–07, 710; see also *id.* at 459, 703. There was simply nothing unclear about this aspect of the proceedings during the hearing or thereafter.

DI Bencomo also testified that, in the first full week of September 2011, during his investigation of the Respondent's application, he was contacted by and met with PA Francis. Tr. 478. According to DI Bencomo, Francis indicated that she wished to lodge a complaint against the Respondent for forging her name on controlled substance prescriptions. Tr. 478–80. When Francis and Bencomo met, the former brought the PMP report she generated with her and recounted her experience with the Respondent and her interaction with PIC Alvis. Tr. 478–80. Bencomo recalled that PA Francis explained the machinations Alvis was forced to invent to finally contact her at McLeod Medical. Tr. 480–81.

According to Bencomo, utilizing very much the same approach as Exec. Dir. Loring, he contacted the pharmacies set forth in the PMP/Marjenhoff Report and sought documentation that corresponded to the dispensed prescriptions that Francis described as forged. Tr. 481. Bencomo testified that, as he was interacting with the pharmacies listed on the PMP, he came to learn that Exec. Dir. Loring from the NM Pharmacy Board had been pursuing the same documents from the same establishments, and had been provided with original documents by the pharmacies. Tr. 481–82. Bencomo stated that the pharmacies provided him with copies because the originals had already been provided to Exec. Dir. Loring. Tr. 481, 500, 507. DI Bencomo testified that he subsequently contacted Loring and that the latter transferred the original documents he had procured from the pharmacies into Bencomo's custody. Tr. 482–84, 501, 627–29.

DI Bencomo testified that, about a week after he spoke with PA Francis, he also interviewed PIC Alvis at the Walmart Pharmacy Edgewood. Tr. 484–85. Bencomo recollected that details supplied by Alvis were consistent with the account provided by to him by PA Francis. Tr. 486.

Among the documents presented by Bencomo was a pair of identical controlled substance scrips that he obtained from two different pharmacies and that reflect that both pharmacies filled the single prescription. Tr. 499; Gov't Ex. 3. Also received into the record were two exhibits containing copies of the documents collected by Exec. Dir. Loring and DI Bencomo from the pharmacies listed in the PMP/Marjenhoff Report.³¹ Gov't Ex. 4; Gov't Ex. 8.

³¹ Although DI Bencomo testified that Government Exhibit 4 is an amalgam of copies of documents he received from Exec. Dir. Loring and

²⁶ Exec. Dir. Loring explained that a disclaimer placed at the bottom of each page of reports generated by the PMP alerts the reader that the accuracy of the data perforce depends on the accuracy of the input by the pharmacies, and is not independently confirmed by the NM Pharmacy Board. Tr. 435–36.

²⁷ Actually, the PMP/Marjenhoff Report introduced by the Government contains two reports generated from two distinct queries. The first query is a "Prescriber Rx History Report" wherein PA Francis's DEA COR number is queried and the prescriptions dispensed to the Respondent are culled out (Gov't Ex. 6, at 2–12), and the second is a "Patient Rx History Report" wherein the Respondent's name is queried for controlled substance medications dispensed on her behalf as the listed patient. *Id.* at 13–15.

²⁸ The Respondent's objection to the documents supplied to Exec. Dir. Loring by the pharmacies was sustained to the extent that notations on the documents that lacked an adequate foundation were excluded from consideration. Tr. 679–81.

DI Bencomo's testimony was certainly not without its warts. There were points where his testimony lacked clarity in describing the manner in which he procured and maintained important documentation. He initially testified that he obtained documentation from the Iowa Board by implementing a download from its Web site, but was unable to testify about who he spoke with at the Iowa Board, what they said, when the conversation took place, or the Web site address he was referred to. Tr. 553–54, 556–57. Similarly, DI Bencomo testified that he collected

documentation from several pharmacies regarding the Respondent's New Mexico prescriptions, but he was initially unable to tease out which documents were obtained by him and which were provided by Exec. Dir. Loring. Tr. 541–42. DI Bencomo was ultimately able to resolve numerous evidentiary issues, but only after being granted leave in the midst of his testimony to do so. Still, DI Bencomo, whose testimony was largely corroborated by other testimony and evidence, presented as an objective, experienced regulator who clearly has no stake in the outcome of the proceedings, and, taken as a whole, his testimony was sufficiently detailed, plausible, and internally consistent enough to merit full credibility here.

The Government's Documentary Evidence

The Government submitted documentary evidence in support of purported misconduct that took place in Iowa (Iowa Misconduct) and New Mexico (New Mexico Misconduct).

Iowa Misconduct Documents

The record contains an affidavit executed by the DEA's Chief of the Registration and Program Support Section, Richard A. Boyd, regarding the history of the Respondent's registration with the DEA (DEA Records Affidavit). Gov't Ex. 2. The DEA Records Affidavit states that the Respondent applied³² for a DEA COR on January 14, 2011, at the address of 1108 U.S. Route 66 W., P.O. Box 1520, Moriarty, New Mexico 87035, and that, on January 17, 2011, the DEA

directly from the pharmacies listed in the PMP/Marjenhoff Report (Tr. 531), as his testimony progressed, it became apparent as he was describing another noticed exhibit that he was not altogether confident as to which documents he collected from the pharmacies and which he received from Loring. See, e.g., Tr. 537–47. That said, Bencomo was consistent in testifying that every document in the exhibit came from one source or the other. To clarify the record, DI Bencomo brought the original documents provided by Exec. Dir. Loring to make them available for examination by the Respondent's counsel and this tribunal. Tr. 614, 627–31, 661–63; Gov't Ex. 8.

³² Gov't Ex. 1.

assigned the Respondent with a COR control number (W11002696C) while her application was pending. *Id.* at 1. The DEA Records Affidavit further provides that the Respondent provided an affirmative answer to the third liability question contained in the COR application, *to wit*: whether she had “ever surrendered (for cause) or had a state professional license or controlled substance registration, revoked, suspended, denied, restricted, or placed on probation, or is any such action pending?”³³ *Id.*

The DEA Records Affidavit also contains language provided by the Respondent in her COR application explaining her liability-question response regarding any prior adverse state license history.³⁴ *Id.* at 1–2. According to the language supplied by the Respondent³⁵ explaining the facts surrounding her Iowa license surrender:

Incident Date: 03/15/2000, Incident Location: Corydon, IA, Incident Nature: Patient was on long-term opioids for Antiphospholipid antibody syndrome. Had consults from hematology and pain clinic, who suggested above meds. After 1 yr on meds, unknown person sent complaint to Iowa Board of Medicine that patient was “addicted to the pain medicine[.]” IA Board did not inform DEA, as no investigation was needed. Incident Result: I voluntarily took CME course on prescribing controlled substances from Vanderbilt University.

Id.

The Government also introduced a copy of the Iowa Board Order/Settlement Agreement entered into by the Respondent and the Iowa Board in 2005, as well as the corresponding IBCD, which set forth the charges. Gov't Ex. 9. The IBO/SA cites the Respondent for “*inappropriately and repeatedly* prescribing controlled drugs to *numerous patients* in violation of the laws and rules governing the practice of medicine.” *Id.* at 2 (emphasis added). The IBO/SA reflects that the Respondent became licensed in Iowa on April 5, 2000, which would be the month following the incident date she provided in her application explanation.

³³ DI Bencomo testified that this affirmative answer and explanation was the likely genesis of the referral of the Respondent's application to a DI for in-depth examination. Tr. 476–77.

³⁴ During her testimony at the hearing, the Respondent attested to the veracity of this explanation and acknowledged that this information was supplied to DEA by her in connection with her application. Tr. 763–64, 937–39.

³⁵ DI Bencomo testified that this language was taken from the Respondent's COR application, which is the position that the Respondent's counsel took at the hearing, and is consistent with the Respondent's testimony. Tr. 636–37, 639, 643–46, 937–39.

Compare Gov't Ex. 9, at 1 ¶ 2 (memorializing that the Iowa Board and the Respondent agree that her state license was issued on April 5, 2000), with Gov't Ex. 2, at 1–2 ¶ 3 (noting that, in her COR application, the Respondent listed the Iowa Board license incident as March 15, 2000). Thus, even a cursory examination of the plain language of the two documents supports either two Iowa Board actions, only one of which is explained in the Respondent's COR application, or one Board action regarding which the Respondent supplied a puzzling date and a markedly incomplete/disingenuous explanation. Confusingly, in her brief, the Respondent clarified that Iowa administrative proceedings were initiated in March 2000 (which, if credited, would mean that proceedings to discipline her license commenced a month prior to the time she was even licensed in Iowa). ALJ Ex. 60, at 2. In their briefs, both parties are in apparent agreement that there was only one Iowa Board disciplinary action.³⁶ ALJ Ex. 59, at 29; ALJ Ex. 60, at 12.

The Iowa Board Charging Document³⁷ alleges that the Respondent violated Iowa's pain management rule, Iowa Admin. Code r. 653–13.2, which, *inter alia*, serves “to minimize the potential for substance abuse and drug diversion.” Iowa Admin. Code r. 653–13.2(1) (2013). At the DEA hearing, the Respondent adopted the IBO/SA as an accurate account of the events that occurred surrounding the incident, and official notice³⁸ was taken of the actions of the Iowa Board depicted in the IBO/SA and IBCD.³⁹ Tr. 625, 764–65.

New Mexico Misconduct Documents

According to the testimony of Exec. Dir. Loring, the investigation he conducted on behalf of the NM Pharmacy Board (and ultimately the Government's case here) is structured from the PMP/Marjenhoff Report he generated from his query on the New Mexico PMP. Tr. 441–43, 447–48; Gov't Ex. 6. The PMP/Marjenhoff Report reflects twelve (12) dispensing events on scrips purportedly authorized by PA Francis that resulted in controlled substances being issued to the Respondent, or members of her family on her behalf, during a two-year period

³⁶ Inasmuch as it is the Government who is the proponent of this evidence and the party that seeks to rely on the Iowa Misconduct to sustain the COR denial it seeks, it was incumbent upon the Government to provide a logical explanation.

³⁷ Gov't Ex. 9, at 10.

³⁸ See 5 U.S.C. 556(e).

³⁹ At the hearing of this matter, the Respondent was afforded until May 28, 2014 (over 30 days) to challenge the factual basis of this official notice and declined to do so.

commencing on October 12, 2010. Gov't Ex. 6. As discussed, *supra*, documents corresponding to the prescription transaction numbers on the PMP/Marjenhoff Report were independently procured from the relevant pharmacies by Exec. Dir. Loring and DI Bencomo. Gov't Ex. 4; Gov't Ex. 8. Exec. Dir. Loring turned over nine original prescription documents to DI Bencomo.⁴⁰ Tr. 687; Gov't Ex. 8. DI Bencomo's prescription documents, which appear to be a combination of Loring's documents supplemented with documents he procured independently of Loring,⁴¹ related to twelve transactions. Gov't Ex. 3; Gov't Ex. 4. Each of the twelve dispensing events referenced in the PMP/Marjenhoff Report and its significance is discussed below.

Dispensing Event 1: February 14, 2011

The PMP/Marjenhoff Report reflects that, on this date, a prescription, dated February 14, 2011 (same date) for Hydrocodone Bitartrate and Acetaminophen 10–500 mg⁴² and issued on behalf of the Respondent, was dispensed at the Walmart Pharmacy Edgewood.⁴³ Gov't Ex. 6, at 3, 14. A copy of a scrip and corresponding dispensing label procured from the Walmart Pharmacy Edgewood by DI Bencomo⁴⁴ shares the same transaction number (#4411974), “issue” date, medication/dosage description⁴⁵ issued

⁴⁰ Although Exec. Dir. Loring testified that he visited all pharmacies listed in the PMP/Marjenhoff Report and did not recall any of the pharmacies declining or being unable to comply with his documentary requests, he was unable to explain why he only turned over nine sets of prescription documents to DI Bencomo. Tr. 686–90.

⁴¹ DI Bencomo originally testified that his documents were copies collected from the pharmacies. Tr. 501–02. However, the notations on some of these documents are consistent with the notations made by Exec. Dir. Loring recording the location and date the scrips were picked up by him from the pharmacies. Tr. 664. In light of the fact that the Government presented other documents that were an amalgamation of the documents collected by DI Bencomo and Exec. Dir. Loring (Tr. 531), it is safe to assume that these prescriptions presented by DI Bencomo also include copies of documents obtained by Exec. Dir. Loring.

⁴² Hydrocodone Bitartrate and Acetaminophen 10–500 mg is a Schedule III controlled substance. Stip. 5; 21 CFR 1308.13(e)(1)(iv).

⁴³ According to a key included in the PMP/Marjenhoff Report, the pharmacy identification number associated with this dispensing event corresponds to the number assigned to the Walmart Pharmacy Edgewood. Gov't Ex. 6, at 11, 15.

⁴⁴ These documents were not among the documents procured by Exec. Dir. Loring. Tr. 689–90.

⁴⁵ The scrip reflects a prescription for Lortab 10–500 mg (Gov't Ex. 3, at 1), which is a brand name for Hydrocodone Bitartrate and Acetaminophen 10–500 mg. *Nursing97 Drug Handbook* 351 (1997). The dispensing label reflects a prescription for Hydro/ Apap 10–500 mg. Gov't Ex. 3, at 1. “Apap” is an

under PA Francis's COR number and purported signature, and patient (the Respondent) as this entry in the PMP/Marjenhoff Report. Gov't Ex. 3, at 1.

On the present record, it is undisputed that the Respondent validly received this scrip from PA Francis,⁴⁶ that it was faxed to the Walmart Pharmacy Edgewood where it was validly dispensed. According to the PMP/Marjenhoff Report, a 30-day supply of medication was dispensed. Gov't Ex. 6, at 3, 14.

Dispensing Event 2: February 16, 2011

The PMP/Marjenhoff Report reflects that, on this date, a prescription, dated February 14, 2011 for Hydrocodone Bitartrate and Acetaminophen 10–500 mg and issued on behalf of the Respondent, was dispensed at the Walgreens Pharmacy⁴⁷ in Edgewood, New Mexico (Walgreens Pharmacy). Gov't Ex. 6, at 3, 14. A copy of a scrip and corresponding dispensing label that was procured from the Walgreens Pharmacy by Exec. Dir. Loring shares the same transaction number (#369902), “issue” date, medication/dosage description under PA Francis's COR number and purported signature, and patient (the Respondent) as this entry in the PMP/Marjenhoff Report. Gov't Ex. 8, at 1; Gov't Ex. 3, at 2.

A comparison of the copy of the scrip presented during the course of this dispensing event to the scrip presented to the Walmart Pharmacy Edgewood in Dispensing Event 1 (two days before Dispensing Event 2) shows that the same scrip was presented in both transactions. *Compare* Gov't Ex. 8, at 1, and Gov't Ex. 3, at 2, with Gov't Ex. 3, at 1. PA Francis credibly testified that she prepared and personally handed the scrip to the Respondent. Tr. 188. But there was no indication that the scrip was authorized for multiple pharmacy presentations to procure multiple doses of the same medication. On its face, the scrip does not even purport to authorize refills. Gov't Ex. 3. PA Francis also credibly testified that this was the one and only controlled substance prescription that she issued on behalf of the Respondent. Tr. 185, 202.

This dispensing event resulted in the Respondent receiving a 30-day supply of the medication, notwithstanding the fact that only 2 days earlier she had received a 30-day supply of the same

abbreviation for Acetaminophen. *Nursing97 Drug Handbook* 315.

⁴⁶ Tr. 688–89.

⁴⁷ According to a key included in the PMP/Marjenhoff Report, the pharmacy identification number associated with this dispensing event corresponds to the number assigned to the Walgreens Pharmacy. Gov't Ex. 6, at 10, 15.

medication (Dispensing Event 1). Gov't Ex. 6, at 3, 4. Thus, by presenting the same scrip twice, over the course of 2 days, the Respondent acquired an aggregate amount of medication that should have lasted 60 days.

Dispensing Event 3: March 1, 2011

The PMP/Marjenhoff Report reflects that, on this date, a prescription, dated February 28, 2011 for Hydrocodone Bitartrate and Acetaminophen 10–500 mg and issued on behalf of the Respondent, was dispensed at May Pharmacy⁴⁸ in Moriarty, New Mexico (May Pharmacy). Gov't Ex. 6, at 3, 14. A copy of a scrip and corresponding dispensing label obtained from May Pharmacy by Exec. Dir. Loring shares the same transaction number (#9142353), “issue” date, medication/dosage description under PA Francis's COR number and purported signature, and patient (the Respondent) as the PMP/Marjenhoff report. Gov't Ex. 8, at 3; Gov't Ex. 4, at 1.

At the hearing, PA Francis testified that she neither signed this scrip nor authorized this prescription. Tr. 205–06, 261.

This dispensing event resulted in the Respondent receiving a 23-day supply of the medication, notwithstanding the fact that only 15 days earlier she had received a 30-day supply of the same medication (Dispensing Event 1), and 13 days earlier she had received yet another 30-day provision of the same medication (Dispensing Event 2). Gov't Ex. 6, at 3, 14. Thus, even by the terms of the scrips (one of which was presented twice and the other forged), over the course of the 15 days that elapsed from Dispensing Event 1, the Respondent had received an aggregate amount of medication that should have lasted 60 days (45 extra dosage days) before this prescription was filled.

Dispensing Event 4: March 11, 2011

The PMP/Marjenhoff Report reflects that, on this date, a prescription, dated March 11, 2011 (same date) for Hydrocodone Bitartrate and Acetaminophen 10–500 mg and issued on behalf of the Respondent, was dispensed at the Walgreens Pharmacy. Gov't Ex. 6, at 3, 14. DI Bencomo⁴⁹ procured a copy of a scrip⁵⁰ from the

⁴⁸ According to a key included in the PMP/Marjenhoff Report, the pharmacy identification number associated with this dispensing event corresponds to the number assigned to May Pharmacy. Gov't Ex. 6, at 7, 15.

⁴⁹ These documents were not among the documents procured by Exec. Dir. Loring. Tr. 689–90.

⁵⁰ As initially supplied by the Government, this document was illegible and excluded. Prior to the commencement of the hearing, the Government

Walgreens Pharmacy that shares the same "issue" date, medication/dosage description under PA Francis's COR number and purported signature, and patient (the Respondent) as this entry in the PMP/Marjenhoff Report. Gov't Ex. 4, at 2. This exhibit does not bear a corresponding dispensing label. *Id.* Upon examination, this scrip was also used to effect Dispensing Events 5 and 6. *Compare* Gov't Ex. 4 at 2, 2a, with Gov't Ex. 8, at 5, 7, and Gov't Ex. 4, at 4, 4a, 5.

At the hearing, PA Francis testified that she neither signed this scrip nor authorized this prescription. Tr. 205–06, 261.

This dispensing event resulted in the Respondent receiving a 15-day supply of the medication, notwithstanding the fact that only 25 days earlier she had received a 30-day supply of the same medication (Dispensing Event 1), 23 days earlier she had received yet another 30-day provision of the same medication (Dispensing Event 2), and 10 days earlier she had received a 23-day supply of the same medication (Dispensing Event 3). Gov't Ex. 6, at 3, 14. Thus, even by the terms of the scrips (some of which were presented on multiple occasions and some of which were forged), over the course of the 25 days that elapsed from Dispensing Event 1, the Respondent had received an aggregate amount of medication that should have lasted 83 days (58 extra dosage days) before this prescription was filled.

Dispensing Event 5: March 15, 2011

The PMP/Marjenhoff Report reflects that, on this date, a prescription, dated March 15, 2011 for Hydrocodone Bitartrate and Acetaminophen 10–500 mg and issued on behalf of the Respondent, was dispensed at the Walmart Pharmacy Edgewood. Gov't Ex. 6, at 3, 14. A physical copy of a document entitled "Telephonic Prescription," completed by hand, with an attached corresponding dispensing label, was procured by Exec. Dir. Loring from the Walmart Pharmacy Edgewood. Gov't Ex. 8, at 5; Gov't Ex. 4, at 3. Loring testified that, based on his over two-dozen years of experience, a pharmacist must (and it must be a pharmacist, not a technician) complete this type of form when a controlled substance prescription is telephoned into the pharmacy. Tr. 672–74, 704–05. Although the prescription must be taken by a pharmacist and reduced to writing at the pharmacy end, the prescriber can

supplied a copy that was sufficiently enhanced through magnification that its content could be somewhat better deciphered and considered.

have the prescription phoned in by an authorized administrative person. Tr. 704–05. In reviewing the documents associated with this transaction, Exec. Dir. Loring determined that the paperwork reflects that a controlled substance prescription was telephoned into Walmart Pharmacy Edgewood on March 15, 2011, that, the following day, it was followed up by a fax version of the scrip, and that the dispensing sticker indicates that the medication was processed for dispensing.⁵¹ Tr. 674–77.

The record also contains a hard-copy of a scrip, dated March 11, 2011, with a signature placed above PA Francis's name as the prescriber. Gov't Ex. 8, at 5; Gov't Ex. 4, at 4, 4a. The dispensing label affixed to the hard-copy scrip shares the same transaction number (#4412395), medication/dosage⁵² description issued under PA Francis's COR number and purported signature, and patient (the Respondent) as the entry in the PMP/Marjenhoff Report. Gov't Ex. 8, at 5; Gov't Ex. 4, at 4, 4a.

At the hearing, PA Francis testified that she neither signed this scrip nor authorized this prescription. Tr. 205–06, 261. Further, upon examination, it appears that the March 11 hard-copy scrip, utilized by facsimile to effect this dispensing event, is the same scrip utilized in Dispensing Events 4 (via facsimile) and 6 (via presentation of the original document).⁵³ A comparison of the copy of this scrip presented to the Walmart Pharmacy Edgewood to the copy of the scrip presented to the Walgreens Pharmacy (in connection to Dispensing Event 4) shows that the same document was presented to both pharmacies, and that the dispensing events were separated by four days. *Compare* Gov't Ex. 8, at 5, and Gov't Ex. 4, at 4, with Gov't Ex. 4, at 2.

Furthermore, this same scrip was presented to, and filled at, another Walmart Pharmacy in Albuquerque six days later (Dispensing Event 6). *Compare* Gov't Ex. 8, at 5, and Gov't Ex. 4, at 4, 4a, with Gov't Ex. 8, at 7, and Gov't Ex. 4, at 5.

This dispensing event resulted in the Respondent receiving a 15-day supply of the medication, notwithstanding the fact that only 29 days earlier she had

⁵¹ Exec. Dir. Loring testified that the presence of a dispensing sticker indicates that the medication was processed for dispensing, but not necessarily that it was dispensed. Tr. 676–77.

⁵² The telephonic and hard-copy scrip prescribe "Lortab," a brand name for Hydrocodone Bitartrate and Acetaminophen. *Nursing97 Drug Handbook* 351 (1997).

⁵³ Upon careful examination of the original documents during the hearing, Exec. Dir. Loring opined that the scrip utilized for Dispensing Event 5 was the same scrip utilized for Dispensing Event 6. Tr. 681–85.

received a 30-day supply of the same medication (Dispensing Event 1), 27 days earlier she had received another 30-day provision of the same medication (Dispensing Event 2), 14 days earlier she had received a 23-day supply of the same medication (Dispensing Event 3), and 4 days earlier she had received a 15-day supply of the same medication (Dispensing Event 4). Gov't Ex. 6, at 3, 14. As of the date of this dispensing event, although only 29 days had elapsed since the first scrip was filled (Dispensing Event 1), the Respondent had accumulated an aggregate amount of medication sufficient to last 98 days (69 extra dosage days) before this prescription was filled.

Dispensing Event 6: March 21, 2011

The PMP/Marjenhoff Report reflects that, on this date, a prescription, dated March 11, 2011 for Hydrocodone Bitartrate and Acetaminophen 10–500 mg and issued on behalf of the Respondent, was dispensed at the Walmart Pharmacy⁵⁴ in Albuquerque, New Mexico (Walmart Pharmacy Albuquerque). Gov't Ex. 6, at 3, 14. The copies of the scrip and corresponding dispensing label procured by Exec. Dir. Loring from the Walmart Pharmacy Albuquerque share the same transaction number (#4407701), "issue" date, medication/dosage description under PA Francis's COR number and purported signature, and patient (the Respondent) as this entry in the PMP/Marjenhoff Report. Gov't Ex. 8, at 7–8; Gov't Ex. 4, at 5–6. The scrip copy received into the record is not obscured by the security features that indicate photocopy or facsimile transmission. Gov't Ex. 8, at 7–8; Gov't Ex. 4, at 5–6.

At the hearing, PA Francis testified that she neither signed this scrip nor authorized this prescription. Tr. 205–06, 261. In the opinion of Exec. Dir. Loring, the signature on the scrip was manually signed (*i.e.*, not electronically generated). Tr. 706.

Upon examination, it appears that the scrip utilized to effect this dispensing event is the same scrip utilized via facsimile to consummate Dispensing Events 4 and 5. *Compare* Gov't Ex. 8, at 7–8, and Gov't Ex. 4, at 5–6, with Gov't Ex. 8, at 5, and Gov't Ex. 4, at 2, 2a, 4, 4a. Thus, this scrip, which bears the Respondent's name as the patient, was presented three times to three separate pharmacies to procure the controlled substances described therein.

⁵⁴ According to a key included in the PMP/Marjenhoff Report, the pharmacy identification number associated with this dispensing event corresponds to the number assigned to the Walmart Pharmacy Albuquerque. Gov't Ex. 6, at 12, 15.

This dispensing event resulted in the Respondent receiving a 15-day supply of the medication, notwithstanding the fact that only 20 days earlier she had received a 23-day supply of the same medication (Dispensing Event 3), 10 days earlier she had received a 15-day provision of the same medication (Dispensing Event 4), and 6 days earlier she had received a 15-day supply of the same medication (Dispensing Event 5). Gov't Ex. 6, at 3, 14. Thus, even by the terms of the scrips (some of which were presented on multiple occasions and most of which were forged), over the course of the 35 days that elapsed from the date of Dispensing Event 1 to this dispensing event, the Respondent had received an aggregate number of medication to last 113 days (78 extra dosage days) before this prescription was filled.

Dispensing Event 7: March 31, 2011

The PMP/Marjenhoff Report reflects that, on this date, a prescription, dated March 31, 2011 (same date) for Hydrocodone Bitartrate and Acetaminophen 10–500 mg and issued on behalf of the Respondent, was dispensed at May Pharmacy. Gov't Ex. 6, at 3, 14. Copies of a scrip⁵⁵ procured from May Pharmacy by Exec. Dir. Loring and its corresponding dispensing label share the same transaction number (#9145722), "issue" date, medication/dosage description under PA Francis's COR number and purported signature, and patient (the Respondent) as this entry in the PMP/Marjenhoff Report. Gov't Ex. 8, at 9–10; Gov't Ex. 4, at 7–8.

At the hearing, PA Francis testified that she neither signed this scrip nor authorized this prescription. Tr. 205–06, 261.

This dispensing event resulted in the Respondent receiving a 30-day supply of the medication, notwithstanding the fact that 10 days earlier she had received a 15-day supply of the same medication (Dispensing Event 6). Gov't Ex. 6, at 3, 14. Thus, even by the terms of the scrips (some of which were presented on multiple occasions and some of which were forged), over the course of the 45 days that elapsed from the date of Dispensing Event 1 to this dispensing event, the Respondent had received an aggregate number of medication to last 128 days (83 extra dosage days).

⁵⁵ As initially supplied by the Government, this document was illegible and excluded. Prior to the commencement of the hearing, the Government supplied a copy that was sufficiently enhanced through magnification that its content could be deciphered and considered.

Dispensing Event 8: April 6, 2011

The PMP/Marjenhoff Report reflects that, on this date, a prescription, dated April 6, 2011 (same date) for Hydrocodone Bitartrate and Acetaminophen 10–500 mg and issued on behalf of the Respondent, was dispensed at the Walmart Pharmacy Albuquerque. Gov't Ex. 6, at 3, 14. A copy of a scrip obtained by Exec. Dir. Loring from the Walmart Pharmacy Albuquerque and its corresponding dispensing label shares the same transaction number (#4407973), "issue" date, medication/dosage description under PA Francis's COR number and purported signature, and patient (the Respondent) as this entry in the PMP/Marjenhoff Report. Gov't Ex. 8, at 11–12; Gov't Ex. 4, at 9.

At the hearing, PA Francis testified that she neither signed this scrip nor authorized this prescription. Tr. 205–06, 261.

This dispensing event resulted in the Respondent receiving a 15-day supply of the medication, notwithstanding the fact that 6 days earlier she had received a 30-day supply of the same medication (Dispensing Event 7). Gov't Ex. 6, at 3, 14. Thus, even by the terms of the scrips (some of which were presented on multiple occasions and most of which were forged), over the course of the 51 days that elapsed from Dispensing Event 1, the Respondent had received an aggregate amount of medication that should have lasted 158 days (107 extra dosage days) before this prescription was filled.

Dispensing Event 9: July 9, 2011

The PMP/Marjenhoff Report reflects that, on this date, a prescription, dated July 8, 2011 for Hydrocodone Bitartrate and Acetaminophen 10–500 mg and issued on behalf of the Respondent, was dispensed at the Walmart Pharmacy Edgewood. Gov't Ex. 6, at 2, 13. A copy of a scrip, which was procured from the Walmart Pharmacy Edgewood by Exec. Dir. Loring, and corresponding dispensing label share the same transaction number (#4413861), "issue" date, medication⁵⁶/dosage description issued under PA Francis's COR number and purported signature, and patient (the Respondent) as this entry in the PMP/Marjenhoff Report. Gov't Ex. 8, at 13; Gov't Ex. 4, at 10.

At the hearing, PA Francis testified that she neither signed this scrip nor authorized this prescription. Tr. 205–06, 261.

⁵⁶ Lortab, which is reflected on the scrip, is a brand name for Hydrocodone Bitartrate and Acetaminophen 10–500 mg. *Nursing97 Drug Handbook* 351 (1997).

This dispensing event resulted in the Respondent receiving a 30-day supply of the medication. Gov't Ex. 6, at 2, 13. Thus, even by the terms of the scrips (some of which were presented on multiple occasions and most of which were forged), over the course of the 145 days that elapsed from Dispensing Event 1, the Respondent had received an aggregate amount of medication that should have lasted 173 days (28 extra dosage days) before this prescription was filled.

Dispensing Event 10: August 4, 2011

The PMP/Marjenhoff Report reflects that, on this date, a prescription, dated August 4, 2011 (same date) for Hydrocodone Bitartrate and Acetaminophen 10–325 mg and issued on behalf of the Respondent, was dispensed at May Pharmacy. Gov't Ex. 6, at 2, 13. A copy of a scrip and corresponding dispensing label acquired by Exec. Dir. Loring from May Pharmacy shares the same transaction number (#9157693), "issue" date, medication⁵⁷/dosage description issued under PA Francis's COR number and purported signature, and patient (the Respondent) as this entry in the PMP/Marjenhoff Report. Gov't Ex. 8, at 15; Gov't Ex. 4, at 11.

At the hearing, PA Francis testified that she neither signed this scrip nor authorized this prescription. Tr. 205–06, 261.

This dispensing event resulted in the Respondent receiving a 23-day supply of the medication, notwithstanding the fact that 26 days earlier she had received a 30-day supply of the same medication (Dispensing Event 9). Gov't Ex. 6, at 2, 13. Thus, even by the terms of the scrips (some of which were presented on multiple occasions and most of which were forged), over the course of the 171 days that elapsed from Dispensing Event 1, the Respondent had received an aggregate amount of medication that should have lasted 203 days (32 extra dosage days) before this prescription was filled.

Dispensing Event 11: August 9, 2011

The PMP/Marjenhoff Report reflects that, on this date, a prescription, dated August 9, 2011 (same date) for Hydrocodone/Apap 10–325 mg and issued on behalf of the Respondent, was dispensed at the Walgreens Pharmacy. Gov't Ex. 6, at 2, 13. A copy of a scrip DI Bencomo⁵⁸ procured from Walgreens Pharmacy shares the same "issue" date,

⁵⁷ The scrip describes the medication as hydrocodone-acetaminophen. Gov't Ex. 8, at 15.

⁵⁸ These documents were not among the documents procured by Exec. Dir. Loring. Tr. 687.

medication/dosage description under PA Francis's COR number and purported signature, and patient (the Respondent). Gov't Ex. 4, at 12. No dispensing label is attached to this document. *Id.*

At the hearing, PA Francis testified that she neither signed this scrip nor authorized this prescription. Tr. 205–06, 261.

This dispensing event resulted in the Respondent receiving a 22-day supply of the medication, notwithstanding the fact that 5 days earlier she had received a 23-day supply of the same medication (Dispensing Event 10). Gov't Ex. 6, at 2. Thus, even by the terms of the scrips (some of which were presented on multiple occasions and most of which were forged), over the course of the 176 days that elapsed from Dispensing Event 1, the Respondent had received an aggregate amount of medication that should have lasted 226 days (50 extra dosage days) before this prescription was filled.

Dispensing Event 12: September 10, 2011

The PMP/Marjenhoff Report reflects that, on this date, a prescription, dated September 10, 2011 (same date) for Hydrocodone Bitartrate and Acetaminophen 10–325 mg and issued on behalf of the Respondent, was dispensed at CVS Pharmacy⁵⁹ in Albuquerque, New Mexico (CVS Pharmacy). Gov't Ex. 6, at 2, 13. A copy of a scrip procured by Exec. Dir. Loring from CVS Pharmacy reflects that the same prescription was purportedly issued under PA Francis's COR number and purported signature on September 8, 2011 (2 days prior to the "issue" date reflected in the PMP/Marjenhoff Report).⁶⁰ Gov't Ex. 8, at 17–18; Gov't Ex. 4, at 13–14. A corresponding dispensing label attached to the scrip, bearing the same transaction number as the entry in the PMP/Marjenhoff Report (#0354748), reflects a September 10, 2011 "issue" date, which is consistent with the PMP, but inconsistent with the date on the scrip. *Compare* Gov't Ex. 8,

⁵⁹ According to a key included in the PMP/Marjenhoff Report, the pharmacy identification number associated with this dispensing event corresponds to the number assigned to the CVS Pharmacy. Gov't Ex. 6, at 11, 15.

⁶⁰ This anomaly remains unexplained by any Government witness, but likewise received no attention from the Respondent. In light of the other data in the scrip and dispensing label, which correspond to the data on the PMP/Marjenhoff Report, this discrepancy does not undermine the weight afforded to the exhibit. Still, it would have been helpful for the Government, as the proponent of the exhibit to explain this aspect of the document.

at 17–18, *and* Gov't Ex. 4, at 13–14, *with* Gov't Ex. 6, at 2, 13.

At the hearing, PA Francis testified that she neither signed this scrip nor authorized this prescription. Tr. 205–06, 261. Exec. Dir. Loring testified that, in his opinion, the signature on the scrip was handwritten (*i.e.*, not computer generated). Tr. 711.

This dispensing event resulted in a 23-day supply of the medication. Gov't Ex. 6, at 2, 13. Thus, even by the terms of the scrips (some of which were presented on multiple occasions and most of which were forged), over the course of the 208 days that elapsed from Dispensing Event 1, the Respondent had received an aggregate amount of medication that should have lasted 248 days (40 extra dosage days)⁶¹ before this prescription was filled.⁶²

The Respondent's Evidence

The Respondent's case-in-chief was presented through her own testimony and the testimony of her former medical assistant at McLeod Medical, Malana Diminovich.

Malana Diminovich testified that she has been a certified medical assistant for eleven years, and currently works at the ABQ Health Partners (ABQ) in Albuquerque, New Mexico. Tr. 719–20. Prior to beginning her current position at ABQ, Ms. Diminovich worked as a medical assistant at McLeod Medical for approximately five years, and left when the McLeod Medical HR manager accused her of forgery. Tr. 720–21, 739. Diminovich explained that she worked as the Respondent's medical assistant and that, during the Respondent's tenure at McLeod Medical, there were approximately six providers, each one of whom generally had two assigned medical assistants. Tr. 721, 739. Ms. Diminovich explained that she worked towards the back of the office in a space she shared with the HR manager, PA Francis, and the Respondent. Tr. 721–22. Diminovich testified that she observed some level of tension between the Respondent and the HR manager,

⁶¹ It is worth noting that these amounts do not include whatever controlled substance medication the Respondent was receiving through prescriptions issued by Dr. Black and/or members of Dr. Black's staff.

⁶² The Respondent's argument that "the spacing of prescriptions follows a pattern one would expect to see if a professional was prescribing a controlled substance for a medical reason" (ALJ Ex. 60, at 11) is completely bereft of any competent opinion of record to support it. No expert testified about the type or quantities of medication that could be appropriate here. On this record, the only comparison that can competently be examined is the dosages of medication set forth on forged, illegitimate scrips, and the Respondent regularly exceeded even those fictitious levels.

PA Francis, and Dr. Edmonds. Tr. 741–42.

Ms. Diminovich stated that, when they worked together, she knew the Respondent's medical record system passcode and that she had sufficient computer access with that passcode to print out a prescription for controlled substances under the Respondent's name. Tr. 727. She testified that the scrips would then be printed out on blue (security-feature) paper by a printer located in Dr. Edmonds's office towards the front of the building. Tr. 724–26. Diminovich believed that Dr. Edmonds and PA Francis handled most of the patients requiring narcotics prescriptions,⁶³ but on those occasions when the Respondent would need to issue a controlled substance prescription, Ms. Diminovich would log into the computer system, select the Respondent's name as the provider, print out the prescription, and then present it to Dr. Edmonds for his signature. Tr. 730–31.

Diminovich testified that she was aware that PA Francis was prescribing pain medication for the Respondent, and testified that she even remembered being in the room at times when Francis prepared the scrips. Tr. 732–33. She explained that she would see PA Francis write out a prescription and then either hand it to the Respondent or leave it on her desk. Tr. 732. Diminovich even remembered "an occasional time" when, at Francis's direction, she called prescriptions into pharmacies for the Respondent. Tr. 733.

Ms. Diminovich testified that she has been trained as an emergency medical technician (EMT) and that she received training on how to detect when an individual is under the influence of medication. Tr. 735–36. Applying her training as a volunteer EMT to her observations of the Respondent, Diminovich testified that she had no reason to believe that the Respondent was under the influence of narcotics or inappropriately seeking medication. Tr. 733–38.

There are several aspects of Ms. Diminovich's testimony that tend to somewhat diminish the extent to which it can and should be relied upon. Although the witness testified that she observed "animosity" between the Respondent and Dr. Edmonds, PA Francis, and the McLeod Medical HR manager, this testimony is not consistent with other credible evidence of record. Francis and Edmonds both described their working relationship

⁶³ Tr. 728–29.

with the Respondent as “good,”⁶⁴ and the Respondent described Dr. Edmonds as “a very kind man” and “very polite and professional.” Tr. 825–26. Additionally, the fact that the Respondent chose PA Francis to be her principal medical provider⁶⁵ when there were other choices in the office, including the “very kind” Dr. Edmonds,⁶⁶ tends to undermine any claim of tension between Francis and the Respondent. Furthermore, Diminovich never indicates whether the animosity she perceived predated or postdated the discovery at McLeod that the Respondent was the beneficiary of about a dozen forged controlled substance prescriptions on office scrip stationary. The testimony regarding office tension is vague and not entirely consistent with reliable record evidence.

Similarly, there are issues regarding Diminovich’s testimony that, based on her training as an EMT, she is able to competently conclude that the Respondent was never observed to be under the influence of controlled substances during the time the two worked together at McLeod Medical. Tr. 733–34. Diminovich testified to having received some EMT training related to recognizing individuals under the influence of controlled substances. Tr. 735–37. Even if her competence in this area were to be conceded, *arguendo*, it conflicts with the Respondent’s own testimony that she was receiving and (presumably) taking controlled substances from PA Francis, Dr. Black, and one of Dr. Black’s associates during this time, as well as the Respondent’s opiate-positive random urinalysis result. Tr. 364–66, 392, 400. Even the Respondent does not contest the fact that during this time she was taking controlled medications. Tr. 802–03, 810–11, 820–23, 838–39, 907–08, 914, 926. Diminovich’s testimony in this regard even stands at some odds with her own testimony that she was aware that the Respondent was receiving controlled substance prescriptions from PA Francis. Tr. 732–33. If Ms. Diminovich’s expertise to divine controlled substance use by patients is assumed at face value, and the Respondent’s posture that she validly received controlled substances from PA Francis and Dr. Black’s office is credited, it raises the issue of where the controlled substances she did receive were going. Put simply, either the Respondent was taking the prescribed medication and Diminovich (not withstanding her purported expertise)

was unable to accurately perceive that, or Diminovich was correct, the Respondent had no opiates in her system, and the medication was being diverted for another purpose. A third (more likely) alternative is that Ms. Diminovich has no idea whether there were controlled substances in the Respondent’s system, and that she testified in this manner in an effort to help the Respondent defend herself in these proceedings. To the extent that Ms. Diminovich’s testimony was offered to establish that the Respondent never appeared to slur her words, sway in her gait, or in other ways appear over-medicated, this issue was never alleged by the Government or raised by the evidence.

Additionally, much of Ms. Diminovich’s testimony was too vague and lacking in detail to stand up against other record evidence. She said she saw PA Francis prescribe controlled substances to the Respondent and hand the scrips over, but never says when or how often, and does not provide details about a single such event she recalls. In a similar vein, she says there was animosity, but never provides any timeframe, specific conversations, incidents, or areas of contention. She says that the Respondent did not seem like she was under the influence of medication but disregards the fact that, by every bit of uncontested evidence, the Respondent was receiving powerful controlled medications in significant doses. Additionally, by virtue of the fact that, like the Respondent (by whom she was supervised, and apparently amicably so), Ms. Diminovich left McLeod Medical in the midst of allegations of forgery leveled against her, it would be difficult to view her as a completely impartial witness regarding similar allegations related to her former supervisor during the time when they worked together. Tr. 739. In short, Ms. Diminovich’s testimony was lacking in detail, inconsistent with other credible record evidence, and not entirely objective or plausible. While there were certainly credible aspects of her testimony, it must be viewed skeptically to the extent it conflicts with other, more credible record evidence.

The Respondent also testified as a part of her case-in-chief, and, during the course of her testimony, she listed a long and commendable professional history of varied experience in the medical profession, hospital administration, and academia. She explained that she is a licensed doctor of osteopathic medicine (D.O.), and that she is currently employed by the Indian Health Service (IHS) at its Crownpoint, New Mexico facility. Tr. 748–49, 752.

Additionally, the Respondent stated that she is also the medical director at Corrections Corporation of America (CCA) in Estancia, New Mexico. Tr. 749.

The Respondent testified that she received her Bachelor of Arts degree in biology and science in 1983 from St. Thomas University in Miami and, in 1987, was awarded her medical degree from Nova Southeastern University, College of Osteopathic Medicine, in Fort Lauderdale. Tr. 750–51. According to the Respondent, she commenced her medical career as a rural health practitioner in Tennessee,⁶⁷ and eventually transitioned to solo practices in Indiana and then in Corydon, Iowa. Tr. 753–56. The Respondent related that before leaving Indiana for Iowa in 2000, she was involved in a severe automobile accident,⁶⁸ wherein she suffered multiple neck and femur fractures. Tr. 754–55. The Respondent testified that, as a result of the car accident, she was the beneficiary of eight reconstructive surgeries and was unable to work for a year. Tr. 754–55.

The Respondent testified that once she had recovered sufficiently to return to work, she spent four to five years practicing in Corydon, Iowa. Tr. 755–56. Because of restrictions placed on her license by the Iowa Medical Board,⁶⁹ and reckoning that she “was fed up with medicine,”⁷⁰ the Respondent testified that she temporarily left the practice of medicine and took a position as a billing and coding specialist at a hospital in Ganado, Arizona. Tr. 756–58, 764. The Respondent’s professional odyssey next took her to Albuquerque, New Mexico, where, prior to her association with McLeod Medical, she joined the faculty of Brookline College as the Dean of Allied Health, a position with both administrative and teaching responsibilities.⁷¹ Tr. 757, 759.

The Respondent explained that the restrictions put upon her by the Iowa Medical Board were the result of a settlement agreement she entered into with the Board, which placed her state medical license on probation while she completed several requirements. Tr. 763–65; Gov’t Ex. 9. These requirements included a monetary fine, a series of continuing education courses, and monitoring by a preceptor doctor. Tr. 765. The Respondent testified that she

⁶⁷ Tr. 752.

⁶⁸ The Respondent testified that the accident occurred while she was driving to attend to a patient who was in labor. Tr. 754.

⁶⁹ See Gov’t Ex. 9.

⁷⁰ Tr. 757.

⁷¹ The Respondent testified that she taught courses in coding and billing at times when the college did not have a professor to teach those course offerings. Tr. 759.

⁶⁴ Tr. 219, 359.

⁶⁵ Tr. 805.

⁶⁶ Tr. 825.

fulfilled her obligations, completed a course on issues associated with prescribing controlled substances,⁷² and worked (part-time and without compensation) under the supervision of a preceptor-physician⁷³ (“to keep [her] skills up”⁷⁴) at an IHS facility while she was working in Ganado. Tr. 766–70. When she began working at Brookline College, the Respondent applied for her state license to practice medicine in New Mexico. Tr. 770–71. In November 2010, one month after the Iowa Medical Board discharged her from her probation,⁷⁵ and upon receiving her New Mexico D.O. license,⁷⁶ the Respondent went to work at McLeod Medical, a position she held for approximately one year before she was fired. Tr. 760, 770–71.

At the time when she was hired at McLeod Medical, the Respondent no longer had a DEA COR (a previous COR having expired during the time she was “fed up with medicine”⁷⁷), and McLeod Medical paid her COR application fee. Tr. 771–73. According to the Respondent, because she could not prescribe controlled substances without a COR, the staff at McLeod attempted to give her only patients that would not likely require prescriptions for controlled substances. Tr. 773–74. By the Respondent’s recollection, when she worked at McLeod Medical, Dr. Edmonds and PA Francis bore the bulk of the practice’s pain management patients. Tr. 773–75. On occasions, however, where one of her patients required such medication, the Respondent would write a prescription for controlled substances, and either Dr. Edmonds or PA Francis would authorize the prescription. Tr. 775–76. The Respondent testified that, on such occasions, she would write a note on a piece of paper and then hand it to her medical assistant, Ms. Diminovich. Tr. 788. Diminovich, who knew the Respondent’s system passcode, would then log onto one of the office computers (sometimes the Respondent’s

computer) and, using the Respondent’s passcode, generate the e-scrip. Tr. 785–86, 788, 796. At one point during her testimony, the Respondent indicated that Ms. Diminovich generated the scrips,⁷⁸ and, at another point, she indicated that the scrips would be printed out by Dr. Edmonds or PA Francis. Tr. 788. In both versions of the Respondent’s account of things, irrespective of who did the actual printing, the scrip would be signed by Francis⁷⁹ or Edmonds. Tr. 788–89. The Respondent described McLeod Medical as a large office, with as many as thirteen to fourteen staff employees working there during the weekdays. Tr. 777, 782. She worked toward the rear of the office in an eight-by-ten foot area along with PA Francis and the HR manager. Tr. 777, 779. Dr. Edmonds’s office and the reception area were situated in the front half of the office. Tr. 780. The Respondent said she worked full days at McLeod Medical from Monday through Thursday and a shorter day on Fridays. Tr. 782–83. The Respondent testified that, on Friday afternoons, she worked at the prison in Estancia. Tr. 783. PA Francis would typically arrive and leave an hour earlier than the Respondent, and Dr. Edmonds shared similar hours to the Respondent, with different days off. *Id.*

The Respondent indicated that, contrary to McLeod Medical IT policy, she remained logged onto her computer with her password for an entire day “a few times.” Tr. 789–90. When pressed on how frequently this occurred, the “few times” morphed into “maybe once a week” and, ultimately, to a clarification where she insisted that she had testified to “one or two times a week.” Tr. 790, 792. In any event, it seems that the office IT policy regarding password integrity was not strictly enforced, and that the computer on the Respondent’s cubicle⁸⁰ likely remained for lengthy periods in a signed-in posture several times a week. Inasmuch as the Respondent testified that she regularly tasked Ms. Diminovich with the preparation of scrips and securing the required provider authorization, it is more likely than not that the extended sign-in periods were not “mistake[s],”⁸¹ as she had presented, but, rather, done by design borne of convenience. The medical software in use at the time at

McLeod did not extend medical assistants, such as Ms. Diminovich, the privilege of preparing controlled substance e-scrips.⁸² By leaving the Respondent’s computer logged on with the Respondent’s password, it allowed the Respondent to regularly task Diminovich with preparing e-scrips from the “piece of paper in front of the chart”⁸³ to be presented for signature by Francis or Edmonds. The Respondent stated as much at another point in her testimony, where she agreed that Ms. Diminovich would sit at her desk and access the computer where the Respondent remained signed in. Tr. 796–97. The Respondent indicated that she “never got into the controlled substance part [of the medical software program] because, you know, I never had a need for it. I was always asking people to do it for me.” Tr. 797. However, when asked why Diminovich would be using the Respondent’s computer instead of her own or one of the other computers in the office, the Respondent unconvincingly offered that it was “[b]ecause the medical assistants’ computers were like way down the hall, and if we were in a hurry and we were down in the corner there.” Tr. 797. The Respondent further described Diminovich’s computer as being “at the nurse’s station which was . . . a long way down the hall and very inconvenient.” Tr. 799. This becomes even more confusing in view of the fact that, because the Respondent testified that her cubicle was in the rear of the office,⁸⁴ the nurse’s station would have to have been closer to the exam rooms where the patients were seen, and that each exam room had its own computer that Diminovich presumably could have used. Tr. 800. In light of the working dynamic that the Respondent had developed with Diminovich, attributing this practice of allowing Diminovich to use her computer while she remained signed in to a “mistake” that occurred “a few times”⁸⁵ is simply not plausible, and the Respondent ultimately conceded as much. Tr. 798–99. Once the point was conceded, the Respondent stated that “if I wanted [Diminovich] to write a—you know, she could also sign under her password at my computer and write out prescriptions, too.” Tr. 798. But inasmuch as Diminovich’s password did not authorize the preparation of controlled substance prescriptions, this answer is a bit confusing. The equivocation by the Respondent on this otherwise relatively

⁷² The Respondent testified that she took a course entitled “Prescribing Controlled Substance Pitfalls,” and, subsequently, she has completed 160 hours of pain management training. Tr. 769. The coursework was in compliance of the terms of the IBO/SA. Tr. 770.

⁷³ The Respondent indicated that practicing with at preceptor was a condition placed upon her by the Iowa Medical Board in the IBO/SA. Tr. 758; Gov’t Ex. 9, at 4.

⁷⁴ Tr. 768.

⁷⁵ Tr. 770.

⁷⁶ The Respondent explained that “[a]nytime there’s a doctor who’s had any kind of sanctions or anything, it takes a little bit longer to get a [state medical] license, so that’s what I was doing, working as a dean in the process of getting my New Mexico license.” Tr. 771.

⁷⁷ Tr. 757.

⁷⁸ Tr. 785.

⁷⁹ The Respondent testified that because she and Dr. Edmonds had opposite days off and that, because of her close physical proximity in the office to PA Francis, her controlled substance scrips were more often authorized by Francis than by Edmonds. Tr. 788–89.

⁸⁰ Tr. 794–96.

⁸¹ Tr. 789.

⁸² Tr. 421.

⁸³ Tr. 788.

⁸⁴ Tr. 777.

⁸⁵ Tr. 789.

unimportant point regarding this arguably benign business practice borne of convenience says less about the merits of the Respondent's case than it does about her overall credibility.

The Respondent acknowledged that, on February 14, 2011, she asked to be placed on PA Francis's patient schedule.⁸⁶ Tr. 801–02, 813. The Respondent testified that while she did not relish the idea of being treated by a colleague in the same office,⁸⁷ in order to take advantage of the healthcare insurance provided by McLeod Medical, all employees were required to use McLeod Medical as their primary provider. Tr. 801–02. PA Francis agreed to see the Respondent and, after Francis's assigned medical assistant (Leilani) took a medical history, the Respondent testified that PA Francis asked some questions and conducted a brief examination. Tr. 802. By the Respondent's account, she explained to Francis that she needed a refill on a year's supply of thyroid medication, blood pressure medication, and Cymbalta (a non-controlled medication) for what she described as "chronic pain."⁸⁸ Tr. 802–03, 806, 810. The Respondent testified that she also explained to Francis that she had attempted to make an appointment with a pain specialist, Dr. Pamela Black, for chronic pain in her neck, but that the appointment would "be months down the line." Tr. 810. Although the Respondent testified that she could not get in to see Dr. Black for *months*, Francis recalled that the Respondent said it would be several *weeks* and that, on the day of her appointment, the Respondent only sought a one-month supply of medication. Tr. 175. The Respondent remembered telling Francis that "well you know, I am under so much stress here, and I'm working so many hours, my neck is just killing me and I can't function. And in the past, you know, hydrocodone has worked, and could you write me a scrip for that[?]" Tr. 810. According to the Respondent, PA Francis said "no problem," and wrote prescriptions for

all of the medications she had requested. Tr. 810.

During her testimony, the Respondent provided some details about her efforts to establish herself as a patient at Dr. Black's pain management practice and the difficulties she perceived in getting seen personally by Dr. Black. Tr. 808, 810, 820, 925. The Respondent testified that she contacted Dr. Black's office in July 2011⁸⁹ to set up an appointment and that she was told to provide the office with x-rays, MRIs, and other medical records. Tr. 924–25. Then, in either July or August of that year, she met with a physician's assistant in Black's office, who prescribed her morphine.⁹⁰ Tr. 925–26. It would not be until a month later (August 2011), according to the Respondent, that she would have her first face-to-face visit with Dr. Black, at which point she received another controlled substance prescription. Tr. 926–27.

While Francis's account of her treatment relationship was restricted to the single, February 14, 2011 encounter and another where she administered an anti-nausea injection in the office,⁹¹ the Respondent's recollection was quite different. According to the Respondent, PA Francis became her primary care provider, and she saw her "periodically for refills on [her] medications," "off and on for neck pain [and] trigger-point injections," as well as on an occasion where Francis administered an intravenous medication for dehydration caused by a virus. Tr. 811–14, 818. Also contrary to Francis's testimony (but consistent with Diminovich's testimony), the Respondent indicated that she "periodically" would ask (and

presumably receive) hydrocodone prescriptions from PA Francis. Tr. 820. The Respondent described the interaction in this way:

I would ask [PA Francis], I said, I just need—can you refill my hydrocodone and write me another prescription or whatever. And she said, Sure. And, you know, at that point, I would go on in and see another patient. And like I said, she left an hour ahead of me, so the majority of the time, it would be on my desk or I would—you know, she would ask [Ms. Diminovich]. She said, Can you print it out or whatever, and then I'll sign it.

Tr. 821. In addition to being inconsistent with PA Francis's testimony, this version of events also relies on Ms. Diminovich's ability to access a computer that can print out controlled substance prescriptions, a functionality not available to her without the Respondent intentionally permitting her access to the office medical software signed in as a practitioner. In view of the Respondent's testimony that she had others prepare controlled substance scrips for her, it would seem unlikely that, even if the Respondent's version were credited, the Respondent was not fully aware that Ms. Diminovich was regularly accessing the office software using the Respondent's credentials.

In an additional recollection that exceeded not only Francis's, but even Diminovich's, the Respondent also testified that sometimes Francis authorized Diminovich to administer injections of Toradol.⁹² Tr. 819. According to the Respondent, when she would ask PA Francis "can you give me a shot of Toradol . . . she'd say, Malana, get her some." Tr. 819.

Regarding the ill-fated phone call where the Respondent called out sick and subsequently met with Dr. Edmonds and PA Francis about employee-to-employee narcotics prescribing, the Respondent categorically denied ever telling anyone at McLeod Medical that she suffered a reaction to the hydrocodone prescribed by Francis on February 14, 2011. By the Respondent's account, she called in sick due to a headache or virus. Tr. 823. In the Respondent's words, "I mean, I didn't think I'd have an adverse reaction to something I'd been on before." Tr. 823. The Respondent offered no explanation as to why the headache or virus would precipitate a meeting about the evils of controlled substance prescribing between employees, or any possible motivation for Francis to falsely attribute her illness to a medication reaction. The Respondent acknowledged that such a meeting did

⁸⁶ Although Francis was a physician's assistant at McLeod Medical, and Dr. Edmonds was a D.O. and, in her words, "a very kind man" (Tr. 825), the Respondent testified that she chose to establish with Francis because she "was not comfortable seeing Dr. Edmonds as a provider, as my provider." Tr. 805.

⁸⁷ Tr. 802.

⁸⁸ The Respondent testified that she was not aware of any legal impediment that would have prevented her from prescribing these non-controlled substances to herself, but indicated that she did not do so because she had "always been taught it was unethical, so [she] never did it." Tr. 804.

⁸⁹ This represents a significant departure from her representation to PA Francis during her February 14, 2011 appointment that she was already in contact with Dr. Black's office.

⁹⁰ Interestingly, the Patient Rx History Report portion of the PMP/Marjehoff Report only lists two prescribers, "FRA RA92" (PA Francis) and "BLA PA76." Gov't Ex. 6, at 14. Although this portion of the report, including the second prescriber's name, is redacted, the Respondent's version of events would seem to dictate that the report would reflect the presence of a third prescriber—which it does not. This also reflects on that portion of the Respondent's brief which points to the absence of any August 30, 2011 entry regarding a dispensing event from May Pharmacy. ALJ Ex. 60, at 5. The PMP/Marjehoff Report only represents a query for prescriptions authorized by PA Francis (FRA RA92), with entries regarding the only other prescriber (BLA PA76) redacted. Gov't Ex. 6, at 14. While it is beyond argument that the record would have benefited from additional, competent testimony regarding the PMP/Marjehoff Report, notwithstanding the Respondent's protestation to the contrary, the absence of an entry concerning the August 30th prescription that was partially dispensed by May Pharmacy (Tr. 393), at least on the present record, does not undermine the strength of the Government's case.

⁹¹ Tr. 202, 240–44.

⁹² Toradol is not a controlled substance.

take place, but, contrary to the testimony of Edmonds and Francis, the Respondent characterized the tenor of the meeting as “very casual” and insisted that “[t]here was no policy made.” Tr. 824–25.

The Respondent testified that she saw PA Francis as her primary care provider approximately four to five times.⁹³ Tr. 819. She testified that she received refills of medication, trigger point injections of Novocain, treatment for dehydration, and MRIs and x-rays to be provided to Dr. Black. Tr. 811, 813–15, 818–20. The Respondent indicated that on those occasions when she asked for more hydrocodone prescriptions, PA Francis would leave a completed prescription on the Respondent’s desk, or she would ask MA Diminovich to print it out for her. Tr. 820–22. At one point during her testimony, the Respondent stated that she received seven to eight prescriptions for controlled substances from PA Francis, and, at another point, she testified that the number could have been ten. Tr. 899. She also admitted, at first, that she received all ten prescriptions listed on the PMP/Marjenhoff Report as being dispensed from February 28, 2011 and onward and that she, or someone acting on her behalf, picked up each of these prescriptions. Tr. 901–03. At another stage of the proceedings, in response to a question by her counsel, the Respondent retreated from this position, demurring instead that she was not sure if she had obtained every one of those prescriptions. Tr. 918–21, 923.

Regarding her July 2011 positive drug test for opiates conducted by McLeod Medical, the Respondent testified that she had warned Dr. Edmonds to expect a positive result. Tr. 907. This was at some odds with the recollection of Dr. Edmonds, who testified that the Respondent did not indicate prior to the test that she was on opiates⁹⁴ and that, when the screen test administered at the office yielded a positive result, the Respondent told him she felt she was “being singled out.” Tr. 971. The Respondent testified that, contrary to Dr. Edmonds’s testimony, the prescription bottle she produced in response to the positive urinalysis result was not dated subsequent to the urinalysis, but prior to it. Tr. 908. The Respondent initially testified that she had received a prescription for morphine from one of Dr. Black’s associates,⁹⁵ but subsequently stated

that the prescription for the morphine that triggered the positive drug test came from Dr. Black herself, and not from one of her associates. Tr. 927–28.

The Respondent related that, one Saturday morning following the positive urinalysis result, she received a phone call at home from Dr. Edmonds. Tr. 831–32. She explained that Dr. Edmonds told her that he had reason to believe that she had been forging prescriptions. Tr. 832. During her testimony, the Respondent took the position that Dr. Edmonds was mistaken in his recollection of their conversation. The Respondent recalled providing an answer with the word “twice” in it, but, according to her, she was responding to Edmonds’s inquiry of how many times she had requested controlled substance prescriptions from Francis. Tr. 832–33. The Respondent never explained why, in July 2011, she would answer such a question with the word “twice” when she (and Ms. Diminovich) had previously testified that she was receiving controlled substances from PA Francis on a fairly regular basis since the preceding February, and certainly more than “twice.” In fact, when asked, the Respondent testified that she could not remember how many prescriptions she had received from PA Francis “off the top of [her] head.” Tr. 826. At another point in her testimony, the Respondent acknowledged that she had received “seven or eight” such prescriptions from PA Francis. Tr. 899. Even if it were momentarily assumed, *arguendo*, that the Respondent perceived the question to be how many controlled substance prescriptions she received from Francis, the answer “twice” makes no sense whatsoever.

The Respondent also denied ever admitting on the phone that she had forged prescriptions,⁹⁶ and, at the hearing, she flatly denied ever having forged a single scrip. Tr. 822, 834. The Respondent recalled being placed on administrative leave and being directed to both enroll in the MTP and write a letter of apology to PA Francis as conditions upon returning to work. Tr. 834–35. The Respondent testified that she wrote a letter of apology to PA Francis, pursuant to the conditions placed on her return to employment by Dr. Edmonds. Tr. 882. While the Respondent indicated that she did not apologize regarding the forgery accusations being levelled against her, she expressed her regret to PA Francis for having asked her to be her provider because her condition was possibly “a little bit more complicated for her than [the Respondent] thought.” Tr. 883. The

Respondent also testified that she voluntarily contacted the MTP and underwent psychological and psychiatric examinations before being placed in a program of random drug screening. Tr. 840–42. According to the Respondent’s testimony, the program assigned her a color code, and, each day, she was required to call a phone number. Tr. 842. If the Respondent’s color was selected on any given day, she was required to report to a clinic and provide a urine sample that would be tested for indications of drug use. Tr. 842.

The Respondent presented evidence of a series of nineteen (19) MTP urine drug sample (UDS) test reports for alcohol and controlled substances occurring between October 21, 2011 and March 23, 2012.⁹⁷ Resp’t Ex. 1. The UDS reports supplied by the Respondent indicated that (at least on those pages) the Respondent’s urine was consistently negative for all tested substances.⁹⁸ *Id.* Consistent with the paperwork she provided, the Respondent testified that she never received any indication of a positive result for controlled substances during the time she was monitored by MTP. Tr. 881–82; Resp’t Ex. 1. It is worthy of note that an examination of the nineteen urinalysis reports reveals no discernible pattern of testing, indicating that, consistent with the Respondent’s testimony, the tests were taken at random. Resp’t Ex. 1. However, five of the nineteen reports also contain handwritten notations (the origins of which do not benefit from any level of explanation on the record)⁹⁹ stating that the Respondent had missed certain test dates or that certain tests were conducted to “make up” for other dates.¹⁰⁰ *Id.* at 7, 9, 10, 13, 18. A

⁹⁷ The admissibility of this exhibit was adjudicated in a post-hearing order dated May 27, 2014. ALJ Ex. 56.

⁹⁸ The tests purportedly monitored use of the following substances: Ethanol, Amphetamines, MDMA, Barbiturates, Benzodiazepines, Cannabinoids, Cocaine, Meperidine, Methadone, Methaqualone, Opiates, Oxycodone, PCP, and Propoxyphene. Resp’t Ex. 1, at 1–19.

⁹⁹ During the post-hearing motion practice that ultimately resulted in the admission of the UDS reports over the Government’s objection, the Respondent offered a letter from the Executive Director/Drug Screen Coordinator at MTP, and an attachment purporting to explain the notations. Resp’t Ex. 1A(ID). Although considered on the narrow issue of establishing admissibility, the proposed exhibit was not offered or received in evidence, but even if it had been, the proposed exhibit did little more than attempt to translate the handwriting on the UDS reports, and, on some occasions, it did not even accurately do that.

¹⁰⁰ Resp’t Ex. 1, at 7 (noting, on report of December 6, 2011 test, “make up for 12/5 Snow”); *id.* at 9 (noting, on report of December 23, 2011 test, “not called on 12/23” and “M/U for 12/21/11”); *id.* at 10 (noting, on report of December 30, 2011 test,

⁹³ This is in substantial conflict to PA Francis’s recollection that she had seen the Respondent once to administer an in-office injection for nausea and once as a pain patient. Tr. 185, 241, 243–44.

⁹⁴ Tr. 968–70.

⁹⁵ Tr. 836, 838–39.

⁹⁶ Tr. 832.

notation on another report indicates that the test was a “non[-]random extra test.” *Id.* at 12. While the results of each of the provided nineteen tests were benign, the unexplained notations on several of the reports suggest that the Respondent’s record for appearing for urinalysis tests as directed was less than even. Tr. 860–73. The Respondent’s testimony about her UDS rescheduling was likewise uneven. The Respondent testified to having missed at least four of the tests and, possibly, to missing two others. Tr. 861, 863, 865–66, 869–70, 870–71, 872–73. At first, the Respondent stated that she only missed tests because of inclement weather. Tr. 864; Resp’t Ex. 1, at 7. However, as her testimony progressed, the Respondent conceded that other UDS test dates were missed due to conflicts with her work schedule. Tr. 866, 869, 871–73. Missed tests scheduled for December 21st and 28th were apparently made up two days later, on the 23rd and 30th respectively. Resp’t Ex. 1, at 9–10. A test the Respondent apparently missed on March 2, 2012 was made up four days later, on March 6th. *Id.* at 18. A missed test originally scheduled for January 10, 2012 was not made up until eight days later, on January 18th,¹⁰¹ but, curiously, a January 13, 2012 test was labeled “non-random extra test,” without any explanation in the paperwork, and took place three days after the January 10th miss. *Id.* at 12. The Respondent testified that she volunteered for this “extra test” via email because she had “missed the week before,” and she “was just proving [her]self.” Tr. 968–69.

Standing in isolation, there is nothing categorically pernicious about rescheduling one (or even several) random urinalysis test(s). As with many issues, it is generally a question of degree. Of eighteen random tests, the Respondent missed and rescheduled six. Resp’t Ex. 1. Assuming (as she urges) that the UDS package she provided contains all testing, excluding the “extra” test, this presents a missed test rate of 33% of all randomly-scheduled UDS tests. Although rescheduling one-third of all random tests is by no means an insignificant number, the issue is (once again) less with the substance of her testimony than with its internal consistency. Initially, the Respondent stated that she only missed UDS tests due to inclement weather. Tr. 864. That position later morphed into misses borne of weather

“not called but maybe a test for 12/28 miss”); *id.* at 13 (noting, on report of January 18, 2012 test, “make up for 1/10 working”); *id.* at 18 (noting, on report of March 6, 2012 test, “make up for 3/2 working”).

¹⁰¹ *Id.* at 13.

and work schedule. Tr. 866, 869, 871–73. The equivocation in her recollection and pattern of testimonial adjustments crafted on the spot to address uncontroverted evidence she was confronted with on the witness stand (such as the rescheduling notes from the UDS reports) diminishes the extent to which her testimony can be credited where it conflicts with other available evidence and testimony—and—she rescheduled one-third of her random urinalysis tests.

Despite her participation in the MTP program, the Respondent was eventually terminated from her employment at McLeod Medical by Dr. Edmonds in October 2011. Tr. 882. Even after losing her job, the Respondent testified that, “to prove a point,” she continued in the MTP program through March 2012 while she was also in the process of “job seeking.”¹⁰² Tr. 847–48, 882.

The Respondent consistently and unambiguously eschewed any wrongdoing on her part. She denied ever presenting the prescription for hydrocodone written by PA Francis on February 14, 2011 to be filled at two different pharmacies,¹⁰³ and categorically denied ever forging any prescription for controlled substances. Tr. 822. She was likewise steadfast in her view that she never telephoned PIC Alvis and asked him to refrain from submitting her prescription through her insurance company. Tr. 947–48. According to the Respondent, the entire misadventure was the result of a mix-up caused by Dr. Black, who, without telling the Respondent, “apparently had faxed this thing to [May Pharmacy].” Tr. 947. The Respondent explained: “I didn’t realize that Dr. Black had done that, because, you know, she’ll do it the day before, and you won’t know it, you know, until you call the pharmacy.” Tr. 948. Under the Respondent’s version of events, she asked PIC Alvis to cancel the prescription, not because of an insurance issue, but because, before Alvis telephoned, she fortuitously received a phone call from May Pharmacy alerting her that a prescription she did not know about had been called in by Dr. Black and was ready for pickup. Tr. 947. Regrettably, this scenario does not explain the fact that PIC Alvis had been told by Pharmacist Romp at May Pharmacy that

¹⁰² Since the Respondent indicated she had already secured her current position at Indian Health Services in Crownpoint, New Mexico as of December 2011 (Tr. 752), it is difficult to understand her testimony as to why she still considered herself to be “job seeking” as late as March 2012.

¹⁰³ Tr. 942, 944.

the Respondent picked up the prescription herself the day before she placed the phone call to Alvis and told him she was unaware of its existence. Tr. 284–85, 292–95. What’s more, in view of the fact that May Pharmacy was only able to partially fill her medication, it is unclear why the staff there would have called her out of the blue to inform her that her prescription was ready for pick up, when the store did not yet possess the complete amount of the ordered quantity. The Respondent’s account of events is simply not plausible.

At the hearing, the Respondent acknowledged that she knew it was wrong for a patient to see multiple prescribers for controlled substances and to fill those prescriptions at multiple pharmacies. Tr. 950–51. In her testimony, the Respondent initially ascribed her use of multiple pharmacies to present controlled substance prescriptions and collect them to convenience borne of the various routes she would take to commute from her home to McLeod Medical and back, based largely on seeking to avoid “snow and ice.” Tr. 828–31. This testimony was singularly unpersuasive and only enhanced in that respect by the fact that ten of the dispensing events in question took place between March and September, and, of that number, four occurred between July and September. Gov’t Ex. 6, at 2–3, 13–14. This aspect of the Respondent’s testimony was particularly telling on the issue of her credibility when viewed in light of her admissions that she is and was aware and understood that the principal reason that standard pain management contracts with patients include a clause prohibiting the use of multiple pharmacies is to avoid the risk of pharmacy-shopping and doctor-shopping, and that these are by no means new concepts in medical care. Tr. 933–34. The Respondent conceded that even under her view of events, she had been simultaneously utilizing multiple pharmacies and multiple practitioners,¹⁰⁴ and attributed this behavior as the result of the severity of the stress and pain she was experiencing. Tr. 948–49.

There were multiple additional areas where the Respondent’s testimony was problematic. For example, the Respondent adamantly testified at great length that the prescriptions for hydrocodone written after February 14, 2011 were legitimately authorized by PA Francis. Tr. 820–22, 922. However, when she failed the random drug test conducted at McLeod Medical in July

¹⁰⁴ Tr. 950–51.

2011 by testing positive for opiates, the Respondent did not testify that she explained to Dr. Edmonds that she was receiving controlled substance prescriptions from PA Francis.¹⁰⁵ Instead, the Respondent testified that she presented to Dr. Edmonds a bottle of morphine prescribed by Dr. Black in an effort to explain why she had tested positive.¹⁰⁶ Tr. 907–08. If the Respondent truly believed she was legitimately obtaining prescriptions for hydrocodone, it defies reason why she would not have quickly and freely disclosed to Dr. Edmonds that she was receiving the medication from PA Francis, especially since this fact could have been quickly confirmed by McLeod Medical's own records.¹⁰⁷ The Respondent's testimony that she was unaware of any policy against employees prescribing narcotics to other employees¹⁰⁸ makes this even more bewildering.

Moreover, at the time her urinalysis was conducted, the Respondent had been presented with a form that would have allowed her to list medications she was taking. Tr. 964. The Respondent did not list any medications on the form. Tr. 958, 964, 966–70. The absence of an appropriate note on the applicable form, and the Respondent's decision not to inform Dr. Edmonds that she was receiving controlled substances from PA Francis at the time the screen test showed positive, as well as her decision to only explain the positive drug test by presenting a prescription bottle dated after the test, all undermine her testimony. On this record, it is far more likely that the Respondent's positive urinalysis test was the result of taking medications procured over PA Francis's forged signatures, and for which the Respondent had no ready, lawful explanation that lent itself to disclosure to Dr. Edmonds.

The Respondent's testimony regarding her relationship with Dr. Black was also confusing, and its apparent contradictions call further into question her credibility as a witness. At first, the Respondent testified that when she first asked to be seen by PA Francis as a patient on February 14, 2011, she had already set up an appointment with Dr. Black. Tr. 801, 808. Then, she stated that she told PA Francis during that

initial visit that she had attempted to make an appointment with Dr. Black but that the appointment would be "months down the line." Tr. 810. This would mean that, notwithstanding the severe pain she claimed she was enduring, the appointment that the Respondent had purportedly set up with Dr. Black's pain practice was scheduled five to six months hence. The Respondent later testified that her initial contact with Dr. Black's office occurred (five months later) in July 2011 when she attempted then to schedule an appointment with her. Tr. 924–25. Even setting aside PA Francis's (credible) recollection that the Respondent told her she would be seeing Dr. Black in several weeks, and only needed medication for one month,¹⁰⁹ the Respondent's testimony regarding when she initially made appointment arrangements with Dr. Black, as well as her purported timeline of her history with Black's practice, labors under this unexplained, internal inconsistency of the time when she had her first contact with Black's practice.

At one point in her testimony, the Respondent was confident that the morphine prescription that resulted in the positive McLeod Medical office UDS was written by Dr. Black. Tr. 932–33. At another point in her testimony, the Respondent was equally resolute that the causal prescription was issued by "Dr. Black's associate." Tr. 839. This is another in a pattern of testimonial inconsistencies, but regardless of which version reflects reality, for the reasons that follow, neither version is helpful to the Respondent's cause. The Respondent testified that her telephone call to Dr. Black's office to set up an initial appointment took place sometime in July 2011, with the first appointment occurring approximately two weeks later. Tr. 925–26. During that initial visit (which would have to be mid-July at the earliest), she was seen by a PA, who, according to the Respondent, wrote her a prescription for morphine. Tr. 926. The Respondent then stated that she finally met with Dr. Black approximately one month after the first appointment, which, according to the rough timeline of events given by the Respondent at the hearing, would have taken place sometime between mid-August through mid-September 2011. Tr. 926–27. The date of the McLeod Medical urinalysis, however, was July 19, 2011, at least a month prior to her appointment with Dr. Black herself.¹¹⁰ If that version of her testimony is credited, which recollects that the morphine that resulted in the positive test was

prescribed by Dr. Black herself (not a staff member)¹¹¹ at the Respondent's second visit to her office (in mid-August), that would mean that the prescription issued by Dr. Black was issued at least a month after the urinalysis took place.

The Respondent's timeline is even problematic if that portion of her testimony is credited which holds that it was a prescription from "Dr. Black's associate"¹¹² that caused the positive result. Dr. Edmonds credibly testified that the Respondent presented him with a prescription bottle dated July 25, 2011. Tr. 366. Even assuming that the opiate-positive result on the July 19th urinalysis was the result of a mid-July prescription written by a PA in Dr. Black's office prior to the test, there would be no reason for the Respondent to be in possession of a July 25, 2011 prescription bottle. July 25th would be a date between the appointment with Dr. Black's PA and the date (a month later by her account) when she was seen by Dr. Black. During her testimony, there was no mention of an additional appointment between the first PA appointment and the appointment with Black, and the Respondent's recollection of her conversation with the PA reflected that she would be seeing Dr. Black on her next visit. Tr. 926. Even if the positive urinalysis was the result of a morphine prescription she received from Dr. Black's PA in mid-July (a month prior to her first encounter with Dr. Black), there is no explanation as to why (as credibly testified to by Dr. Edmonds) she would have had a prescription bottle dated July 25, 2011,¹¹³ a date that occurred during the month between the PA and Dr. Black appointments.

Needless to say, the conflict in the Respondent's timeline of events here does not enhance her credibility. In one telling exchange, the Respondent testified that she did not remember the date of the McLeod urinalysis, and thought that it may have occurred in October of 2011,¹¹⁴ a date that would have lent itself much better to the Respondent's testimonial timeline, irrespective of the dates of treatment she proposed as having occurred at Dr. Black's practice.

During her testimony, the Respondent indicated that all her prescriptions were picked up from the various pharmacies by herself or a member of her family. Tr. 901–03. Later, in response to questioning from her counsel, the

¹⁰⁵ Neither did Dr. Edmonds testify to such a conversation.

¹⁰⁶ Dr. Edmonds testified that the bottle was dated subsequent to the urinalysis. Tr. 363.

¹⁰⁷ Indeed, perhaps the greatest puzzlement of this case is the odd avoidance on the part of both parties to *subpoena* and produce medical records from McLeod Medical and Dr. Black that would likely have resolved almost all contested issues.

¹⁰⁸ Tr. 828.

¹⁰⁹ Tr. 175, 182–83.

¹¹⁰ Tr. 365.

¹¹¹ Tr. 927–28.

¹¹² Tr. 839.

¹¹³ Tr. 366.

¹¹⁴ Tr. 932.

Respondent claimed that she could not recall whether she had obtained all of those same prescriptions. Tr. 918–19, 921, 923. The initial response, asked and answered directly, rings as more credible, and is corroborated, at least to some extent, by PIC Alvis's recollection that the Respondent's prescriptions dispensed at the Walmart Pharmacy Edgewood were picked up by either the Respondent or members of her family. Tr. 315–16.

As described above, in addition to being the witness with the most at stake in the outcome of the proceedings, the Respondent's testimony throughout this hearing was punctuated by internal inconsistencies, implausibility, and chronic equivocation. As discussed in great detail, *supra*, there were several times where her answers seemed to evolve with objective evidence and dates she was confronted with. Accordingly, while there were parts of the Respondent's testimony that were credible, where her testimony conflicts with other, more credible aspects of the record, it cannot prevail.

The Analysis

The Government urges that the Respondent's application for DEA COR be denied because the granting of a COR to the Respondent would be inconsistent with the public interest. Under 21 U.S.C. 823(f),¹¹⁵ the Agency may deny the application for a COR upon supported findings that “the issuance of such registration . . . would be inconsistent with the public interest.” 21 U.S.C. 823(f). The following factors have been supplied by Congress in determining “the public interest”:

- (1) The recommendation of the appropriate State licensing board or professional disciplinary authority.
- (2) The applicant's experience in dispensing, or conducting research with respect to controlled substances.
- (3) The applicant's conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.
- (4) Compliance with applicable State, Federal, or local laws relating to controlled substances.
- (5) Such other conduct which may threaten the public health and safety.

Id.

“[T]hese factors are considered in the disjunctive.” *Robert A. Leslie, M.D.*, 68

FR 15227, 15230 (2003). Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Agency may properly give each factor whatever weight it deems appropriate in determining whether an application for a registration should be denied. *Id.*; *David H. Gillis, M.D.*, 58 FR 37507, 37508 (1993); see *Morall v. DEA*, 412 F.3d 165, 173–74 (D.C. Cir. 2005); *Joy's Ideas*, 70 FR 33195, 33197 (2005); *Henry J. Schwarz, Jr., M.D.*, 54 FR 16422, 16424 (1989). Moreover, the Agency is “not required to make findings as to all of the factors.” *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005); *Morall*, 412 F.3d at 173. The Agency is not required to discuss consideration of each factor in equal detail, or even every factor in any given level of detail. *Trawick v. DEA*, 861 F.2d 72, 76 (4th Cir. 1988) (holding that the Agency's obligation to explain the decision rationale may be satisfied even if only minimal consideration is given to the relevant factors and that remand is required only when it is unclear whether the relevant factors were considered at all). The balancing of the public interest factors “is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest. . . .” *Jayam Krishna-Iyer*, 74 FR 459, 462 (2009).

In the adjudication of an application for a DEA COR, the DEA has the burden of proving that the requirements for registration are not satisfied. 21 CFR 1301.44(d). Where the Government has sustained its burden and established that an applicant has committed acts inconsistent with the public interest, that applicant must present sufficient mitigating evidence to assure the Agency that he or she can be entrusted with the responsibility commensurate with such a registration. *Steven M. Abbadessa, D.O.*, 74 FR 10077, 10078, 10081 (2009); *Jackson*, 72 FR at 23853. Where the Government has met this burden, the applicant must show an acceptance of responsibility for its misconduct and a demonstration that corrective measures have been undertaken to prevent the re-occurrence of similar acts. *Jeri Hassman, M.D.*, 75 FR 8194, 8236 (2010). In determining whether and to what extent a sanction is appropriate, consideration must be given to both the egregiousness of the offense established by the Government's evidence and the Agency's interest in both specific and general deterrence.

Fred Samimi, M.D., 79 FR 18698, 18713 & n.40 (2014); *David A. Ruben, M.D.*, 78 FR 38363, 38364, 38385 (2013).

Normal hardships to the practitioner, and even the surrounding community, which are attendant upon the denial of a registration, are not a relevant consideration. *Linda Sue Cheek, M.D.*, 76 FR 66972, 66972–73 (2011); *Gregory D. Owens, D.D.S.*, 74 FR 36751, 36757 (2009). The Agency's conclusion that past performance is the best predictor of future performance has been sustained on review in the courts, *Alra Labs., Inc. v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995), as has the Agency's consistent policy of strongly weighing whether an applicant who has committed acts inconsistent with the public interest has accepted responsibility and demonstrated that he or she will not engage in future misconduct, *Hoxie*, 419 F.3d at 483; see also *Ronald Lynch, M.D.*, 75 FR 78745, 78754 (2010) (holding that the Respondent's attempts to minimize misconduct undermined acceptance of responsibility); *George Mathew, M.D.*, 75 FR 66138, 66140, 66145, 66148 (2010); *George C. Aycock, M.D.*, 74 FR 17529, 17543 (2009); *Abbadessa*, 74 FR at 10078; *Krishna-Iyer*, 74 FR at 463; *Medicine Shoppe-Jonesborough*, 73 FR 364, 387 (2008).

Factors 1 & 3: The Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority; and Any Conviction Record Under Federal or State Laws Relating to the Manufacture, Distribution, or Dispensing of Controlled Substances

Regarding Factor 1, it is undisputed that the record contains no specific recommendation from authorities in New Mexico, the state where the Respondent seeks to hold a COR. However, the record does contain a settlement agreement and final order from the Board of Medical Examiners of the State of Iowa (Iowa Board).

Although the plain language of the CSA appears to require a recommendation addressed to DEA's COR decision, the Agency has indicated that it has “typically taken a broader view as to the scope of this factor.” *Ralph J. Chambers, M.D.*, 79 FR 4962, 4969 (2014) (citing *Tony T. Bui, M.D.*, 75 FR 49979, 49986 (2010)); see also *Kenneth Harold Bull, M.D.*, 78 FR 62666, 62672 (2013). Whatever the outer limits are of the Agency's “broader view,” it is not so broad that it includes recommendations from a state beyond the state where the Respondent seeks to hold her DEA COR. *Zizhuang Li, M.D.*, 78 FR 71660, 71663 (2013) (holding that the state where an applicant seeks to hold a COR is “the appropriate State

¹¹⁵ Regrettably, in its OSC, prehearing statements, and closing brief, the Government consistently and erroneously relies upon 21 U.S.C. 824, the CSA revocation statute. ALJ Ex. 1, at 1; ALJ Ex. 4, at 1; ALJ Ex. 7, at 1; ALJ Ex. 40, at 1; ALJ Ex. 59, at 1.

licensing board or professional disciplinary authority” within the meaning of 21 U.S.C. 823(f), not a state where the applicant formerly practiced and is no longer authorized to handle controlled substances). Hence, even to the extent that a COR recommendation intent could be extrapolated from the order of the Iowa Board, it will carry no weight under this factor.

As discussed, *supra*, the record does not contain any recommendation from New Mexico state authorities. However, the fact that a state has not acted against an applicant’s state authority is not dispositive in this administrative determination as to whether granting her registration is consistent with the public interest. *Patrick W. Stodola, M.D.*, 74 FR 20727, 20730 (2009); *Krishna-Iyer*, 74 FR at 461. It is well-established Agency precedent that “state [authority] is a necessary, but not sufficient condition for registration.” *John H. Kennedy, M.D.*, 71 FR 35705, 35708 (2006) (quoting *Leslie*, 68 FR at 15230). DEA bears an independent responsibility to determine whether a registration is in the public interest. *Mortimer B. Levin, D.O.*, 55 FR 8209, 8210 (1990). The ultimate responsibility to determine whether a registration is consistent with the public interest has been delegated exclusively to the DEA, not to entities within state government. *Edmund Chein, M.D.*, 72 FR 6580, 6590 (2007), *aff’d*, *Chein v. DEA*, 533 F.3d 828 (D.C. Cir. 2008), *cert. denied*, 555 U.S. 1139 (2009). Congress vested authority to enforce the CSA in the Attorney General, not state officials. *Stodola*, 74 FR at 20735 n.31. Thus, contrary to the position taken by the Respondent in her brief,¹¹⁶ on these facts, the absence of a recommendation by the appropriate state licensing board does not weigh for or against a determination as to whether granting the Respondent’s COR application would be consistent with the public interest. See *Roni Dreszer, M.D.*, 76 FR 19434, 19444 (2011) (“[T]he fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether continuation of the Respondent’s DEA certification is consistent with the public interest.”).

Regarding Factor Three, the record in this case does not contain evidence that the Respondent has been convicted of (or even charged with)¹¹⁷ a crime related to any of the controlled

substance activities designated under this provision in the CSA. Although the standard of proof in a criminal case is more stringent than the standard required at an administrative proceeding, and the elements of both federal and state crimes relating to controlled substances are not always co-extensive with conduct that is relevant to a determination of whether registration is within the public interest, evidence that an applicant has been convicted of crimes related to controlled substances is a factor to be evaluated in reaching a determination as to whether he or she should be entrusted with a DEA COR. The probative value of an absence of any evidence of criminal prosecution is somewhat diminished by the myriad of considerations that are factored into a decision to initiate, pursue, and dispose of criminal proceedings by federal, state, and local prosecution authorities. See *Robert L. Dougherty, M.D.*, 76 FR 16823, 16833 n.13 (2011); *Dewey C. MacKay, M.D.*, 75 FR 49956, 49973 (2010) (“[W]hile a history of criminal convictions for offenses involving the distribution or dispensing of controlled substances is a highly relevant consideration, there are any number of reasons why a registrant may not have been convicted of such an offense, and thus, the absence of such a conviction is of considerably less consequence in the public interest inquiry.”), *aff’d*, *MacKay v. DEA*, 664 F.3d 808 (10th Cir. 2011); *Ladapo O. Shyngle, M.D.*, 74 FR 6056, 6057 n.2 (2009). Therefore, contrary to the position taken by the Respondent,¹¹⁸ the absence of criminal convictions militates neither for nor against the denial sought by the Government.

Accordingly, consideration of the record evidence under Factors One and Three weighs neither for nor against the Government’s petition to deny the Respondent’s COR application.

Factors 2 & 4: The Respondent’s Experience in Dispensing Controlled Substances; and Compliance With Applicable State, Federal, or Local Laws Relating to Controlled Substances

Regarding Factor 2, in requiring an examination of an applicant’s experience in dispensing controlled substances, Congress manifested an acknowledgement that the qualitative manner and the quantitative volume in which an applicant has engaged in the dispensing of controlled substances may be significant factors to be evaluated in reaching a determination as to whether an applicant should be (or continue to be) entrusted with a DEA COR. In some

(but not all) cases, viewing an applicant’s actions against a backdrop of how her regulated activities have been performed within the scope of her registration can provide a contextual lens to assist in a fair adjudication of whether registration is in the public interest. In this regard, however, the Agency has applied principles of reason, coupled with its own expertise, in the application of this factor. For example, the Agency has taken the reasonable position that this factor can be readily outweighed by acts held to be inconsistent with the public interest. *Krishna-Iyer*, 74 FR at 463; see also *Hassman*, 75 FR at 8235 (acknowledging Agency precedential rejection of the concept that conduct inconsistent with the public interest is rendered less so by comparing it with a respondent’s legitimate activities that occurred in substantially higher numbers); *Paul J. Cargine, Jr.*, 63 FR 51592, 51560 (1998) (“[E]ven though the patients at issue are only a small portion of Respondent’s patient population, his prescribing of controlled substances to these individuals raises serious concerns regarding [his] ability to responsibly handle controlled substances in the future.”). Similarly, in *Cynthia M. Cadet, M.D.*, the Agency determined that existing List I precedent¹¹⁹ clarifying that experience related to conduct within the scope of the COR sheds light on a practitioner’s knowledge of applicable rules and regulations would not be applied to cases where intentional diversion allegations were sustained. 76 FR 19450, 19450 n.3 (2011). The Agency’s approach in this regard has been sustained on review. *MacKay*, 664 F.3d at 819.

In addition to Factor 2 (experience in dispensing), Factor 4 (compliance with laws related to controlled substances) is also germane to a correct resolution of the present case. In order to maintain the “closed regulatory system” designed by Congress in the CSA to “prevent the diversion of drugs from legitimate to illicit channels,” *Gonzales v. Raich*, 545 U.S. 1, 13 (2005), Factor 4 looks to the applicant’s compliance with federal and state laws related to controlled substances as an indicator of whether an applicant should be entrusted with the responsibilities of a registrant, 21 U.S.C. 823(f)(4). A careful look at the testimony and evidence presented at the hearing demonstrates that the Respondent has failed to comply with both federal and state laws related to controlled substances, and her conduct in this

¹¹⁶ ALJ Ex. 60, at 14.

¹¹⁷ DI Bencomo’s testimony that DEA “tried” to bring criminal charges was not considered for any purpose in this recommended decision. Tr. 655.

¹¹⁸ ALJ Ex. 60, at 14.

¹¹⁹ See, e.g., *Volusia Wholesale*, 69 FR 69409, 69410 (2004).

respect must be considered in regard to her ability to assume the responsibilities of a registrant in accordance with the public interest.

The evidence of record establishes that, in 2011, the Respondent committed controlled substance-related transgressions in New Mexico (New Mexico Misconduct), and, in 2005, was disciplined in Iowa for misconduct that occurred in that state (Iowa Misconduct). The New Mexico Misconduct is relevant under Factor 4, and the Iowa Misconduct is relevant under both Factors 2 and 4.

The CSA provides that it is “unlawful for any person knowingly or intentionally . . . to acquire or obtain possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge.” 21 U.S.C. 843(a)(3). The evidence presented at the hearing regarding the New Mexico Misconduct shows that the Respondent violated this provision of the CSA on eleven (11) separate occasions.

On February 16, 2011 (Dispensing Event 2), the Respondent improperly presented the same February 14 controlled substance scrip to Walgreens Pharmacy that she had previously presented to Walmart Pharmacy Edgewood (Dispensing Event 1) via facsimile. The scrip, which was validly authorized by PA Francis,¹²⁰ indicated that the prescription was not to be refilled. Gov’t Ex. 3, at 1–2; Gov’t Ex. 8, at 1. The second presentation was made two days after the first, at a different pharmacy. There is little question that the Respondent’s actions were intentional and calculated to procure twice as much medication as PA Francis prescribed. The preponderant evidence supports the Respondent’s fraudulent, deceptive use of the February 14 scrip to obtain controlled substances in Dispensing Event 2 through subterfuge. See 21 U.S.C. 843(a)(3).

In the same way, the evidence establishes that the Respondent presented the same March 11 scrip to acquire controlled substances at Walgreens Pharmacy (Dispensing Event 4), Walmart Pharmacy Edgewood (Dispensing Event 5), and Walmart Pharmacy Albuquerque (Dispensing Event 6) on March 11, 15, and 21, respectively. Even apart from forged signatures on the scrip (discussed, *infra*), the successive presentation of these scrips to dupe multiple pharmacies into dispensing controlled substances was also done in violation of 21 U.S.C. 843(a)(3).

The evidence of record also preponderantly establishes that the

Respondent, on ten occasions (Dispensing Events 3–12),¹²¹ presented scrips that contained the forged signature¹²² of PA Francis to multiple pharmacies, and that when she presented these scrips, the Respondent was well aware that the signatures were forged. It is clear that the Respondent had access to the computer system that generated these scrips, and that she, or members of her immediate family, picked up the dispensed medications. Tr. 208, 217, 283, 314, 382–85, 725–28, 826, 901–03. Further, the lengths that the Respondent went to in obstructing PIC Alvis’s telephonic inquiries to McLeod Medical to resolve his (ultimately justified) misgivings about the legitimacy of the prescription, demonstrated significant consciousness of guilt on the part of the Respondent, as did her request to the Walmart Pharmacy Edgewood staff to refrain from submitting the prescription to her insurance carrier due to a contrived coverage issue. Tr. 285–88, 268–69. Additional evidence of knowing culpability can be inferred by the Respondent’s decision to present the scrips at multiple pharmacies. This approach was plainly calculated to reduce the likelihood of detection by vigilant pharmacists who would be likely to ask probing questions about the frequency of new scrips for the same medication. Utilizing multiple pharmacies facilitated the presentation of a single scrip to effect multiple dispensing events. Thus, the manner in which these scrips (forged and otherwise) were employed to procure controlled substances by the Respondent violated 21 U.S.C. 843(a)(3).

The Respondent has also violated New Mexico state law related to controlled substances. Under New Mexico state law,

¹²¹ March 1, March 11, March 15, March 21, March 31, April 6, July 9, August 4, August 9, September 10.

¹²² In its brief, the Government argues that its evidence establishes that the “Respondent illegally acquired hydrocodone on ten occasions by forging ten prescriptions . . . using PA Francis’s DEA number.” ALJ Ex. 59, at 25. At another point in its brief, the Government argues that “the evidence shows that the Respondent forged and filled ten hydrocodone prescriptions to herself using PA Francis’s DEA number.” *Id.* at 28. Technically, the prescriptions were filled, not by the Respondent, but by hapless pharmacists, duped by the Respondent into doing so. To the extent that the Respondent argues that no handwriting or forgery evidence is present in the record that directly connects her to the actual scrawling of Francis’s fabricated signature (ALJ Ex. 60, at 11, 15), she is correct. While there is ample evidence of record to support the proposition that PA Francis’s signature was forged on ten scrips, and that these forged scrips were presented to multiple pharmacies by the Respondent to wrongfully obtain controlled substances, there is no evidence that the Respondent, herself, did the actual forging.

[i]t is unlawful for a person intentionally to possess a controlled substance unless the substance was obtained pursuant to a valid prescription or order of a practitioner while acting in the course of professional practice or except as otherwise authorized by the Controlled Substances Act.¹²³

N.M. Stat. Ann. § 30–31–23(A).¹²⁴ Here, the evidence demonstrates that, on those same eleven occasions, the Respondent (or through family members acting on her behalf) obtained possession¹²⁵ of the controlled substances dispensed during Dispensing Events 2–12, and did so through the use of invalid prescriptions.¹²⁶ Gov’t Ex. 5, at 3–12; Tr. 826. As discussed, *supra*, the prescription the Respondent used to obtain controlled substances in Dispensing Event 2 was no longer valid at the time of presentation because the medication it authorized had already been filled in Dispensing Event 1, two days earlier. The scrip authorized the dispensing of a fixed quantity of controlled substances, not double that amount at different pharmacies. Thus, forged scrips were presented on ten occasions, one was improperly presented when it was no longer valid, and the credible evidence establishes that all were picked up by the

¹²³ This statute clearly shares the CSA’s goal of preventing the diversion of controlled substances. See *Fred Samimi, M.D.*, 79 FR 18698, 18710 (2014) (stating that, to be considered under Factors 2 and 4, violations of state law must have a sufficient nexus to the CSA’s goal of preventing the diversion of controlled substances).

¹²⁴ The CSA contains an almost identical provision as this section in New Mexico state law. See 21 U.S.C. § 844(a) (“It shall be unlawful for any person knowingly or intentionally to possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice. . . .”); see also *Tyson D. Quay, M.D.*, 78 FR 47412, 47412 n.1 (2013) (sustaining the finding of a violation of 21 U.S.C. § 844(a) where the respondent obtained controlled substances without a valid prescription). The Government, however, did not allege a violation of this provision.

¹²⁵ The Respondent’s argument that the record contains no evidence that the controlled medications were actually dispensed (ALJ Ex. 60, at 9) is illogical and unpersuasive. The Respondent admitted that she or her family members picked up her prescriptions from the various pharmacies where they had been presented. Tr. 901–03. Furthermore, in light of her litigation posture that all the prescriptions in question were legitimately issued by PA Francis, it would have been illogical and implausible for her (or some mystery person) to have presented these scrips and then left them unclaimed at pharmacies all over the Albuquerque area. There is simply no basis in the record (or in reason) to support the Respondent’s suggestion that an unknown mystery person, for unknown reasons, procured signed, discarded scrips written on behalf of the Respondent, presented them at various pharmacies, and then, unbeknownst to the Respondent, surreptitiously picked them up with a photo identification. ALJ Ex. 60, at 11.

¹²⁶ It is uncontested that the allegations in this case involve only prescriptions and not orders.

Respondent or members of her family on her behalf. Tr. 283, 826, 901–03.

The controlled substances the Respondent procured under Dispensing Events 3–12 were likewise not obtained pursuant to valid prescriptions under federal and state law. Under the implementing regulations of the CSA, in order for a prescription for controlled substances to be valid, it must be “issued for a legitimate medical purpose by an individual *practitioner* acting in the usual course of his professional practice.” 21 C.F.R. 1306.04(a) (emphasis added). As defined by the CSA, a “practitioner” is a “physician . . . or other person licensed, registered, or otherwise permitted, by the United States or the jurisdiction in which he practices . . . , to distribute, dispense, [or] administer . . . a controlled substance in the course of professional practice or research.” 21 U.S.C. 802(21); see 21 C.F.R. 1306.02 (referring back to the definitions found in 21 U.S.C. 802). The record evidence shows that the prescriptions filled by forged scrips on these ten occasions were not authorized by a physician or other person licensed to prescribe controlled substances, but by a forger. PA Francis credibly denied ever signing or authorizing the prescriptions filled at Dispensing Events 3–12. Tr. 205–06, 261. Documents with forged signatures are not issued by one with authority to do so and, as such, are not valid prescriptions under federal law. 21 C.F.R. 1306.04(a)

Neither were the scrips presented in Dispensing Events 3–12 valid under state law. In New Mexico, a “prescription” is defined as “an order given individually for the person for whom is prescribed a controlled substance, either directly from a licensed practitioner or the practitioner’s agent to the pharmacist . . . or indirectly by means of a written order signed by the prescriber.” N.M. Stat. Ann. § 30–31–2(S). Once again, the scrips presented to the pharmacies on these occasions were not authorized or signed by a “licensed practitioner,” and, thus, the Respondent did not obtain the controlled substances dispensed on Dispensing Events 3–12 through a valid prescription. The Respondent’s possession of controlled substances violated New Mexico state law because such possession was not “obtained pursuant to a valid prescription,” as defined by federal and state law. N.M. Stat. Ann. § 30–31–23(A).

Additionally, the sheer amount of the controlled substances obtained by the Respondent adds significantly to the equation. During the 208 days the Respondent was presenting bad prescriptions, she received 248-days’

worth of medication. The exorbitant quantities of controlled substances she was obtaining, where the dates overlapped and exceeded even the dosages set forth in the forged scrips, eviscerates any rational claim of lack of knowledge.

Thus, the evidence demonstrates that the Respondent, on eleven different occasions, violated both the CSA¹²⁷ and New Mexico state law¹²⁸ when she obtained possession of controlled substances through Dispensing Events 2–12, and improperly obtained powerful, controlled drugs in copious amounts. Consideration of the New Mexico Misconduct evidence of record under Factor 4 (compliance with federal and state controlled substances laws), militates so powerfully in favor of denying her COR application, that this evidence, standing alone is sufficient to satisfy the Government’s burden of production to establish a *prima facie* case.

The Iowa Misconduct likewise reflects adversely on Factor 4, but also on Factor 2. In the Iowa Board Order/Settlement Agreement, the Respondent and the Iowa Board agreed that the Respondent “inappropriately and repeatedly prescrib[ed] controlled drugs to numerous patients in violation of the laws and rules governing the practice of medicine” and that the Respondent violated Iowa’s pain management rule, Iowa Admin. Code r. 653–13.2 (2013), which, *inter alia*, serves “to minimize the potential for substance abuse and drug diversion,” *id.* r. 653–13.2(1).¹²⁹ The agreed-to violations provide that the Respondent prescribed and continued to prescribe controlled substances to multiple patients in the face of drug-seeking, doctor-shopping, and drug-abuse indicators, and without appropriately documenting these features in the patients’ charts. Gov’t Ex. 9, at 12–17.

It is worthy of note that while the Iowa proceedings clearly raise issues that are relevant to this determination, the Iowa Board Order/Settlement Agreement, the Government’s arguments to the contrary notwithstanding,¹³⁰ has not been extended preclusive effect. Agency precedent has acknowledged the Supreme Court’s recognition of the applicability of the *res judicata* doctrine in administrative proceedings. *Christopher Henry Lister, P.A.*, 75 FR

28068, 28069 (2010) (citing *Univ. of Tenn. v. Elliot*, 478 U.S. 788, 797–98 (1986)) (“When an administrative agency is acting in a judicial capacity and resolves disputed issues of fact properly before it which the parties have had an adequate opportunity to litigate, the courts have not hesitated to apply *res judicata*[.]”). Factual findings and legal conclusions based on state law reached by state administrative tribunals are given preclusive effect in DEA administrative proceedings under the subset of the doctrine known as collateral estoppel (also referred to as “issue preclusion”). *Thomas Neuschatz, M.D.*, 78 FR 76322, 76325–26 (2013); *Robert L. Dougherty, M.D.*, 76 FR 16823, 16830 (2011); *Gilbert Eugene Johnson, M.D.*, 75 FR 65663, 65666 (2010); see *James William Eisenberg, M.D.*, 77 FR 45663, 45663–64 (2012) (taking official notice of findings in state medical board censure order with preclusive effect).

While the Agency recognizes the preclusive effect of findings and state law conclusions resulting from state administrative hearings, it has not extended, *carte blanche*, the same effect to settlement agreements (or consent agreements) entered between respondents and state agency boards. As discussed, *supra*, the IBO/SA provided by the Government constitutes the ratification of a settlement agreement between the Respondent and the Iowa Board. In *Ralph J. Chambers, M.D.*, the Agency held that a settlement agreement between the respondent and state medical board was not entitled to preclusive effect in the DEA proceedings because the settlement agreement said “nothing about whether [the respondent] would be estopped from challenging the findings in a subsequent proceeding brought by the Board (or another state agency) against him.” 79 FR 4962, 4970 (2014). While the respondent in *Chambers* had agreed not to seek judicial review of the settlement agreement, the Agency held that the Government’s failure to cite state authority holding that such language was entitled to preclude the parties from re-litigating the issues raised in the settlement agreement barred the settlement agreement from having any preclusive effect. *Id.* A similar issue arose in *David A. Ruben, M.D.*, in which the Agency held that the findings memorialized in two orders based on consent agreement between the respondent and state agency board were entitled to preclusive effect in the DEA proceedings because, in the consent agreements, the respondent (1) manifested an intent not to contest the validity of the orders in subsequent

¹²⁷ 21 U.S.C. § 843(a)(3).

¹²⁸ N.M. Stat. Ann. § 30–31–23(A).

¹²⁹ The charging document does not allege a violation of a specific provision within Iowa’s pain management rule.

¹³⁰ ALJ Ex. 59, at 29.

proceedings before the state board, (2) relinquished his right to judicial review of the matters alleged in the orders, and (3) waived his right to any further action related to the orders. 78 FR 38363, 38366 (2013). Because state law allowed for a settlement agreement to have preclusive effect if the parties to the agreement had manifested such intent, the Agency held that the respondent in *Ruben* was precluded from re-litigating the same findings at the DEA proceedings. *Id.* at 38366–67.

While the complex facts in both *Chambers* and *Ruben* do not lend themselves to a discernable bright-line rule for when a settlement or consent agreement should be given preclusive effect, it is clear that Agency precedent dictates that the parties to the agreement must have manifested their intent that the findings and conclusions accompanying the agreement be non-challengeable and binding upon the parties. *Chambers*, 79 FR at 4970; *Ruben*, 78 FR at 38366. Also relevant to this determination is an analysis of whether state law recognizes the nature and wording of the agreement entered into by the parties as creating a preclusive effect upon the parties in subsequent litigation. *Chambers*, 79 FR at 4970; *Ruben*, 78 FR at 38366.

In this case, the settlement agreement memorialized by the IBO/SA contains little evidence that the Respondent and the Iowa Board intended that the findings and conclusions discussed therein would have preclusive effect. While the Respondent agreed to “voluntarily waive[] any rights to a contested hearing on the allegations,”¹³¹ the agreement between the parties contains no language prohibiting the Respondent from seeking judicial review or establishing a waiver of the Respondent’s ability to pursue further action related to the allegations that formed the basis for the IBO/SA. Moreover, in the absence of the manifested intent of the parties that an agreement will have preclusive effect, Iowa state law holds that settlement agreements are not binding on a party through the doctrine of collateral estoppel because the issues in the settlement agreements are not “actually litigated.” *Winnebago Indus., Inc. v. Haverly*, 727 NW.2d 567, 572 (Iowa 2006) (“‘In the case of a judgment entered by confession, consent, or default, none of the issues is actually litigated. . . . The judgment may be conclusive, however, with respect to one or more issues, if the parties have entered an agreement manifesting such an intention.’” (quoting Restatement

(Second) of Judgments § 27 cmt. e (1982))).

Accordingly, on the present record, because the parties to the Iowa Board Order/Settlement Agreement did not manifest the intent that the issues raised in the IBO/SA would preclude the Respondent from re-litigating those issues outside of the Iowa Board’s jurisdiction, and because Iowa state law does not apply the doctrine of collateral estoppel to settlement agreements, the findings and conclusions contained in the IBO/SA are not binding upon this tribunal. As such, the parties in this DEA administrative adjudication were not precluded from re-litigating the issues raised in the Iowa Board Order/Settlement Agreement, and this adjudication must and does make appropriate findings.

All that said, it is beyond argument that the IBO/SA was prepared and submitted to the Iowa Board by the Respondent, and, by the terms of the document, constitutes an accepted offer to be disciplined based on the allegations set forth in the Iowa Board Charging Document. Gov’t Ex. 9, at 2 ¶ 4, 6, ¶ 14. Thus, by executing the IBO/SA, the Respondent admitted multiple serious episodes of controlled substance prescribing that were effected in violation of Iowa state law and practice standards. Iowa Admin. Code r. 653–13.2.

The explanatory language supplied by the Respondent in her COR application relating to the surrender of her Iowa license was reviewed and accepted by the Respondent at her DEA hearing on the merits. Tr. 936–38. The Respondent accepted the truth of the allegations by: (1) executing the Iowa Board Order/Settlement Agreement; (2) supplying an (albeit incomplete, and arguably misleading) explanation of the incident that contains no factual challenge to the Iowa findings in her COR application;¹³² and (3) offering no resistance to official notice regarding the Iowa Board’s findings and actions. Tr. 625–26, 978. Accordingly, the facts as alleged in the Iowa Board Charging Document and IBO/SA are deemed credible, stand unopposed, and are, thus established in this recommended decision.

Even accepting the (unopposed) truth of the Iowa Board’s findings through the Respondent’s admissions contained therein, neither the documents provided by the Government, nor the testimony of any witness, assign a date for the occurrences for which the Respondent was disciplined by the Board. In her (problematic) COR application

explanation, the Respondent lists an “incident date” of March 15, 2000,¹³³ but the IBO/SA and the IBCD both indicate that she was not even licensed in Iowa until April 5, 2000. Gov’t Ex. 9, at 1, 8. Thus, the “incident date” supplied by the Respondent in her COR application would have actually preceded her licensure in Iowa and, presumably, the Iowa Board’s jurisdiction to act. The Iowa Board Charging Document was executed on June 2, 2005, and the IBO/SA was signed on November 15, 2005. *Id.* at 7, 16. Thus, the only knowable parameters of the Respondent’s Iowa Misconduct would seem reasonably to fall between her April 5, 2000 date of licensure and the June 2, 2005 date upon which the Iowa Board issued its charging document, yet the Respondent has provided a date that preceded that period, and the Government has supplied no position on the subject.¹³⁴

Even taking into account that the Iowa Board matter was resolved nine years ago, and six years prior to the commencement of the 2011 misuse of the scrips established in this case, the time is not so long as to have significantly attenuated the nature of the Iowa Misconduct.¹³⁵ This is particularly so where the New Mexico Misconduct that comprises the bulk of the Government’s case here occurred subsequent to the execution of the IBO/SA. Prescribing to multiple patients in the face of known indicia of drug-seeking and drug-abuse behavior, with inadequate documentation, below the standard set by Iowa in its state laws reflects poorly on both the Respondent’s compliance with state laws regarding controlled substances (Factor 4) as well as her experience as an irresponsible and unlawful prescriber of controlled substances (Factor 2), and supports the denial of her COR application.

Thus, consideration of the record evidence regarding the Iowa Misconduct under Factor 2 (experience in dispensing), and the Iowa and New Mexico Misconduct under Factor 4 (compliance with controlled substances laws), powerfully and persuasively supports the DEA COR denial sought by the Government.

¹³³ Gov’t Ex. 2, at 1.

¹³⁴ The Government, as the proponent of this evidence, should have engaged in efforts to discern the date of the misconduct, but the Respondent interposed no objection based upon lack of temporal specificity regarding the dates of the Iowa Board case.

¹³⁵ The Respondent’s prehearing motion to exclude consideration of this matter based on the time the incidents allegedly occurred was denied. ALJ Ex. 43, at 8; ALJ Ex. 45, at 6–7.

¹³¹ Gov’t Ex. 9, at 6.

¹³² Gov’t Ex. 2, at 1–2.

Factor 5: Such Other Conduct Which May Threaten the Public Health and Safety

The fifth statutory public interest factor directs consideration of “[s]uch other conduct which may threaten the public health and safety.” 21 U.S.C. 823(f)(5) (emphasis added). Existing Agency precedent has long held that this factor encompasses “conduct which creates a probable or possible threat (and not only an actual [threat]). . . . to public health and safety.” *Dreszer*, 76 FR at 19434 n.3; *Michael J. Aruta, M.D.*, 76 FR 19420, 19420 n.3 (2011); *Beau Boshers, M.D.*, 76 FR 19401, 19402 n.4 (2011); *Jacobo Dreszer*, 76 FR 19386, 19386 n.3 (2011). Agency precedent has generally embraced the principle that any conduct that is properly the subject of Factor Five must have a nexus to controlled substances and the underlying purposes of the CSA. *Terese, Inc.*, 76 FR 46843, 46848 (2011); *Tony T. Bui, M.D.*, 75 FR 49979, 49989 (2010) (stating that prescribing practices related to a non-controlled substance such as human growth hormone may not provide an independent basis for concluding that a registrant has engaged in conduct which may threaten public health and safety); cf. *Paul Weir Battershell, N.P.*, 76 FR 44359, 44368 n.27 (2011) (noting that although a registrant’s non-compliance with the Food, Drug, and Cosmetic Act is not relevant under Factor Five, consideration of such conduct may properly be considered on the narrow issue of assessing a respondent’s future compliance with the CSA).

Similar “catch-all” language is employed by Congress in the CSA related to the Agency’s authorization to regulate controlled substance manufacturing and List I chemical distribution, but the language is by no means identical. 21 U.S.C. 823(d)(6), (h)(5). Under the language utilized by Congress in those provisions, the Agency may consider “such other factors as are relevant to and consistent with the public health and safety.” 21 U.S.C. 823(h)(5) (emphasis added). In *Holloway Distributing*, the Agency held this catch-all language to be broader than the language directed at practitioners under “other conduct which may threaten the public health and safety” utilized in 21 U.S.C. 823(f)(5). 72 FR 42118, 42126 n.16 (2007). Regarding the List I catch-all language, the Administrator, in *Holloway*, stated:

[T]he Government is not required to prove that the [r]espondent’s conduct poses a threat to public health and safety to obtain an adverse finding under factor five. *See T.*

Young, 71 [FR] at 60572 n.13. Rather, the statutory text directs the consideration of “such other factors as are relevant to and consistent with the public health and safety.” 21 U.S.C. § 823(h)(5). This standard thus grants the Attorney General broader discretion than that which applies in the case of other registrants such as practitioners. *See id.* § 823(f)(5) (directing consideration of “[s]uch other conduct which may threaten the public health and safety”).

*Id.*¹³⁶ Thus, the Agency has recognized that, while the fifth factor applicable to List I chemical distributors—21 U.S.C. § 823(h)(5)—encompasses all “factors,” the Factor Five applied to practitioners—21 U.S.C. 823(f)(5)—considers only “conduct.” However, because § 823(f)(5) only implicates “such other conduct,” it necessarily follows that conduct considered in Factors 1 through 4 may not be considered in Factor Five.

There is no question that Agency precedent has long held that self-abuse of controlled substances is a relevant consideration under Factor 5, even where there is no evidence of malfeasance related to a registrant’s prescribing authority. *Bui*, 75 FR at 49989. Even so, on the facts elicited here, the Government’s argument that the evidence sufficiently establishes self-abuse on the part of the Respondent that merits consideration under Factor 5 is unpersuasive. ALJ Ex. 59, at 32. It is unquestionably true that the Respondent provided a urinalysis sample that tested positive for opiates while she worked at McLeod, and could not (and still cannot) provide a credible explanation for why she was lawfully in possession of a controlled substance. However, PA Francis testified that, upon examining the Respondent and reviewing her x-rays, the Respondent had objective evidence of injuries consistent with the history she presented during the appointment, and that the (only legitimate) hydrocodone prescription Francis issued to her was appropriate under the circumstances. Tr. 181–85. Under the Agency’s precedent, “self-abuse” under Factor 5 contemplates “ingest[ion of] controlled substances for no legitimate medical reason.” *Michael W. Dietz, D.D.S.*, 66 FR 52937, 52938 (2001). The present record leaves little doubt that the Respondent procured controlled substances without legitimate prescriptions and ingested at least some of the medications,¹³⁷ and

¹³⁶ In *Bui*, the Agency clarified that “an adverse finding under [Factor Five] did not require a] showing that the relevant conduct actually constituted a threat to public safety.” 75 FR at 49988 n.12.

¹³⁷ As discussed, *supra*, although not charged by the Government, the possession of these controlled

although there may well have been a recreational component to the Respondent’s drug use, the only evidence received on the issue supports the Respondent’s claim that she had an objective medical basis that could arguably have supported the prescribing of controlled substances for pain. To be clear, the Respondent was in violation of the law, but, on this narrow issue, the record does not support the proposition that ingesting the medication that resulted in the positive urinalysis result at McLeod Medical was self-abuse.¹³⁸

That is not to say that the record evidence does not impact Factor 5. The preponderant evidence of record establishes that, regarding the New Mexico Misconduct, the Respondent engaged in significant, intentional efforts to circumvent the efforts of PIC Alvis at the Walmart Pharmacy Edgewood in his attempt to execute his corresponding responsibility under the DEA regulations. 21 C.F.R. 1306.04(a). At the time she presented a forged controlled substance prescription, the Respondent requested that staff members at the Walmart Pharmacy Edgewood refrain from processing the prescription through her health insurance company, based on her false representation that she was having issues with her health insurance company. Tr. 268–69. During her testimony, the Respondent conceded that she was insured by McLeod Medical and was having no such issues. Tr. 801–02, 946. To the extent that her testimony conflicts with the accounts presented in that regard by both PIC Alvis and PA Francis, her version is not credited.

When a Walmart Pharmacy Edgewood staff member inadvertently processed the prescription through the Respondent’s insurance and the claim was declined because the same medication had been dispensed to the Respondent just days ago, it became apparent that her request to refrain from involving her health insurance company was borne of a desire to remain below the radar of the insurance company’s

substances to ingest them was effected in violation of 21 U.S.C. 844(a); *see Quy*, 78 FR at 47412 n.1.

¹³⁸ As discussed, *supra*, the Respondent utilized illegitimate, forged prescriptions to accumulate quantities of controlled substances that far exceeded even the dosage directions on the false scrips. This aspect of the case is made even more chilling by the Respondent’s argument that she “was regularly tested during short intervals and never tested positive for the opiates she allegedly was forging prescriptions to obtain in large quantities.” ALJ Ex. 60, at 10. On this record, it is simply impossible to know whether she was ingesting all or some of the medications she was procuring. What is uncontested, however, is that she had some objective evidence of a prior neck injury.

monitoring process. On these facts, it is clear that the Respondent's direction to PIC Alvis was a ruse designed to evade the scrutiny of her insurance company and the attention that a rejection based on an early refill would draw to her actions.

PIC Alvis had his staff make inquiry of the insurance company and PA Francis, the purported prescriber. Tr. 272, 281–82. After PIC Alvis (appropriately) declined to dispense medication to the Respondent's daughters on the presented scrip, the Respondent then attempted to mislead PIC Alvis by telephoning him and posturing that the whole affair was a misunderstanding. Tr. 284–85. Compounding the negative impact of the Respondent's plan to avoid detection, when McLeod Medical staff inquired of Walmart Pharmacy Edgewood as to whether they were still seeking to speak to PA Francis, the Respondent commandeered the call and declared that, since she had spoken with Alvis, the matter was closed. Tr. 285, 288–89.

Admirably, PIC Alvis persevered in his regulatory duty to resolve the anomaly with an appropriate level of care.¹³⁹ Tr. 288–89, 291–92. After consulting with a pharmacist at May Pharmacy who remembered the details regarding the filling of the prescription, he reached out to a third pharmacist to call PA Francis. Tr. 292–98. In effect, the actions of the Respondent (who now seeks to be a DEA registrant) made it necessary for PIC Alvis to resort to a covert action by an intermediary to have his (ultimately well-founded) professional reservations addressed.

Under the regulations, PIC Alvis, as the dispensing pharmacist, bears a "corresponding responsibility" to ensure that controlled substances are dispensed only on "effective" prescriptions. 21 C.F.R. § 1306.04(a). The regulations provide that "to be effective [a controlled substance prescription] must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." *Id.* Under this language, a pharmacist has a duty "to fill only those prescriptions that conform in all respects with the requirements of the [CSA] and DEA regulations. . . ." *Electronic Prescriptions for Controlled Substances*, 75 FR 16236, 16266 (Mar. 31, 2010). In short, a pharmacist has a "corresponding responsibility under Federal law" to dispense only lawful prescriptions. *Liddy's Pharmacy, L.L.C.*, 76 FR 48887, 48895 (2011). Settled

Agency precedent has interpreted this corresponding responsibility as prohibiting the filling of a prescription where the pharmacist or pharmacy "knows or has reason to know" that the prescription is invalid. *E. Main St. Pharmacy*, 75 FR 66149, 66163 (2010); *Bob's Pharmacy & Diabetic Supplies*, 74 FR 19599, 19601 (2009) (citing *Medicine Shoppe*, 73 FR at 381); *see also United Prescription Servs.*, 72 FR at 50407–08 (finding a violation of corresponding responsibility where the pharmacy "had ample reason to know" that the practitioner was not acting in the usual course of professional practice). Once PIC Alvis, based on his professional training and experience, had identified a red flag that indicates that a controlled substance scrip was potentially illegal, he was prohibited under the law from dispensing until the red flag had been conclusively resolved. *Holiday CVS*, 77 FR 62316, 62341 (2012). PIC Alvis did not have the luxury of looking the other way,¹⁴⁰ but was duty-bound to take reasonable steps to investigate the issues raised by the Respondent's prescriptions.

Each DEA COR holder bears a responsibility to assure the integrity of the "closed system"¹⁴¹ designed by Congress to ensure controlled substance accountability. Requiring PIC Alvis to resort to subterfuge to investigate the suspicious prescription for controlled substances (after intentionally misleading him by inventing an insurance coverage issue) is completely antithetical to the obligations and privileges the Respondent seeks to once again enjoy as a DEA registrant. PIC Alvis was performing his duty, and the Respondent, a prospective registrant with a pending COR application,¹⁴² was intentionally frustrating his efforts. By intentionally misleading and then intercepting PIC Alvis's phone inquiry to PA Francis, the Respondent knowingly attempted to preclude Alvis from executing the due diligence obligation he bears as a dispensing pharmacist under federal law. Preventing a pharmacist from discharging his lawful duty to resolve a prescription anomaly substantially increases the risk of controlled

substances being dispensed outside the boundaries of the closed regulatory system. The Respondent's attempts to thwart Alvis's efforts to inquire behind the circumstances surrounding the Respondent's scheme to procure controlled substances through the misuse of scrips fits squarely within the bounds of "other¹⁴³ conduct which may threaten the public health and safety." 21 U.S.C. 823(f)(5); *see Jerry Neil Rand, M.D.*, 61 FR 28895, 28897 (1996) (adding false information to medical charts to conceal true nature of prescribing practices is conduct that adversely reflects upon Factor 5); *Nelson A. Smith, M.D.*, 58 FR 65403, 65404 (1993) (employing strategies to avoid detection of improper prescribing, such as falsifying medical chart information and recommending specific pharmacies to patients to avoid detection, reflects adversely on Factor 5). This is a case of a former/prospective DEA registrant in the system attempting to compromise another DEA registrant who was doing his job of guarding against diversion. In light of the fact that the Respondent was clearly utilizing her knowledge of the system as a former DEA registrant and her access to McLeod Medical phone lines as an employee there, coupled with how these actions constitute a calculated and abject betrayal of the very obligations she seeks to once again enjoy as a registrant, the New Mexico Misconduct evidence considered under this factor militates powerfully and persuasively, even standing alone, in favor of the Government's opposition to the Respondent's application for a COR.

Recommendation

In this case, balancing the relative merits of the evidence under the public interest factors, the Government has satisfied its *prima facie* case for denial of the Respondent's COR application. In Iowa, the Respondent repeatedly prescribed inappropriate controlled substances to multiple patients in violation of Iowa Law. In New Mexico, the Respondent presented a controlled substance scrip to multiple pharmacies to procure double the amount of controlled substances that the prescriber (PA Francis) intended to prescribe, presented many other controlled substance scrips that she knew or had reason to know were forged, even presenting one of those forged scrips three times to three different pharmacies, and intentionally impeded

¹⁴⁰ The Agency has never been, and cannot be, persuaded by a policy of "see no evil, hear no evil." *Carlos Gonzalez, M.D.*, 76 FR 63118, 63142 (2011). Even in a criminal context regarding prescriptions illegitimately issued, the courts have held that a factfinder "may consider willful blindness as a basis for knowledge." *United States v. Katz*, 445 F.3d 1023, 1031 (8th Cir. 2006).

¹⁴¹ *Gonzales*, 545 U.S. at 13.

¹⁴² The New Mexico Misconduct took place after the Respondent submitted her COR application and while its adjudication was pending. Stip. 3; Gov't Ex. 1.

¹⁴³ Since this conduct was designed to cover the Respondent's method for obtaining controlled substances, not specifically to obtain more, it is not covered by Factor 4 or any other of the public interest factors.

¹³⁹ 21 C.F.R. 1306.04(a).

a pharmacist and his staff from executing his duty to resolve a prescribing anomaly. There is, thus, no question that, under Factors 2, 4, and 5, the preponderant evidence of record satisfies the Government's burden to make out a *prima facie* case for denial of the Respondent's application.

"[T]o rebut the Government's *prima facie* case, [the Respondent is] required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the re-occurrence of similar acts." *Hassman*, 75 FR at 8236; *see Hoxie*, 419 F.3d at 483; *Lynch*, 75 FR at 78754 (holding that a respondent's attempts to minimize misconduct undermined acceptance of responsibility); *Mathew*, 75 FR at 66140, 66145, 66148; *Aycock*, 74 FR at 17543; *Abbadessa*, 74 FR at 10078; *Krishna-Iyer*, 74 FR at 463; *Medicine Shoppe*, 73 FR at 387. The acceptance of responsibility is a condition precedent for the Respondent to prevail once the Government has established its *prima facie* case. *Mathew*, 75 FR at 66148. This feature of the Agency's interpretation of its statutory mandate on the exercise of its discretionary function under the CSA has been sustained on review. *MacKay*, 664 F.3d at 822. In determining whether and to what extent a sanction, such as revocation of a license or denial of an application, is appropriate, consideration must be given to both the egregiousness of the offenses established by the Government's evidence and the Agency's interest in both specific and general deterrence. *Ruben*, 78 FR at 38364, 38385.

On the present record, the Respondent has neither accepted responsibility at any level, nor demonstrated persuasive remedial steps. Notwithstanding the strength of the evidence against her, the Respondent has persisted in steadfastly denying the veracity of the Government's New Mexico Misconduct charges regarding the presentation of any multiple-presented and/or forged scrips, as well as the deliberate steps she took in that state to undermine PIC Alvis's conscientious efforts to execute his corresponding responsibility as a DEA registrant pharmacist by intercepting his telephonic efforts to consult with PA Francis. Regarding the Iowa Misconduct, as discussed in more detail, *supra*, after interposing an incomplete and misleading rendition of events on her COR application, the Respondent did not challenge the events as portrayed in the IBO/SA, but neither did she discuss a single factual detail of the violations she was disciplined for.

On the issue of remedial steps, while the Respondent did testify that, after the New Mexico Misconduct, she continued her participation in urine drug screening for a relatively brief time after she was terminated from McLeod Medical,¹⁴⁴ and that, following the Iowa Misconduct, she took a class on the subject of the prescribing of pain medications,¹⁴⁵ neither step rises to any convincing of a truly remedial step at any persuasive level. By her own testimony, the urine drug screens were largely (albeit not exclusively) motivated by her desire to continue working for McLeod Medical, and thereafter to clear her name¹⁴⁶ (the opposite of accepting responsibility). Furthermore, the test results were marked with numerous unexplained misses and reschedules for urinalysis appointments that were designed to be administered at random. Tr. 860–73. The class the Respondent completed on pain management is a laudable step, but is significantly undermined by the fact that the New Mexico misconduct commenced well after the course was completed—hardly a convincing testimonial to the efficacy of this particular remedial measure. In any event, even if the propounded remedial steps were afforded some level of enhanced gravity, they are unavailing on the present record in the absence of an acceptance of responsibility. Under the Agency's precedent, remedial steps and acceptance of responsibility can only rebut the Government's *prima facie* case when both are present in the record. *See Samimi*, 79 FR at 18714 (holding that expressions of remorse are not persuasive in the absence of remedial steps). The Agency has held that "[b]oth conditions are essential requirements for rebutting the Government's *prima facie* showing that granting an application or continuing an existing registration would be consistent with the public interest." *Hassman*, 75 FR at 8236 (internal quotation marks and citation omitted). The Respondent's reliance on *Jeffrey Martin Ford, D.D.S.*, 68 FR 10750 (2003), is misplaced. In *Ford*, the Agency granted a restricted registration upon a demonstration that ten-year-old drug use, which was admitted by the Respondent,¹⁴⁷ had been attenuated by time and treated with a formal drug rehabilitation

¹⁴⁴ Tr. 843, 882.

¹⁴⁵ Tr. 769; Gov't Ex. 2, at 2.

¹⁴⁶ Tr. 844, 913.

¹⁴⁷ The respondent in *Ford* complained that a police traffic stop that ultimately resulted in a criminal conviction was effected without the requisite level of probable cause, but did not deny that he had abused controlled substances. *Ford*, 68 FR at 10751, 10753.

program and years of clean urinalysis testing. *Id.* at 10750–53. The Respondent in these proceedings has never admitted to abusing controlled substances and has never participated in drug rehabilitation.¹⁴⁸

In evaluating the appropriate sanction, DEA precedent requires consideration of the egregiousness of the established misconduct and the Agency's need to deter similar misconduct on the part of other registrants. *Ruben*, 78 FR at 38385–86. The New Mexico Misconduct evidence in this case reveals that the Respondent presented a scrip issued for a single controlled substance to procure multiple quantities, utilized multiple scrips that she knew or had reason to know were forged to procure more controlled substances, deliberately obstructed PIC Alvis's attempts to investigate (ultimately well-founded) red flags of diversion, and has expressed not the slightest level of remorse regarding any of her actions. There is a deliberative, calculating quality about the Respondent's actions that elevate the already egregious nature of the accomplished intentional diversion. These are actions that strike at the very heart of the responsibilities entrusted to a DEA registrant and mortally undermine any argument that she could be entrusted with a COR. On the issue of deterrence, it need not be overstated that granting her application under these circumstances would send the message to the regulated community (and the Respondent), in the most unequivocal terms, that there is virtually no level of the betrayal of registrant responsibilities that will result in significant consequences.

The Iowa misconduct also militates in favor of denying her application. The Respondent "inappropriately and repeatedly prescribe[d] controlled drugs in violation of the laws and rules governing the practice of medicine [and] engag[ed] in unprofessional conduct." Gov't Ex. 9, at 2. Even by the terms of the Iowa Board Order/Settlement agreement, the Respondent's controlled substance transgressions extended to multiple patients, and, in these proceedings, the Respondent neither refuted the factual basis of the conduct nor accepted any level of responsibility for them. Indeed, in her COR application, the Respondent's truncated explanation references only a single "patient," notes that "no investigation [by the Iowa Board] was needed," and

¹⁴⁸ The Respondent testified that she was evaluated by MTP and never found to have a substance abuse problem. Tr. 917. This is hardly the same as successful completion of a drug rehabilitation program.

incorrectly represents that the only “incident result” was that she “voluntarily took [a continuing medical education] course on prescribing controlled substances from Vanderbilt University.” Gov’t Ex. 2, at 1–2. The Respondent’s explanation omits any reference to the multiple incidents where she “repeatedly” prescribed controlled substances to “numerous patients,” that she was assessed a \$2,500.00 civil penalty, or that she received a five-year period of license probation with significant limitations, and reporting, monitoring, and notice requirements imposed as conditions of her probation. Gov’t Ex. 9, at 2–6. Even beyond the issue that the Respondent did not accept responsibility for these actions, as discussed, *supra*, the “explanation” she included with her application lacked candor.¹⁴⁹

Based on the present record, this applicant simply cannot be entrusted by DEA with a registration, and, for that reason, it is recommended that her application be **DENIED**.

Dated: June 3, 2014.

John J. Mulrooney, II,
Chief Administrative Law Judge.

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DEPARTMENT OF JUSTICE

Federal Bureau of Investigation

Notice of Charter Reestablishment

In accordance with the provisions of the Federal Advisory Committee Act, Title 5, United States Code, Appendix, and Title 41, Code of Federal Regulations, Section 101–6.1015, with the concurrence of the Attorney General, I have determined that the reestablishment of the Criminal Justice Information Services (CJIS) Advisory Policy Board (APB) is in the public interest. In connection with the performance of duties imposed upon the FBI by law, I hereby give notice of the reestablishment of the APB Charter.

The APB provides me with general policy recommendations with respect to the philosophy, concept, and operational principles of the various criminal justice information systems managed by the FBI’s CJIS Division.

The APB includes representatives from local and state criminal justice agencies; tribal law enforcement representatives; members of the judicial,

prosecutorial, and correctional sectors of the criminal justice community, as well as one individual representing a national security agency; a representative of the National Crime Prevention and Privacy Compact Council; a representative of federal agencies participating in the CJIS Division Systems; and representatives of criminal justice professional associations (*i.e.*, the American Probation and Parole Association; American Society of Crime Laboratory Directors; International Association of Chiefs of Police; National District Attorneys Association; National Sheriffs’ Association; Major Cities Chiefs Association; Major County Sheriffs’ Association; and a representative from a national professional association representing the courts or court administrators nominated by the Conference of Chief Justices). The Attorney General has granted me the authority to appoint all members to the APB.

The APB functions solely as an advisory body in compliance with the provisions of the Federal Advisory Committee Act. The Charter has been filed in accordance with the provisions of the Act.

Dated: May 11, 2015.

James B. Comey,
Director.

[FR Doc. 2015–12200 Filed 5–19–15; 8:45 am]

BILLING CODE 4410–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Water Act and Resource Conservation and Recovery Act

On May 14, 2015, the Department of Justice lodged a proposed Consent Decree with the United States District Court for the Central District of California in the lawsuit entitled *United States v. Anaplex Corporation*, Civil Action No. 2:15–CV–3615.

The United States filed this lawsuit under the Clean Water Act and the Resource Conservation and Recovery Act. The United States’ complaint seeks injunctive relief and civil penalties for violations of regulations that govern discharges of pollutants to a publicly owned treatment works and the storage, disposal, and management of hazardous wastes at Anaplex’s electroplating facility in Paramount, California. The consent decree requires the defendant to undertake a rinsewater use evaluation, implement ongoing pollution monitoring, report on hazardous waste

handling measures, and pay a \$142,200 civil penalty.

The publication of this notice opens a period for public comment on the Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, and should refer to *United States v. Anaplex Corporation*, D.J. Ref. No. 90–5–1–10454. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

<i>To submit comments:</i>	<i>Send them to:</i>
By email	<i>pubcomment-ees.enrd@usdoj.gov.</i>
By mail	Assistant Attorney General, U.S. DOJ–ENRD, P.O. Box 7611, Washington, DC 20044–7611.

During the public comment period, the Consent Decree may be examined and downloaded at this Justice Department Web site: <http://www.justice.gov/enrd/consent-decrees>. We will provide a paper copy of the Consent Decree upon written request and payment of reproduction costs. Please mail your request and payment to: Consent Decree Library, U.S. DOJ–ENRD, P.O. Box 7611, Washington, DC 20044–7611.

Please enclose a check or money order for \$13.50 (25 cents per page reproduction cost) payable to the United States Treasury.

Henry Friedman,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2015–12115 Filed 5–19–15; 8:45 am]

BILLING CODE 4410–CW–P

DEPARTMENT OF LABOR

Office of Labor-Management Standards

Information Collection Request; Comment Request

ACTION: Notice.

SUMMARY: The Department of Labor, as part of its continuing effort to reduce paperwork and respondent burden, conducts a preclearance consultation program to provide the general public and Federal agencies with an opportunity to comment on proposed and/or continuing collections of information in accordance with the Paperwork Reduction Act of 1995

¹⁴⁹ See *George R. Smith, M.D.*, 78 FR 44972, 44979–80 (2013); *Glenn D. Krieger, M.D.*, 76 FR 20020, 20024 (2011); *David A. Hoxie, M.D.*, 69 FR 51477, 51479 (2004); *Maxicare Pharmacy*, 61 FR 27368, 27369 (1996).

(PRA95) [44 U.S.C. 3506(c)(2)(A)]. This program helps to ensure that requested data can be provided in the desired format, reporting burden (time and financial resources) is minimized, collection instruments are clearly understood, and the impact of collection requirements on respondents can be properly assessed. Currently, the Office of Labor-Management Standards (OLMS) of the Department of Labor (Department) is soliciting comments concerning the proposal to amend the information collection request 1245-0003, as well as the Form LM-2, LM-3, and LM-4 Labor Organization Annual Report instructions to require filers of such reports to submit the reports electronically, as well as modify the hardship exemption process for Form LM-2 filers. A copy of the proposed information collection request can be obtained by contacting the office listed below in the addresses section of this Notice.

DATES: Written comments must be submitted to the office listed in the addresses section below on or before July 20, 2015.

ADDRESSES: Andrew R. Davis, Chief of the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue NW., Room N-5609, Washington, DC 20210, olms-public@dol.gov, (202) 693-0123 (this is not a toll-free number), (800) 877-8339 (TTY/TDD).

Please use only one method of transmission (mail or submission via www.regulations.gov using RIN: 1245-AA06) to submit comments or to request a copy of this information collection and its supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden. You may also request a copy of this information collection and its supporting documentation by sending an email to olms-public@dol.gov.

SUPPLEMENTARY INFORMATION:

I. Background

Congress enacted the Labor-Management Reporting and Disclosure Act of 1959, as amended (LMRDA), to provide for the disclosure of information on the financial transactions and administrative practices of labor organizations. The statute also provides, under certain circumstances, for reporting by labor organization officers and employees, employers, labor relations consultants, and surety companies. Section 208 of the LMRDA authorizes the Secretary to issue rules and regulations prescribing

the form of the required reports. The reporting provisions were devised to implement a basic tenet of the LMRDA: The guarantee of democratic procedures and safeguards within labor organizations, which are designed to protect the basic rights of union members.

Pursuant to section 201 of the LMRDA, the Department established annual financial disclosure reports: the Form LM-2, LM-3, and LM-4. These reports detail the receipts, disbursements, assets, and liabilities of covered labor organizations during their previous fiscal year. The Form LM-2 is the most detailed report, for those labor organizations with \$250,000 or more in total annual receipts. The Form LM-3 is available for those labor organizations with fewer than \$250,000 in total annual receipts, and the Form LM-4 is available for those labor organizations with fewer than \$10,000 in total annual receipts.¹

Section 205 of the LMRDA provides that the reports are public information. Filers submit the reports to the Department's Office of Labor-Management Standards (OLMS), pursuant to the OLMS Information Collection Request (ICR), OMB # 1245-0003 (Form LM-1, LM-2, LM-3, LM-4, Simplified Annual Report, LM-10, LM-15, LM-15A, LM-16, LM-20, LM-21, LM-30, and S-1). Currently, filers can submit the Forms LM-2, LM-3, LM-4, and LM-30 electronically through the OLMS free and web-based Electronic Forms System (EFS).² EFS does not rely on third-party software or require the purchase of digital signatures; instead, EFS is a secure, web-based system that uses electronic signatures, which the filing organization's two principal officers register for, along with the union, obtaining a personal identification number (PIN) each year. However, only Form LM-2 filers are currently required to use EFS, although the Form LM-2 instructions provide a temporary and continuing hardship exemption process. Form LM-3 and LM-4 filers, as well as Form LM-30

¹ Pursuant to LMRDA Titles II and III, the Department also established nine other reporting and disclosure forms: The Form LM-1 Information Report; Form LM-10 Employer Report; Forms LM-15, 15-A, and 16 trusteeship reports; Form LM-20 Agreement and Activities Report; Form LM-21 Receipts and Disbursement Report; Form LM-30 Officer and Employee Report; and Form S-1 Surety Report.

² In May 2011, EFS first became available for LM-3 and LM-4 filers, and those unions with fiscal years ending after June 30, 2011 began to take advantage of electronic filing. Prior to this implementation of EFS, few Form LM-3 and LM-4 unions utilized EFS, since they would be required to purchase a digital signature. As stated, EFS is free of charge.

filers, can choose instead to print off the completed form, sign manually, and mail the form to OLMS.

In response to requests from union members, the media, members of Congress, and other interested parties for Internet access to reports filed by unions under the LMRDA, OLMS developed a Web site (<http://www.union-reports.dol.gov>) where individuals may now view union annual financial reports and conduct data searches, displaying the results in a number of preformatted listings, free of charge. OLMS can instantaneously post reports submitted via EFS. Reports submitted via mail must be scanned and then posted, with certain data manually entered.

Authority

The legal authority for this notice is set forth in 35 U.S.C. 3506(c)(2), and sections 203 and 208 of the LMRDA, 29 U.S.C. 432, 438. Section 208 of the LMRDA provides that the Secretary of Labor shall have authority to issue, amend, and rescind rules and regulations prescribing the form and publication of reports required to be filed under Title II of the Act and such other reasonable rules and regulations as he may find necessary to prevent the circumvention or evasion of the reporting requirements. 29 U.S.C. 438. The Secretary has delegated his authority under the LMRDA to the Director of the Office of Labor-Management Standards and permits re-delegation of such authority. See Secretary's Order 8-2009, 74 FR 58835 (Nov. 13, 2009).

Mandatory Electronic Filing of the Forms LM-3 and LM-4

The Department seeks to amend ICR 1245-0003, as well as the Forms LM-3 and LM-4 instructions, to require mandatory electronic filing of these reports, as well as modify the Form LM-2 hardship exemption process to correspond with that proposed for the Form LM-3 and LM-4 reports, which would only permit temporary hardship exemption submissions, not continuing. The Department believes that reasonable changes must be made to the means by which the forms required under LMRDA Title II are filed. The most efficient way to provide meaningful access to this information by interested members of the public is to require that the reports filed by small and medium-sized labor organizations be filed in electronic form. This change will benefit the filers, union members, and the public, as well as the Department.

First, EFS provides significant advantages for filers. Electronic forms

can significantly reduce the burden for filing the Forms LM-3 and LM-4, because they pre-populate a significant amount of informational items and are more efficient for reporting entities. Further, EFS provides error-checking functionality, as well as online, context-sensitive help, which improves the completeness of the reporting. Moreover, a filer can easily acquire a PIN and password and submit the report, free of charge, removing the burden of printing, manually reviewing and signing, and then mailing. As detailed in its last ICR renewal for OMB #1245-0003, Form LM-3 filers will experience a reporting burden hour reduction from an estimated 52 hours to 38.74 hours. With the existing, unchanged 64 recordkeeping burden hours, the total hour burden to complete the Form LM-3 is estimated to be 102.74 hours, a reduction from the previous total of 116 hours. The estimated number of respondents per filer is unchanged, as the proposed changes only affect the method of filing, not the universe of filers. Most labor unions have the information technology resources and capacity to file electronically. Indeed, although no specific data exists regarding the extent to which unions have already embraced the technology necessary to provide reports in electronic form, in 2014, approximately 40% of Form LM-3 unions and 37% of Form LM-4 unions filed their reports electronically. In any event, the Department has also proposed a process for a temporary hardship exemption, whereby filers may apply to temporarily submit paper forms, permitting additional time to complete the report electronically.

Second, EFS offers numerous benefits for the public. In contrast to the efficiency of e-filing, paper reports must be scanned and processed for data entry before they can be posted online for disclosure, which delays their availability for public review. Mandatory e-filing would therefore result in more immediate availability of the reports on the OLMS public disclosure Web site, and improve the efficiency of OLMS in processing the reports and in reviewing them for reporting compliance. Mandatory e-filing will also improve accessibility to the LM-3 and LM-4 forms for people with disabilities. Under Section 508 of the Rehabilitation Act, federal agencies must ensure that members of the public who are disabled and who are seeking information or services from a Federal agency "have access to and use of information and data that is comparable to the access to and use of the

information and data by such members of the public who are not individuals with disabilities." ³ Mandating electronic filing of the Forms LM-3 and LM-4 will help ensure that people with disabilities have access to those forms. Currently, hardcopy submissions of the Forms LM-3 and LM-4 must be scanned and converted to PDF format for posting on the OLMS public disclosure Web site. The scanned reports, which often contain handwritten entries and signatures, would then have to be further processed in order to be made Section 508 compliant. Considering the thousands of reports that are submitted manually every year, the process to make these reports fully accessible would be extremely time-consuming and resource-intensive. Forms filed electronically will be easier and less costly to convert into a format that is accessible to people with disabilities and will facilitate compliance with Section 508.

Third, mandatory e-filing will save the Department resources. Currently, only the Form LM-2 must be submitted to OLMS electronically, and there has been good compliance with this submission requirement. Requiring Form LM-3 and LM-4 reports to be filed electronically using a web-based system provided by OLMS and making the submitted reports available on the Web site will decrease the number of requests for reports that must be handled manually, freeing OLMS staff for other compliance assistance and enforcement work. Furthermore, electronic filing of Form LM-3 and LM-4 reports will enable OLMS to more efficiently sort, review, and analyze data that can be used more effectively for enforcement and compliance assistance purposes.

Overview of Revised Form LM-3 and LM-4 Instructions

Section IV (How to File), Form LM-2 and Form LM-3 Section XI (Completing Form LM-2 or LM-3), and Form LM-4 Section IX (Completing Form LM-4): The instructions in these sections will change to implement mandatory electronic filing. Mandatory electronic filing will minimize the burdens for unions that file the Forms LM-3 or LM-4, and increase efficiency for the Department of Labor as it processes the reports and makes the reports available to union members and the public. The web-based software will pre-populate certain data, perform many calculations, and help ensure the accuracy and completeness of the forms. A union will be permitted to file a paper

format Form LM-3 or LM-4, however, if it claims a temporary hardship exemption. Such process will enable the filer to submit a paper report by the required due date, with an electronic report submitted within ten business days after their required due date. The hardship exemption procedures are modeled after the existing procedures used by Form LM-2 filers, although the Department proposes just a temporary hardship exemption, not a continuing hardship exemption, as Form LM-2 filers have utilized. The Department notes that the continuing hardship exemption process derives from the Department's initial electronic filing system, which was not web-based and required the purchase of a digital signature. The creation of EFS eliminated the problems and costs associated with the prior system, and the Department therefore does not consider the continuing hardship exemption portion of the process to be necessary. The Department therefore also proposes an amendment to the Form LM-2 instructions, eliminating the continuing portion of the hardship exemption process, leaving just the temporary hardship exemption. The temporary hardship exemption process is explained in the instructions to the forms that accompany this notice. The Department invites comments regarding any alternative procedures that might better address problems associated with mandatory electronic filing of the Forms LM-3 and LM-4.

While no other changes to any other forms covered by this ICR are contemplated at this time, the agency seeks comments on any aspect of this information collection. Those comments will be used to revise and extend OMB authorization under the PRA for this information collection.

II. Review Focus: The Department is particularly interested in comments which:

- * 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

³ See 29 U.S.C. 794d(1)(A)(ii).

technological collection techniques or other forms of information technology.

III. Current Actions

The Department seeks to revise this information collection to provide for electronic filing. The information collected by OLMS is used by union members to help self-govern their unions, by workers making decisions regarding their collective bargaining rights, by the general public, and as research material for both outside researchers and within the Department. The information is also used to assist the Department and other government agencies in detecting improper practices on the part of labor organizations, their officers and/or representatives, and is used by Congress in oversight and legislative functions.

Burden Statement

The Department does not anticipate any changes to its burden estimates, as provided in its most recent extension request for OMB #1245-0003.⁴ The only forms affected by this ICR amendment are the Forms LM-3 and LM-4. Further, none of the proposed changes affect the number of respondents. Rather, they would only affect the burden hours per respondent. Additionally, as stated in Part I, the Department already accounted for burden hour and cost savings, associated with EFS filing, in its last ICR revision, as it calculated the burden hour reduction associated with the 2011 implementation of EFS for Form LM-3 and LM-4 filers. Thus, the Department expects all filers to actualize the burden reductions anticipated in 2013, during the most recent ICR renewal, not just the 40% of Form LM-3 filers and 37% of Form LM-4 filers that currently take advantage of EFS.

The total burden for the Labor Organization and Auxiliary Reports information collection is summarized as follows:

Type of Review: Revision.

Agency: DOL-OLMS.

Title of Collection: Labor Organization and Auxiliary Reports.

OMB Control Number: 1245-0003.

Affected Public: Private Sector—businesses or other for-profits, farms, and not-for-profit institutions; and Individuals or Households.

Total Estimated Number of

Responses: 31,501.

Total Estimated Annual Burden Hours: 4,582,392.

Total Estimated Annual Other Costs Burden: \$0.

Comments submitted in response to this notice will be summarized and/or included in the request for the Office of Management and Budget (OMB) approval of the information collection request; they will also become a matter of public record. The Department notes that it has a pending rulemaking concerning two of the reports included in the Labor Organization and Auxiliary Reports information collection: The Form LM-10 Employer Report and the Form LM-20 Agreement and Activities Report filed by labor relations consultants. See 76 FR 37292. The Department received comments on those information collections during the rulemaking, and it will respond to such comments in any final rule issued, as well as in any separate request for amendment to the information collection submitted to OMB in the context of that rulemaking.

Dated: May 14, 2015.

Andrew R. Davis,

Chief of the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor.

[FR Doc. 2015-12272 Filed 5-19-15; 8:45 am]

BILLING CODE P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

[Docket No. OSHA-2015-0008]

OSHA Training Institute (OTI) Education Center Prerequisite Verification Form; Request Office of Management and Budget's (OMB) Approval of Information Collection (Paperwork) Requirements

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

ACTION: Request for public comments.

SUMMARY: OSHA solicits public comments concerning its proposal for completion of a Prerequisite Verification Form for applicants requesting enrollment in Outreach Training Program trainer courses to become an authorized Outreach Training Program trainer and the Office of Management and Budget's (OMB) approval of the information collection requirements specified in the Outreach Training Program Requirements (dated February 2013).

DATES: Comments must be submitted (postmarked, sent, or received) by July 20, 2015.

ADDRESSES:

Electronically: You may submit comments and attachments electronically at <http://www.regulations.gov>, which is the Federal eRulemaking Portal. Follow the instructions online for submitting comments.

Facsimile: If your comments, 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: When using this method, you must submit your comments and attachments to the OSHA Docket Office, Docket No. OSHA-2015-0008, Occupational Safety and Health Administration, U.S. Department of Labor, Room N-2625, 200 Constitution Avenue NW., Washington, DC 20210. Deliveries (hand, express mail, messenger, and courier service) are accepted during the Department of Labor's and Docket Office's normal business hours, 8:15 a.m. to 4:45 p.m., E.T.

Instructions: All submissions must include the Agency name and the OSHA docket number (OSHA-2015-0008) for the Information Collection Request (ICR). 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>. For further information on submitting comments see the "Public Participation" heading in the section of this notice titled **SUPPLEMENTARY INFORMATION**.

Docket: To read or download comments or other material in the docket, go to <http://www.regulations.gov> or the OSHA Docket Office at the address above. All documents in the docket (including this **Federal Register** notice) are listed in the <http://www.regulations.gov> index; however, some information (e.g., copyrighted material) is not publicly available to read or download from the Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. You may also contact Theda Kenney at the address below to obtain a copy of the ICR.

FOR FURTHER INFORMATION CONTACT: Theda Kenney or Todd Owen, Directorate of Standards and Guidance, OSHA, U.S. Department of Labor, Room N-3609, 200 Constitution Avenue NW., Washington, DC 20210; telephone (202) 693-2222.

SUPPLEMENTARY INFORMATION:

I. Background

The Department of Labor, as part of its continuing effort to reduce paperwork

⁴ The Department estimates that Form LM-3 and LM-4 filers will incur a one-time burden of one hour, in order to read the revised instructions and familiarize themselves with EFS.

and respondent (*i.e.*, employer) burden, conducts a preclearance consultation program to provide the public with an opportunity to comment on proposed and continuing information collection requirements in accord with the Paperwork Reduction Act of 1995 (PRA-95) (44 U.S.C. 3506(c)(2)(A)). This program ensures that information is in the desired format, reporting burden (time and costs) is minimal, collection instruments are clearly understood, and OSHA's estimate of the information collection burden is accurate. The Occupational Safety and Health Act of 1970 (the OSH Act) (29 U.S.C. 651 *et seq.*) authorizes information collection by the OSHA Training Institute's (OTI) Education Centers as necessary or appropriate to determine whether an applicant meets the prerequisite requirements for education and safety-related experience to become an authorized Outreach Training Program trainer.

The information collection requirements in the Outreach Training Program Requirements (dated February 2013) provide OTI Education Centers with the ability to determine the training and occupational safety and health experience of an applicant to become an authorized Outreach Training Program trainer to conduct the 10- and 30-hour Outreach Training Program classes for construction, general industry, and maritime, and the disaster site worker class.

II. Special Issues for Comment

OSHA has a particular interest in comments on the following issues:

- Whether the proposed information collection 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 costs) 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 burden on applicants who apply to become authorized Outreach Training Program trainers; for example, by using automated or other technological information collection and transmission techniques.

III. Proposed Actions

The Agency is requesting approval of the OTI Education Center Prerequisite Verification Form. The information collected in the Prerequisite Verification Form will be used by the OTI Education Centers to determine whether an

applicant has met the prerequisite requirements of training and occupational safety and health-related experience to become an authorized Outreach Training Program trainer. Collecting this information prior to allowing an applicant to enroll in the Outreach Training Program trainer courses and become an authorized Outreach Training Program trainer ensures the validity of the Outreach Training Program and reduces the potential for individuals who are inexperienced in the occupational safety and health profession from conducting training through the Outreach Training Program. The Prerequisite Verification Form is provided to all applicants wishing to enroll in the Outreach Training Program trainer courses prior to their enrollment. Applicants are required to have five (5) years of occupational safety and health experience in the construction industry, general industry, or the maritime industry and to have completed the required OSHA standards course prior to their enrollment in the Outreach Training Program trainer course. Upon successful completion of the Outreach Training Program trainer course the applicant is authorized to conduct 10- and 30-hour Outreach Training Program classes in construction, general industry, or maritime, or disaster site worker classes and to provide students with Outreach Training Program class completion cards.

Type of Review: New.

Title: OSHA Training Institute (OTI) Education Center Prerequisite Verification Form.

OMB Control Number: 1218-0NEW.

Affected Public: Individuals.

Number of Respondents: 7,535 average per year.

Frequency of Response: Once.

Total Responses: 7,535 average per year.

Average Time per Response:

Applicants—1 hour, OTI Education Centers—0.5 hour

Estimated Total Burden Hours:

Applicants—7,535 hours per year, OTI Education Centers—3,772 hours per year, Total—11,307 hours per year.

Estimated Cost (Operation and Maintenance): Applicants—\$250,162, OTI Education Centers—\$109,962, Total: \$360,124.

IV. Public Participation—Submission of Comments on this Notice and Internet Access to Comments and Submissions

You may submit comments in response to this document as follows: (1) Electronically at <http://www.regulations.gov>, which is the Federal eRulemaking Portal; (2) by

facsimile; or (3) by hard copy. All comments, attachments, and other material must identify the Agency name and the OSHA docket number for this ICR (Docket No. OSHA-2015-0008). You may supplement electronic submissions by uploading document files electronically. If you wish to mail additional materials in reference to an electronic or facsimile submission, you must submit them to the OSHA Docket Office (see the section of this notice titled **ADDRESSES**). The additional materials must clearly identify your electronic comments by your name, date, and docket number so the Agency can attach them to your comments.

Because of security procedures, the use of regular mail may cause a significant delay in the receipt of comments. For information about security procedures concerning the delivery of materials by hand, express delivery, messenger, or courier service, please contact the OSHA Docket Office at (202) 693-2350, (TTY) (877) 889-5627).

Comments and submissions are posted without change at <http://www.regulations.gov>. Therefore, OSHA cautions commenters about submitting personal information such as their social security number and date of birth. Although all submissions are listed in the <http://www.regulations.gov> index, some information (*e.g.*, copyrighted material) is not publicly available to read or download from this Web site. All submissions, including copyrighted material, are available for inspection and copying at the OSHA Docket Office. Information on using the <http://www.regulations.gov> Web site to submit comments and access the docket is available at the Web site's "User Tips" link. Contact the OSHA Docket Office for information about materials not available from the Web site, and for assistance in using the Internet to locate docket submissions.

V. Authority and Signature

David Michaels, Ph.D., MPH, Assistant Secretary of Labor for Occupational Safety and Health, directed the preparation of this notice. The authority for this notice is the Paperwork Reduction Act of 1995 (44 U.S.C. 3506 *et seq.*) and Secretary of Labor's Order No. 1-2012 (77 FR 3912).

Signed at Washington, DC, on May 15, 2015.

David Michaels,

Assistant Secretary of Labor for Occupational Safety and Health.

[FR Doc. 2015-12244 Filed 5-19-15; 8:45 am]

BILLING CODE 4510-26-P

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

[NARA-2015-038]

Agency Information Collection Activities: Submission for OMB Review; Comment Request**AGENCY:** National Archives and Records Administration (NARA).**ACTION:** Notice.

SUMMARY: NARA gives public notice that it has submitted to OMB for approval the information collection described in this notice. We invite the public to comment on the proposed information collection pursuant to the Paperwork Reduction Act of 1995.

DATES: Submit any written comments to OMB at the address below on or before June 19, 2015.

ADDRESSES: Send comments to Mr. Nicholas A. Fraser, Desk Officer for NARA, by mail to Office of Management and Budget; New Executive Office Building; Washington, DC 20503; by fax to 202-395-5167, or by email to Nicholas_A_Fraser@omb.eop.gov.

FOR FURTHER INFORMATION CONTACT: Contact Tamee Fechhelm by telephone at 301-837-1694 or by fax at 301-713-7409 with requests for additional information or copies of the proposed information collection and supporting statement.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995 (Pub. L. 104-13), NARA invites the public and other Federal agencies to comment on proposed information collections. NARA published a notice of proposed collection for this information collection on December 24, 2014 (79 FR 77534 and 77535). We received no comments. We have submitted the described information collection to OMB for approval. In response to this notice, comments and suggestions should address one or more of the following points: (a) Whether the proposed information collection is necessary for NARA to properly perform its functions; (b) NARA's estimate of the burden of the proposed information collection and its accuracy; (c) ways NARA could enhance the quality, utility, and clarity of the information it collects; (d) ways NARA could minimize the burden on respondents of collecting the information, including through information technology; and (e) whether this collection affects small businesses. In this notice, NARA solicits comments concerning the following information collection:

Title: National Historical Publications and Records Commission (NHPRC)

Grant Program, Budget Form, and Instructions.

OMB number: 3095-0013.

Agency form number: NA Form 17001.

Type of review: Reinstatement of a previously cleared information collection.

Affected public: Nonprofit organizations and institutions, state and local government agencies, and Federally-acknowledged or state-recognized Native American tribes or groups, who apply for and receive NHPRC grants for support of historical documentary editions, archival preservation and planning projects, and other records projects.

Estimated number of respondents: 144 per year submit applications; approximately 45 grantees need to submit revised budgets.

Estimated time per response: 10 hours per application; 5 hours per revised budget.

Frequency of response: On occasion for the application; as needed for revised budget. Currently, the NHPRC considers grant applications 2 times per year. Respondents usually submit no more than one application per year, and, for those who need to submit revised budgets, only one revised budget per year.

Estimated total annual burden hours: 1,665 hours.

Abstract: The NHPRC posts grant announcements to their Web site and to [grants.gov](http://www.grants.gov) (www.grants.gov), where the information will be specific to the grant opportunity named. The basic information collection remains the same. The NA Form 17001 is used by the NHPRC staff, reviewers, and the Commission to determine if the applicant and proposed project are eligible for an NHPRC grant, and whether the proposed project is methodologically sound and suitable for support.

Dated: May 13, 2015.

Swarnali Haldar,

Executive for Information Services/CIO.

[FR Doc. 2015-12211 Filed 5-19-15; 8:45 am]

BILLING CODE 7515-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. 40-1162, NRC-2009-0434]

Western Nuclear, Inc.; Split Rock Conventional Uranium Mill Site**AGENCY:** Nuclear Regulatory Commission.**ACTION:** Approval of indirect transfer of control.

SUMMARY: The U.S. Nuclear Regulatory Commission has approved the indirect transfer of control of Western Nuclear, Inc. (WNI) and Materials License No. SUA-56 from Phelps Dodge Corporation (PDC) to Freeport-McMoRan Copper & Gold, Inc. (Freeport). License No. SUA-56 is for WNI's former Split Rock Conventional Uranium Mill Site near Jeffrey City, Wyoming. The WNI's parent company, PDC (currently named Freeport-McMoRan Corporation), was previously acquired in a reverse triangular merger by Freeport. On March 12, 2007, WNI informed the NRC that PDC would be acquired by Freeport. On March 19, 2007, Freeport acquired the entire interest in PDC, and Freeport now owns 100 percent of PDC. On July 22, 2009, WNI requested NRC approval of an indirect transfer of control with respect to its Materials License No. SUA-56. The NRC has determined that, although the licensee was required to obtain NRC consent prior to the indirect transfer of control, the indirect transfer of control of the license is otherwise consistent with applicable provisions of law and NRC regulations. Therefore, the NRC has approved the indirect transfer of control.

DATES: May 20, 2015.

ADDRESSES: Please refer to Docket ID NRC-2009-0434 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-2009-0434. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; email: 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. The ADAMS accession number for each document referenced (if it 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:

Dominick Orlando, Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001; telephone: 301-415-6749, email: Dominick.orlando@nrc.gov.

SUPPLEMENTARY INFORMATION: The WNI is the holder of NRC Materials License No. SUA-56 for its former Split Rock Conventional Uranium Mill Site near Jeffrey City, Wyoming. The WNI has been an NRC licensee since 1958. The Split Rock Site ceased active uranium recovery operations in 1987 and has been engaging in final site reclamation activities since then. In 1971, WNI became a wholly owned subsidiary of PDC.

On March 12, 2007, WNI informed the NRC that the PDC would be acquired by Freeport (ADAMS Accession No. ML071080087). On September 5, 2007, WNI informed the NRC that the acquisition of WNI by Freeport had occurred (ADAMS Accession No. ML072710031). By letter dated July 22, 2009, WNI submitted a request to the NRC for Consent to Indirect License Transfer of NRC Materials License No. SUA-56 (ADAMS Accession No. ML092100247). On October 13, 2009, the NRC issued a notice of application for indirect change of control and provided interested individuals an opportunity to request a hearing (74 FR 52510).

On December 30, 2009, the NRC requested additional information from WNI on the indirect change of control (ADAMS Accession Nos. ML093480467 and ML093480453). The WNI responded on May 7, 2010 (the NRC staff was unable to locate this response in ADAMS and a copy was provided by WNI on January 13, 2015 (ADAMS Accession No. ML15036A423)). On July 27, 2010, the NRC requested additional information from WNI on the indirect change of control (ADAMS Accession No. ML102040700). On June 24, 2011, WNI provided information in response to the request for additional information (ADAMS Accession No. ML111860086). On December 2, 2014, the NRC requested additional information from WNI on the indirect change of control (ADAMS Accession No. ML14301A290). The WNI responded to the NRC's request on January 13, 2015 (ADAMS Package Accession No. ML15036A423).

The WNI's Materials License No. SUA-56 was issued under part 40 of

Title 10 of the *Code of Federal Regulations* (10 CFR), "Domestic Licensing of Source Material." The Commission is required by 10 CFR 40.46 to determine if the change of control is in accordance with the provisions of the Atomic Energy Act of 1954, as amended and to give its consent in writing.

The NRC staff reviews requests for license transfers using the guidance in NUREG 1556, Volume 15, "Consolidated Guidance About Materials Licenses-Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses," dated November 2000 (NUREG 1556, Vol. 15) (ADAMS Accession No. ML003778305). The purpose of the review is to determine whether the licensee, under the transaction, would continue to meet the regulatory requirements necessary to establish adequate financial assurance for decommissioning as required by 10 CFR part 40. As discussed in NUREG-1556, Volume 15, the NRC uses the term "change of control" rather than the statutory term "transfer" to describe the variety of events that could require prior notification and written consent of the NRC. The central issue is whether the authority over the license has changed. The WNI's request for consent to indirect change of control describes an indirect change of control resulting from a merger between PDC, WNI's former parent company, and Freeport. Following the merger, WNI became a wholly owned subsidiary of Freeport and, as such, the transfer requires NRC consent.

The NRC staff reviewed WNI's request for consent to an indirect change in control of its 10 CFR part 40 license using the guidance in NUREG 1556, Vol. 15. The NRC staff finds that the information submitted by WNI sufficiently describes and documents the commitments made by Freeport is consistent with the guidance in NUREG-1556, Vol. 15. An environmental assessment for this action is not required because this action is categorically excluded under 10 CFR 51.22(c)(21).

Based on the review summarized above, the NRC has approved the indirect change of control, although the licensee was required to obtain NRC consent prior to the indirect change of control occurring. The licensee has further committed in its next parent company guarantee submission to provide a parent company guarantee issued by Freeport to cover the remaining site reclamation costs. The WNI's request meets the requirements of

10 CFR 40.46(b)(1) and (2) as the request includes the identity and technical and financial qualifications of the proposed transferee, and WNI has committed to provide revised financial assurance for decommissioning, during the next parent company guarantee submittal, naming Freeport as parent company guarantor for the reclamation costs at the Split Rock Site.

Dated at Rockville, Maryland, this 5th day of May 2015.

For the Nuclear Regulatory Commission.

Larry W. Camper,

Director, Division of Decommissioning, Uranium Recovery and Waste Programs, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 2015-12266 Filed 5-19-15; 8:45 am]

BILLING CODE 7590-01-P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-336; NRC-2015-0125]

Dominion Nuclear Connecticut, Inc., Millstone Power Station, Unit 2

AGENCY: Nuclear Regulatory Commission.

ACTION: Exemption; issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing an exemption in response to an April 11, 2014, request from Dominion Nuclear Connecticut, Inc., requesting an exemption to use a different fuel rod cladding material (M5™, hereafter referred as M5).

DATES: May 20, 2015.

ADDRESSES: Please refer to Docket ID NRC-2015-0125 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-2015-0125. Address questions about NRC dockets to Carol Gallagher; telephone: 301-415-3463; email: 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. The ADAMS accession number for each document referenced (if it 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:

Richard V. Guzman, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington DC 20555-0001; telephone: 301-415-1030, email: Richard.guzman@nrc.gov.

I. Background

Dominion Nuclear Connecticut, Inc. (the licensee) is the holder of Renewed Facility Operating License No. DPR-65, which authorizes operation of Millstone Power Station, Unit 2 (MPS2), a pressurized water reactor. The license provides, among other things, that the facility is subject to all rules, regulations, and orders of the NRC now or hereafter in effect.

The MPS2 shares the site with Millstone Power Station, Unit 1, a permanently defueled boiling water reactor nuclear unit, and Millstone Power Station, Unit 3, a pressurized water reactor. The facility is located in Waterford, Connecticut, approximately 3.2 miles west southwest of New London, Connecticut. This exemption applies to MPS2 only. The other units, Units 1 and 3, are not covered by this exemption.

II. Request/Action

Pursuant to section 50.12 of Title 10 of the *Code of Federal Regulations* (10 CFR), "Specific exemptions," the licensee has, by letter dated April 11, 2014 (ADAMS Accession No. ML14112A072), requested an exemption from 10 CFR 50.46, "Acceptance criteria for emergency core cooling systems [ECCS] for light-water nuclear power reactors," and 10 CFR part 50, appendix K, "ECCS Evaluation Models," to allow the use of fuel rod cladding with M5 alloy for future reload applications. The regulations in 10 CFR 50.46 contain acceptance criteria for the ECCS for reactors fueled with Zircaloy or ZIRLO® fuel rod cladding material. In addition, paragraph I.A.5 of appendix K to 10 CFR part 50 requires that the Baker-Just equation be used to predict the rates of energy release, hydrogen concentration, and cladding oxidation from the metal/water reaction. The Baker-Just equation

assumes the use of a zirconium alloy, which is a material different from M5. Thus, the strict application of these regulations does not permit the use of fuel rod cladding material other than Zircaloy or ZIRLO®. Because the material specifications of M5 differ from the specifications for Zircaloy or ZIRLO®, and the regulations specify a cladding material other than M5, a plant-specific exemption is required to allow the use of, and application of these regulations to, M5 at MPS2.

The exemption request relates solely to the cladding material specified in these regulations (*i.e.*, fuel rods with Zircaloy or ZIRLO® cladding material). This exemption would allow application of the acceptance criteria of 10 CFR 50.46 and appendix K to 10 CFR part 50, to fuel assembly designs using M5 fuel rod cladding material. The licensee is not seeking an exemption from the acceptance and analytical criteria of these regulations. The intent of the request is to allow the use of the criteria set forth in these regulations for the use of M5 fuel rod cladding material at MPS2. The detailed technical basis of the licensee's proposed use of M5 cladding is being addressed by the Nuclear Regulatory Commission staff under a proposed amendment to the MPS2 operating license; the amendment is issued concurrently with the issuance of this exemption.

III. Discussion

Pursuant to 10 CFR 50.12, the Commission may, upon application by any interested person or upon its own initiative, grant exemptions from the requirements of 10 CFR part 50 when: (1) The exemptions are authorized by law, will not present an undue risk to public health or safety, and are consistent with the common defense and security; and (2) when special circumstances are present. Under 10 CFR 50.12(a)(2)(ii), special circumstances include, among other things, when application of the specific regulation in the particular circumstance would not serve, or is not necessary to achieve, the underlying purpose of the rule.

A. Special Circumstances

Special circumstances, in accordance with 10 CFR 50.12(a)(2)(ii), are present whenever application of the regulation in the particular circumstances is not necessary to achieve the underlying purpose of the rule. The underlying purpose of 10 CFR 50.46 and appendix K to 10 CFR part 50 is to establish acceptance criteria for ECCS performance to provide reasonable assurance of safety in the event of a loss-

of-coolant accident (LOCA). Although the regulations in 10 CFR 50.46 and appendix K to 10 CFR part 50 are not expressly applicable to M5 alloy cladding, the evaluations described in the following sections of this exemption show that the purpose of the regulations are met by this exemption, in that the effectiveness of the ECCS will not be affected by a change from Zircaloy or ZIRLO® clad fuel rod to M5 clad fuel rod. Normal reload safety analyses will confirm that there is no adverse impact on ECCS performance. Thus, a strict application of the rule (which would preclude the applicability of ECCS performance acceptance criteria to, and the use of, M5 fuel cladding material) is not necessary to achieve the underlying purposes of 10 CFR 50.46 and appendix K to 10 CFR part 50. The purpose of these regulations is achieved through application of the requirements to the use of M5 fuel rod clad material. Therefore, the special circumstances required by 10 CFR 50.12(a)(2)(ii) for the granting of an exemption exist.

B. Authorized by Law

This exemption would allow the use of M5 fuel rod cladding material for future reload operations at MPS2. As stated above, 10 CFR 50.12 allows the NRC to grant exemptions from the requirements of 10 CFR part 50 provided that special circumstances are present. As described above, the NRC staff has determined that special circumstances exist to grant the requested exemption. In addition, granting the exemption will not result in a violation any part of the Atomic Energy Act of 1954, as amended, or the Commission's regulations. Therefore, the exemption is authorized by law.

C. No Undue Risk to Public Health and Safety

Section 10 CFR 50.46 requires that each boiling or pressurized light-water nuclear power reactor fueled with uranium dioxide pellets within cylindrical Zircaloy or ZIRLO® cladding must be provided with an ECCS that must be designed so that its calculated cooling performance following a postulated LOCA conforms to the criteria set forth in paragraph (B) of this section. The underlying purpose of 10 CFR 50.46 is to establish acceptance criteria for adequate ECCS performance.

The NRC-approved topical report BAW-10227(P)-A, "Evaluation of Advanced Cladding and Structural Material (M5) in PWR Reactor Fuel" (ADAMS Accession No. ML003686365) has demonstrated that predicted chemical, mechanical, and material performance characteristics of the M5

alloy cladding are bound for those approved for Zircaloy under anticipated operational occurrences and postulated accidents. The NRC staff's Safety Evaluation (ADAMS Accession No. ML003671021) evaluating this topical report concluded that the M5 properties and mechanical design methodology are acceptable for fuel reload licensing applications. Topical report BAW-10227(P)-A also confirms that no new or different type of accident will be initiated that could pose a risk to public health and safety.

The NRC-approved topical Report BAW-10240(P)-A, Revision 0, "Incorporation of M5 Properties in Framatome-ANP Approved Methods" (ADAMS Accession No. ML042800314) describes the incorporation of the NRC-approved M5 material properties in a set of mechanical analyses, small-break loss-of-coolant accident (SBOCA) and non-LOCA methodologies. This topical report demonstrates that the effectiveness of the ECCS will not be affected by changing the cladding from Zircaloy to M5 alloy.

The objective of 10 CFR 50.46(b)(2) and (b)(3), and appendix K to 10 CFR part 50, paragraph I.A.5 is to ensure that cladding oxidation and hydrogen generation are appropriately limited during a LOCA and conservatively accounted for in a plant's ECCS evaluation model. Paragraph I.A.5 of appendix K requires that the Baker-Just equation be used in the ECCS evaluation model to determine the rate of energy release, cladding oxidation, and hydrogen generation. Based on the above, the NRC staff concludes that the intent of 10 CFR 50.46 and appendix K to 10 CFR part 50 will continue to be satisfied for the planned operation of MPS2 with M5 alloy fuel cladding and fuel assembly material.

D. Consistent With the Common Defense and Security

The M5 cladding material is similar in design to Zircaloy, the current cladding material used at MPS2. Thus, the change in cladding material from Zircaloy to M5 will not require any change to the security and control of special nuclear material. The licensee will continue to be required to handle and control special nuclear material in these assemblies in accordance with its approved procedures. This change to reactor core internals is adequately controlled by NRC requirements and is not related to security issues. Therefore, the NRC staff determined that this exemption does not impact, and thus is consistent with, the common defense and security.

E. Environmental Considerations

The NRC staff determined that the exemption discussed herein meets the eligibility criteria for the categorical exclusion set forth in 10 CFR 51.22(c)(9) because it is related to a requirement concerning the installation or use of a facility component located within the restricted area, as defined in 10 CFR part 20, and issuance of this exemption involves: (i) no significant hazards consideration, (ii) no significant change in the types or a significant increase in the amounts of any effluents that may be released offsite, and (iii) no significant increase in individual or cumulative occupational radiation exposure. Therefore, in accordance with 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the NRC's consideration of this exemption request. The basis for the NRC staff's determination is discussed as follows with an evaluation against each of the requirements in 10 CFR 51.22(c)(9)(i)-(iii).

Requirements in 10 CFR 51.22(c)(9)(i)

The NRC staff evaluated whether the exemption involves no significant hazards consideration using the standards described in 10 CFR 50.92(c), as presented below:

1. Does the proposed exemption involve a significant increase in the probability or consequences of an accident previously evaluated?

Response: No.

The proposed exemption would allow the use of M5 fuel rod cladding material in the MPS2 reactor. The NRC approved topical reports cited above demonstrate that M5 alloy has similar properties as the currently licensed Zircaloy. The fuel cladding itself is not a postulated initiator of previously evaluated accidents; thus, fuel cladding material does not affect the probability of occurrence of any accident. The consequences of none of the previously evaluated accidents were affected by fuel cladding material, and M5, likewise, is not expected to have any effect on the consequences of any previously evaluated accidents.

Therefore, the proposed exemption does not involve a significant increase in the probability or consequences of an accident previously evaluated.

2. Does the proposed exemption create the possibility of a new or different kind of accident from any accident previously evaluated?

Response: No.

The use of M5 fuel rod cladding material will not result in changes in the operation or configuration of the

facility. The above cited topical reports demonstrated that the material properties of M5 are similar to those of standard Zircaloy. Therefore, M5 fuel rod cladding material will perform similarly to those fabricated from standard Zircaloy. The fuel cladding itself is not a postulated initiator of previously evaluated accidents and does not create the possibility of a new or different kind of accident.

Therefore, the proposed exemption does not create the possibility of a new or different kind of accident from any previously evaluated.

3. Does the proposed exemption involve a significant reduction in a margin of safety?

Response: No.

The proposed exemption will not involve a significant reduction in the margin of safety because it has been demonstrated that the material properties of the M5 alloy are not significantly different from those of standard Zircaloy. M5 alloy is expected to perform similarly to standard Zircaloy for all normal operating and accident scenarios. Use of M5 alloy does not require changing any of the current regulatory acceptance criteria, or relaxation of the methods of analysis.

Therefore, the proposed exemption does not involve a significant reduction in a margin of safety.

Based on the above evaluation of the standards set forth in 10 CFR 50.92(c), the NRC staff concludes that the proposed exemption involves no significant hazards consideration. Accordingly, the requirements of 10 CFR 51.22(c)(9)(i) are met.

Requirements in 10 CFR 51.22(c)(9)(ii)

The proposed exemption would allow the use of M5 fuel rod cladding material in the MPS2 reactor. M5 alloy has similar material properties and performance characteristics as the currently licensed Zircaloy cladding. Thus, the use of M5 fuel rod cladding material will not significantly change the types of effluents that may be released offsite, or significantly increase the amount of effluents that may be released offsite. Therefore, the requirements of 10 CFR 51.22(c)(9)(ii) are met.

Requirements in 10 CFR 51.22(c)(9)(iii)

The proposed exemption would allow the use of M5 fuel rod cladding material in the reactors. M5 alloy has similar material properties and performance characteristics as the currently licensed Zircaloy cladding. Thus, the use of M5 fuel rod cladding material will not significantly increase individual occupational radiation exposure, or

significantly increase cumulative occupational radiation exposure. Therefore, the requirements of 10 CFR 51.22(c)(9)(iii) are met.

Conclusion

Based on the above, the NRC staff concludes that the proposed exemption meets the eligibility criteria for the categorical exclusion set forth in 10 CFR 51.22(c)(9). Therefore, in accordance with 10 CFR 51.22(b), no environmental impact statement or environmental assessment need be prepared in connection with the NRC's proposed issuance of this exemption.

IV. Conclusions

Accordingly, the Commission has determined that, pursuant to 10 CFR 50.12, the exemption is authorized by law, will not present an undue risk to the public health and safety, and is consistent with the common defense and security. Also, special circumstances pursuant to 10 CFR 50.12(a)(2)(ii) are present. Therefore, the Commission hereby grants Dominion Nuclear Connecticut, Inc., an exemption from the requirements of 10 CFR 50.46 and Appendix K to 10 CFR part 50, to allow the application of those criteria to, and the use of, M5 fuel rod cladding material at MPS2.

This exemption is effective upon issuance.

Dated at Rockville, Maryland, this 12th Day of May, 2015.

For the Nuclear Regulatory Commission

Louise Lund,

Acting Director, Division of Operating Reactor Licensing, Office of Nuclear Reactor Regulation.

[FR Doc. 2015-12264 Filed 5-19-15; 8:45 am]

BILLING CODE 7590-01-P

POSTAL REGULATORY COMMISSION

[Docket No. CP2015-9; Order No. 2483]

New Postal Product

AGENCY: Postal Regulatory Commission.
ACTION: Notice.

SUMMARY: The Commission is noticing a recent Postal Service filing concerning a modification to a 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:* May 21, 2015.

ADDRESSES: Submit comments electronically via the Commission's Filing Online system at <http://www.prc.gov>.

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 Filing
- III. Ordering Paragraphs

I. Introduction

On May 13, 2015, the Postal Service filed notice that it has agreed to a Modification to the existing Global Expedited Package Services 3 negotiated service agreement approved in this docket.¹ In support of its Notice, the Postal Service includes a redacted copy of the Modification and a certification of compliance with 39 U.S.C. 3633(a), as required by 39 CFR 3015.5. Notice, Attachments 1 and 2.

The Postal Service also filed the unredacted Modification and supporting financial information under seal. Notice at 1. 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 1-2.

The Modification adds a new paragraph to Article 5 addressing the use of permit imprints, adds a new paragraph to Article 5 (text under seal), revises the minimum commitment in Article 11, and replaces Annex 2 (price charts). *Id.* at 1. The Postal Service intends the rates in the Modification to take effect June 1, 2015. *Id.* at 1. The Postal Service asserts that the Modification will not impair the ability of the contract to comply with 39 U.S.C. 3633. *Id.* Attachment 2.

II. Notice of Filing

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 May 21, 2015. The public portions of these filings can be accessed via the Commission's Web site (<http://www.prc.gov>).

The Commission appoints Lyudmila Y. Bzhilyanskaya to represent the

¹ Notice of the United States Postal Service of Filing Modification to Global Expedited Package Services 3 Negotiated Service Agreement, May 13, 2015 (Notice).

interests of the general public (Public Representative) in this docket.

III. Ordering Paragraphs

It is ordered:

1. The Commission reopens Docket No. CP2015-9 for consideration of matters raised by the Postal Service's Notice.

2. Pursuant to 39 U.S.C. 505, the Commission appoints Lyudmila Y. Bzhilyanskaya 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 May 21, 2015.

4. The Secretary shall arrange for publication of this order in the **Federal Register**.

By the Commission.

Shoshana M. Grove,

Secretary.

[FR Doc. 2015-12119 Filed 5-19-15; 8:45 am]

BILLING CODE 7710-FW-P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Microbiome Research

ACTION: Notice of Request for Information

SUMMARY: Advanced sequencing technologies have illuminated vast networks of microorganisms that drive essential functions in all environments on Earth. The study of these communities of microorganisms, or microbiomes, is nascent, and the potential of microbiome research has only begun to be tapped. Primary to achieving this potential is a functional understanding of microbiomes, which would be greatly advanced by addressing fundamental questions common to all fields of microbiome research; developing platform technologies useful to all fields; and identifying gaps in training or fields of research that should be addressed. The Office of Science and Technology Policy (OSTP) is interested in developing an effort to unify and focus microbiome research across sectors. The views of stakeholders—academic and industry researchers, private companies, and charitable foundations—are important to inform an understanding of current and future needs in diverse fields.

DATES: Responses must be received by June 15, 2015, to be considered.

ADDRESSES: You may submit comments by any of the following methods:

- *Email:* MicrobiomeRFT@ostp.eop.gov.

Include [*Microbiome RFT*] in the subject line of the message.

• *Fax:* (202) 456-6027, Attn: Elizabeth Stulberg.
 • *Mail:* Attn: Elizabeth Stulberg, Office of Science and Technology Policy, Eisenhower Executive Office Building, 1650 Pennsylvania Ave., NW., Washington, DC 20504.

Instructions: Electronic responses must be provided as attachments to an email. It is recommended that attachments with file sizes exceeding 25MB be compressed (*i.e.*, zipped) to ensure message delivery. Please identify your answers by responding to a specific question or topic if possible. Respondents may answer as many or as few questions as they wish. Comments of up to two pages or fewer (1,000 words) are requested; longer responses will not be considered. Any information obtained as a result of this RFI is intended to be used by the Government on a non-attribution basis for planning and strategy development. OSTP will not respond to individual submissions. A response to this RFI will not be viewed as a binding commitment to develop or pursue the project or ideas discussed. OSTP will not pay for information provided under this RFI. This RFI is not accepting applications for financial assistance or financial incentives. OSTP requests that no proprietary information, copyrighted information, or personally identifiable information be submitted in response to this RFI.

FOR FURTHER INFORMATION CONTACT: Elizabeth Stulberg at *MicrobiomeRFI@ostp.eop.gov*, (202) 456-4444.

SUPPLEMENTARY INFORMATION: The purpose of this RFI is to solicit feedback from industry, academia, research laboratories, and other stakeholder groups on both the overarching questions that unite all microbiome research and the tools, technologies, and training that are needed to answer these questions. OSTP is specifically interested in information that corresponds to the mission statements of multiple Federal agencies, private sector interests, and current White House Policy Initiatives. In particular, respondents may wish to address the following topics:

- What are the most pressing, fundamental questions in microbiome research, common to most or all fields?
- Over the next ten years, what are the most important research gaps that must be addressed to advance this field?
- What tools, platform technologies, or technological advances would propel microbiome research from correlative to predictive?
- What crucial types of scientific and technical training will be needed to take

advantage of harnessing the microbiome's potential?

- What fields of microbiome research are currently underfunded or underrepresented?

- What specific steps could be taken by the federal government, research institutes, universities, and philanthropies to encourage multi-disciplinary microbiome research?

- Is there any additional information, not requested above, that you believe OSTP should consider in identifying crucial areas of microbiome research?

Ted Wackler,

Deputy Chief of Staff and Assistant Director.

[FR Doc. 2015-12191 Filed 5-19-15; 8:45 am]

BILLING CODE 3270-F5-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-74970; File No. SR-ISE-2015-14]

Self-Regulatory Organizations; International Securities Exchange, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Schedule of Fees To Introduce a New “Retail” Designation for Priority Customer Orders

May 14, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the “Act”),¹ and Rule 19b-4 thereunder,² notice is hereby given that on April 29, 2015, the International Securities Exchange, LLC (the “Exchange” or the “ISE”) filed with the Securities and Exchange Commission the proposed rule change, as described in Items I, II, and III below, which items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The ISE proposes to amend the Schedule of Fees to introduce a new “Retail” designation for Priority Customer orders. The text of the proposed rule change is available on the Exchange's Web site (<http://www.ise.com>), at the principal office of the Exchange, and at the Commission's Public Reference Room.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Schedule of Fees to introduce a new “Retail” designation for Priority Customer orders. A “Priority Customer” is a person or entity that is not a broker/dealer in securities, and does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s), as defined in Rule 100(a)(37A). This market participant type is one of six currently recognized for purposes of determining applicable fees and rebates, along with: Market Maker,³ Non-ISE Market Maker,⁴ Firm Proprietary,⁵ Broker-Dealer,⁶ and Professional Customer.⁷ The Priority Customer designation was adopted by the Exchange to provide competitive pricing and market structure advantages to retail investors, and to level the playing field between retail investors and market professionals. As such, Priority Customer orders executed on the Exchange are generally afforded more favorable fees and rebates than other market participants, including Professional Customers. The Exchange now believes that it is appropriate to introduce a further distinction between

³ The term “Market Makers” refers to “Competitive Market Makers” and “Primary Market Makers” collectively. See Rule 100(a)(25).

⁴ A “Non-ISE Market Maker” is a market maker as defined in Section 3(a)(38) of the Securities Exchange Act of 1934, as amended, registered in the same options class on another options exchange. See Schedule of Fees, Preface.

⁵ A “Firm Proprietary” order is an order submitted by a member for its own proprietary account. See Schedule of Fees, Preface.

⁶ A “Broker-Dealer” order is an order submitted by a member for a broker-dealer account that is not its own proprietary account. See Schedule of Fees, Preface.

⁷ A “Professional Customer” is a person or entity that is not a broker/dealer and is not a Priority Customer. See Schedule of Fees, Preface.

market participants that fall within the definition of Priority Customer.

In particular, the Exchange proposes to introduce a new "Retail" designation for Priority Customer orders for the purpose of determining applicable fees and rebates. As proposed, a Retail order is a Priority Customer order that originates from a natural person, provided that no change is made to the terms of the order with respect to price or side of market and the order does not originate from a trading algorithm or any other computerized methodology. The proposed definition of a Retail order is designed to mirror a similar concept introduced by the New York Stock Exchange ("NYSE"), NYSE Amex ("Amex"), and other equities exchanges to promote price improvement for orders submitted by retail investors.⁸ The proposed rule change, however, is intended to provide benefits to retail options investors in the form of more favorable pricing rather than market structure changes.⁹ While the Exchange is not amending fees and rebates applicable to Priority Customer orders that are designated Retail at this time, the Exchange intends to introduce special fees and rebates for Retail orders at a later date, such that Retail orders will potentially be entitled to the most favorable fees and rebates available on the Exchange. Until such time, Retail orders will be charged the same fees and provided the same rebates as other Priority Customer orders.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.¹⁰ In particular, the proposal is consistent with Section 6(b)(5) of the Act,¹¹ because it is designed to promote just and equitable principles of trade,

⁸ See Securities Exchange Act Release No. 67347 (July 3, 2012), 77 FR 40673 (July 10, 2012) (SR-NYSE-2011-55; SR-NYSEAmex-2011-84) (Approval Order). See also NYSE and Amex Rule 107C(a)(3).

NYSE and Amex define a "Retail Order" as an agency order or a riskless principal order that meets the criteria of FINRA Rule 5320.03 that originates from a natural person and is submitted to the Exchange by a Retail Member Organization, provided that no change is made to the terms of the order with respect to price or side of market and the order does not originate from a trading algorithm or any other computerized methodology.

⁹ In addition, the Exchange notes that unlike the related equities programs, all members will be eligible to mark orders as Retail provided that the orders meet the requirements discussed above.

¹⁰ 15 U.S.C. 78f(b).

¹¹ 15 U.S.C. 78f(b)(5).

remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

Specifically, the proposed rule change will allow the Exchange to potentially offer more favorable fees and rebates to Retail orders that originate from natural persons. Currently, the Exchange distinguishes between orders executed for two categories of Public Customer:¹² Priority and Professional Customers. Priority Customers are distinguished from Professional Customers by the requirement that they not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). Because of this limitation, Priority Customer orders are generally afforded more favorable fees and rebates than market professionals, including Professional Customers. The Exchange now believes that it is appropriate to distinguish further between orders that originate from a natural person (*i.e.*, Retail orders) and other Priority Customer orders.

The equities markets already provide benefits to order flow that originates from a natural person and not a trading algorithm or any other computerized methodology. The Exchange believes that the proposed definition of a Retail order is appropriate as it is substantially similar to the definition already used in the equities context, and is therefore already familiar to market participants. The Exchange notes, however, that unlike equities exchanges such as NYSE and Amex, it is not proposing any market structure changes at this time to accompany the introduction of a Retail designation for Priority Customer orders. All Priority Customer orders will continue to benefit from the current market structure benefits that they receive on the Exchange. In addition, Priority Customer orders other than Retail orders will continue to benefit from pricing that is generally more favorable than pricing adopted for Professional Customer and non-Customer orders.

By adopting a definition of Retail order, the Exchange hopes to be able to offer potentially more favorable fees and rebates to retail investors. The Exchange believes that this will advance the goals identified when the Exchange first introduced the Priority Customer designation, by providing genuine retail investors with the best prices available on the Exchange. In this regard, the Exchange notes that the fees and rebates

¹² A "Public Customer" is a person or entity that is not a broker or dealer in securities. See Rule 100(a)(38).

for Retail orders will initially be the same as fees and rebates for other Priority Customer orders; however, the Exchange will introduce additional pricing advantages for Retail orders at a later date pursuant to a proposed rule change filed with the Commission.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,¹³ the Exchange does not believe that the proposed rule change will impose any burden on intermarket or intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the Exchange believes the proposed Retail designation is an innovative change that evidences strong competition between options markets. In particular, the proposed rule change is designed to allow the Exchange to potentially offer the most favorable fees and rebates available to Retail orders that originate from natural persons. The Exchange operates in a highly competitive market in which market participants can readily direct their order flow to competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and rebates to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed changes reflect this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange believes that the foregoing proposed rule change may take effect upon filing with the Commission pursuant to Section 19(b)(3)(A)¹⁴ of the Act and Rule 19b-4(f)(6) thereunder¹⁵ because the foregoing proposed rule change does not (i) significantly affect the protection of investors or the public interest, (ii) impose any significant burden on competition, and (iii) become operative for 30 days after its filing date, or such

¹³ 15 U.S.C. 78f(b)(8).

¹⁴ 15 U.S.C. 78s(b)(3)(A).

¹⁵ 17 CFR 240.19b-4(f)(6).

shorter time as the Commission may designate. The Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five business days prior to the date of filing the proposed rule change.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposal is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an Email to rule-comments@sec.gov. Please include File No. SR-ISE-2015-14 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549.

All submissions should refer to File No. SR-ISE-2015-14. 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 changes between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official

business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the ISE. 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 No. SR-ISE-2015-14 and should be submitted on or before June 10, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁶

Robert W. Errett,
Deputy Secretary.

[FR Doc. 2015-12149 Filed 5-19-15; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

Notice is hereby given, pursuant to the provisions of the Government in the Sunshine Act, Public Law 94-409, that the Securities and Exchange Commission will hold a Closed Meeting on Tuesday, May 19, 2015 at 3:30 p.m.

Commissioners, Counsel to the Commissioners, the Secretary to the Commission, and recording secretaries will attend the Closed Meeting. Certain staff members who have an interest in the matters also may be present.

The General Counsel of the Commission, or her designee, has certified that, in her opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(3), (5), (7), 9(B) and (10) and 17 CFR 200.402(a)(3), (5), (7), 9(ii) and (10), permit consideration of the scheduled matter at the Closed Meeting.

Commissioner Stein, as duty officer, voted to consider the items listed for the Closed Meeting in closed session, and determined that Commission business required consideration earlier than one week from today. No earlier notice of this Meeting was practicable.

The subject matter of the Closed Meeting will be:

- Institution of injunctive actions;
- Institution and settlement of administrative proceedings; and
- Other matters relating to enforcement proceedings.

At times, changes in Commission priorities require alterations in the scheduling of meeting items.

For further information and to ascertain what, if any, matters have been

added, deleted or postponed, please contact the Office of the Secretary at (202) 551-5400.

Dated: May 18, 2015.

Jill M. Peterson,
Assistant Secretary.

[FR Doc. 2015-12380 Filed 5-18-15; 4:15 pm]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

Submission for OMB Review; Comment Request

Upon Written Request, Copies Available From: Securities and Exchange Commission, Office of FOIA Services, 100 F Street NE., Washington, DC 20549-2736.

Extension:

Rule 17a-6; SEC File No. 270-433, OMB Control No. 3235-0489.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 ("PRA") (44 U.S.C. 3501 *et seq.*), the Securities and Exchange Commission ("Commission") has submitted to the Office of Management and Budget ("OMB") a request for extension of the previously approved collection of information provided for in Rule 17a-6 (17 CFR 240.17a-6) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*).

Rule 17a-6 permits national securities exchanges, national securities associations, registered clearing agencies, and the Municipal Securities Rulemaking Board ("MSRB") (collectively, "SROs") to destroy or convert to microfilm or other recording media records maintained under Rule 17a-1, if they have filed a record destruction plan with the Commission and the Commission has declared such plan effective.

There are currently 29 SROs: 18 national securities exchanges, 1 national securities association, the MSRB, and 9 registered clearing agencies. Of the 29 SROs, only 2 SRO respondents have filed a record destruction plan with the Commission. The staff calculates that the preparation and filing of a new record destruction plan should take 160 hours. Further, any existing SRO record destruction plans may require revision, over time, in response to, for example, changes in document retention technology, which the Commission estimates will take much less than the 160 hours estimated for a new plan. The Commission estimates that each SRO that has filed a destruction plan will spend approximately 30 hours per year making required revisions. Thus, the

¹⁶ 17 CFR 200.30-3(a)(12).

total annual compliance burden is estimated to be 60 hours per year based on two respondents. The approximate compliance cost per hour is \$380, resulting in a total internal cost of compliance for these respondents of \$22,800 per year (60 hours @ \$380 per hour).

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information under the PRA unless it displays a currently valid OMB control number.

The public may view background documentation for this information collection at the following Web site: www.reginfo.gov. Comments should be directed to: (i) Desk Officer for the Securities and Exchange Commission, Office of Information and Regulatory Affairs, Office of Management and Budget, Room 10102, New Executive Office Building, Washington, DC 20503, or by sending an email to: [Shagufta Ahmed@omb.eop.gov](mailto:ShaguftaAhmed@omb.eop.gov); and (ii) Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549, or by sending an email to: PRA_Mailbox@sec.gov. Comments must be submitted to OMB within 30 days of this notice.

Dated: May 14, 2015.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015-12152 Filed 5-19-15; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-74964; File No. SR-C2-2015-010]

Self-Regulatory Organizations; C2 Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Regarding Limitation of Liability

May 14, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on May 5, 2015, C2 Options Exchange, Incorporated (the "Exchange" or "C2") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Commission is publishing this notice to

solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend its Rule 6.42 governing Exchange liability and payments to Permit Holders³ in connection with certain types of losses that Permit Holders may allege arose out of the business conducted on or through the Exchange or in connection with the use of the Exchange's facilities. The Exchange also proposes conforming changes to Rules 2.2 and 6.44. The text of the proposed rule change is available on the Exchange's Web site (<http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx>), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

C2 proposes to amend Rule 6.42 to eliminate any implication of liability with respect to the Exchange and its subsidiaries or affiliates, or any of their directors, officers, committee members, other officials, employees, contractors, or agents, (including the Exchange, collectively, "Covered Persons") for losses arising out of the use or enjoyment of Exchange facilities. The proposed rule change is consistent with and supplements existing law, and would ensure that self-regulatory organizations ("SROs") can operate within the sphere of their regulatory duties without fear of endless, costly litigation and potential catastrophic

³ Permit Holders are also referred to in the Exchange Rules and herein this rule change filing as "Participants." See e.g., the Rule 1.1 definition of "Participant."

loss.⁴ As discussed below, the proposed rule change is also consistent with the rules of other exchanges limiting exchange liability (see, e.g., EDGA Exchange, Inc. ("EDGA") Rule 11.14 BOX Options Exchange, LLC ("BOX") Rule 7230, International Securities Exchange, LLC ("ISE") Rule 705, and New York Stock Exchange LLC ("NYSE") Rule 18).

Under C2's proposal, although the Exchange would not be liable for losses, it would have the discretion to compensate Permit Holders for losses alleged to have resulted from the Exchange's failure to correctly process an order or quote due to the acts or omissions of the Exchange or due to the failure of its systems or facilities (each, a "Loss Event"), up to specified limits. The proposed rule change would also establish timeframes within which Permit Holders would be required to bring requests for compensation (and provide supporting documentation), provide factors the Exchange may consider in determining whether to provide compensation in response to such requests, and establish that the Exchange's determinations on compensation are final and not appealable. The proposed rule change would also provide that claims arising under a previous version of Rule 6.42 for losses occurring more than one year prior to July 1, 2015 (the "Effective Date") would not be considered valid, and that claims for any losses occurring prior to the Effective Date must be brought within one month of the Effective Date to be considered valid. Specific changes to Exchange Rules are discussed below.

Proposed Amendment to Rule Title

The proposed rule change would change the title of Rule 6.42 from "Exchange Liability" to "Exchange Liability Disclaimers and Limitations." The proposed amendment to the Rule title would clarify that the Rule does not impose liability on the Exchange, but

⁴ Courts have recognized the importance of protecting exchanges from such loss in deciding that SROs must be absolutely immune from civil actions for losses arising out of the SRO function. See *Dexter v. Depository Trust & Clearing Corp.*, 406 F. Supp. 2d 260, 263 (S.D.N.Y. 2005) (absolute immunity possessed by SROs "is an integral part of the American system of self-regulation"), *aff'd* 219 F. App'x 91 (2d Cir. 2007). Without such protection, an SRO's "exercise of its quasi-governmental functions would be unduly hampered by disruptive and recriminatory lawsuits." *D'Alessio v. NYSE*, 258 F.3d 93, 105 (2d Cir. 2001). It is critical that SROs, which stand in the shoes of the SEC in performing their quasi-governmental regulatory function, be free from "the fear of burdensome damage suits that would inhibit the exercise of their independent judgment." *Dexter*, 406 F.Supp. 2d at 263.

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

rather disclaims Exchange liability for any losses that arise out of the use or enjoyment of the facilities afforded by the Exchange, any interruption in or failure or unavailability of any such facilities, or any action taken or omitted to be taken in respect to the business of the Exchange, the calculation or dissemination of specified values, or quotes or transaction reports for options or other securities (the “General Disclaimer”).

Proposed Amendments to Scope of General Disclaimer

Proposed amendments to Rule 6.42(a) would clarify that “contractors” are included within the term “Covered Persons,” and are therefore included within the General Disclaimer. This proposed change is needed because the Exchange at times contracts with outside firms to provide products and services to the Exchange for use by Permit Holders in connection with regulated business conducted on or through the Exchange and that arise out of the use or enjoyment of the facilities afforded by the Exchange and/or the calculation or dissemination of specified values, or quotes or transaction reports for options or other securities. C2 notes that this proposed rule change is consistent with the exclusion from liability for contractors found in EDGA Rule 11.14, BOX Rule 7230 and ISE Rule 705. Proposed amendments to Rule 6.42(a) would also clarify that “other officials” of the Exchange or “any subsidiaries or affiliates of the Exchange” are included within the term “Covered Persons,” and are therefore included within the General Disclaimer. We note that this proposed rule change to include other officials and subsidiaries is consistent with the existing provisions of Rule 6.44.⁵ The term “Covered Persons” would also include such subsidiaries’ and affiliates’ directors, officers, committee members, other officials, employees, contractors, or agents.

The proposed rule change would also clarify that implicit in the General

⁵ Exchange Rule 6.44 currently limits the rights of any Participant or any person associated with a Participant to institute a lawsuit or other legal proceeding against the Exchange or any director, officer, employee, agent or contractor or other official of the Exchange or any subsidiary of the Exchange for any actions taken or omitted to be taken in connection with the official business of the Exchange or any subsidiary, except to the extent such actions or omissions constitute violations of the federal securities laws for which a private right of action exist. The rule also permits appeals of Exchange disciplinary actions as provided in Exchange Rule. Proposed amendments to Rule 6.44 (discussed below) would clarify that this limitation applies to committee members and affiliates of the Exchange.

Disclaimer is the Exchange’s disclaimer of any warranties, express or implied, with respect to the use or enjoyment of facilities afforded by the Exchange, including without limitation, of any data provided by the Exchange. The current language of the rule states that the Exchange does not warrant “the use of any data transmitted or disseminated by or on behalf of the Exchange or any reporting authority designated by the Exchange, including but not limited to reports of transactions in or quotations for securities traded on the Exchange or underlying securities, or reports of interest rate measures or index values or related data.” Under the proposed rule change, the Exchange would make explicit that the General Disclaimer is intended to contain within it a disclaimer of any warranties as to the use or enjoyment of the facilities offered by the Exchange. The proposed rule change would thereby clarify that such use or enjoyment of Exchange facilities by Permit Holders is provided “as is,” without specific warranties of merchantability or of fitness for a particular purpose. For the avoidance of doubt, the explicit list of the types of data for which the Exchange disclaims any warranties would also include, without limitation, “any current or closing index value, any current or closing value of interest rate options, or any report of transactions in or quotations for options or other securities, including underlying securities.”⁶

The proposed rule change would also clarify that all limitations on liability and disclaimers within paragraph (a) of Rule 6.42 are in addition to, and not in limitation of, any limitations on liability otherwise existing under law. This proposed rule change is intended to ensure that the protection of Rule 6.42 does not circumscribe protections that otherwise would exist under the principles of law.⁷ This and other limitations on liability operate independently from, and in addition to, both the current and proposed amended versions of Rule 6.42 and C2’s other rules.

Proposed Limits on Discretionary Payments for Alleged Losses

Currently, Rule 6.42(b) provides that whenever custody of an unexecuted order is transmitted by a Permit Holder

⁶ The Exchange also proposes to replace the phrase “facilities or services” with simply “facilities” in two locations within the existing text of Rule 6.42(a). The Exchange believes use of the term “services” is duplicative of the term “facilities” and is therefore unnecessary.

⁷ For example, as C2 is organized under Delaware law, the principals of Delaware law also apply.

to or through the Exchange’s System or to any other automated facility of the Exchange whereby the Exchange assumes responsibility for the transmission or execution of the order, and provided that the Exchange has acknowledged receipt of such order, the Exchange’s liability for the negligent acts or omissions of its employees or for the failure of its systems or facilities shall not exceed certain limits set forth in Rule 6.42(b). The Exchange first proposes to provide that Rule 6.42(b) applies to quotes as well as unexecuted orders. Additionally, the Exchange proposes to eliminate the word “automated” from “automated facility of the Exchange”, as not all facilities of the Exchange may be considered automated and the Exchange did not intend to restrict the scope of rule as such. The Exchange also seeks to amend Rule 6.42(b) to explicitly provide that, although the Exchange would not be liable with respect to regulated Exchange business for losses that arise out of the use or enjoyment of the facilities afforded by the Exchange and/or the calculation or dissemination of specified values, or quotes or transaction reports for options or other securities, as provided in Rule 6.42(a),⁸

⁸ Specifically, Rule 6.42(a), as proposed to be amended, would provide as follows:

Neither the Exchange nor any of its directors, officers, committee members, other officials, employees, contractors, or agents, nor any subsidiaries or affiliates of the Exchange or any of their directors, officers, committee members, other officials, employees, contractors, or agents (“Covered Persons”) shall be liable to Participants or to persons associated therewith for any loss, expense, damages or claims that arise out of the use or enjoyment of the facilities afforded by the Exchange, any interruption in or failure or unavailability of any such facilities, or any action taken or omitted to be taken in respect to the business of the Exchange except to the extent such loss, expense, damages or claims are attributable to the willful misconduct, gross negligence, bad faith or fraudulent or criminal acts of the Exchange or its officers, employees or agents acting within the scope of their authority. Without limiting the generality of the foregoing, and subject to the same exception, no Covered Person shall have any liability to any person or entity for any loss, expense, damages or claims that result from any error, omission or delay in calculating or disseminating any current or closing index value, any current or closing value of interest rate options, or any reports of transactions in or quotations for options or other securities, including underlying securities. The Exchange makes no warranty, express or implied, as to results to be obtained by any person or entity from the use or enjoyment of the facilities afforded by the Exchange, including without limitation, of any data transmitted or disseminated by or on behalf of the Exchange or any reporting authority designated by the Exchange, including but not limited to any data described in the preceding sentence, and the Exchange makes no express or implied warranties of merchantability or fitness for a particular purpose or use with respect to any such data. The foregoing limitations of liability and disclaimers shall be in addition to, and not in limitation of, the provisions of Article Eighth

the Exchange may make discretionary payments to Permit Holders for certain losses alleged to have occurred due to Loss Events. Specifically, the proposed rule change would permit the Exchange to make discretionary payments to Permit Holders for their losses alleged to have resulted from Loss Events up to the following limits. As to any one or more requests for compensation made by a single Permit Holder that arose out of one or more Loss Events occurring on a single trading day, the Exchange could compensate the Permit Holder up to but not exceeding the larger of \$100,000 or the amount of any recovery obtained by the Exchange under applicable insurance maintained by the Exchange. As to the aggregate of all requests for compensation made by all Permit Holders that arose out of one or more Loss Events occurring: (i) On a single trading day, the Exchange could compensate the Permit Holders, in the aggregate, up to but not exceeding the larger of \$250,000 or the amount of recovery obtained by the Exchange under any applicable insurance policy; and (ii) during a single calendar month, the Exchange could compensate the Permit Holders, in the aggregate, up to but not exceeding the larger of \$500,000 or the amount of the recovery obtained by the Exchange under any applicable insurance maintained by the Exchange. The proposed rule change would also state that no request for compensation by a Permit Holder may be in an amount less than \$100. Losses incurred on the same trading day and arising out of the same underlying act or omission of the Exchange or failure of the Exchange's systems or facilities may be aggregated to meet the \$100 minimum.⁹ This is intended as a de minimis threshold to avoid requiring the Exchange to devote the resources to considering relatively small requests for payment. The proposed rule change also would state that nothing in Rule 6.42 would obligate the Exchange to seek recovery under any applicable insurance policy. The proposed changes to Rule 6.42(b) would therefore, consistent with Rule 6.42(a), permit the Exchange to make

of the Exchange's Certificate of Incorporation or any limitations otherwise available under law.

⁹ For example, if a Permit Holder incurs a loss of \$30 on one day due to a certain glitch in the Exchange's systems and a loss of \$75 on the same day due to a separate unrelated glitch in the Exchange's systems, the Permit Holder could not request compensation for either loss. However, if for example, the Permit Holder incurs a loss of \$105 on one day due to a certain glitch in the Exchange's system, the Permit Holder may request compensation. In this second example, the Permit Holder may request compensation even if such losses were incurred over a number of different transactions so long as it was the result of the same systems issue.

discretionary payments to Permit Holders to compensate them for such losses, up to specified limits, even though the Exchange would not be legally liable to pay for such losses.

Timeframes Within Which To Notify Exchange and Submit Requests

Proposed new Rule 6.42(c) would establish timeframes within which a valid request for compensation must be brought under the Rule. Under the proposed rule change, notice of all requests would be required to be in writing and to be submitted to the Exchange no later than 12:00 p.m. Central Time on the next business day following the Loss Event giving rise to such request. All requests would be required to be in writing and to be submitted, along with supporting documentation, by 5:00 p.m. Central Time on the third business day following the Loss Event giving rise to each such request.¹⁰ Additional information related to the request as demanded by the Exchange is also required to be provided. The proposed rule change would also specify that the Exchange would not consider requests for which timely notice and submission had not been provided as required under amended Rule 6.42(c).

The proposed provisions of new Rule 6.42(c) would benefit Permit Holders by providing them with clear timeframes within which to submit notices of requests, requests for compensation, and supporting documentation. The proposed changes would also provide the Exchange with certainty as to the deadlines by which notices of requests and completed requests would be required to be submitted in order for the Exchange to consider them for compensation under Rule 6.42.

Exchange Treatment of Aggregate Requests Exceeding Maximum Amount Permitted To Be Paid

Currently, Rule 6.42(c) provides that if all of the claims cannot be fully satisfied because in the aggregate they exceed the applicable maximum amount of liability provided in paragraph (b) [of Rule 6.42] [sic], then such maximum amount would be allocated among all

¹⁰ Other exchanges have similar submission requirements. See, e.g., NYSE Rule 18—*Compensation in Relation to Exchange System Failure*, which provides in relevant part that NYSE members provide oral notice to NYSE's Division of Floor Operations by the market opening on the next business day following the system failure and written notice by the end of the third business day following the system failure (T+3). See also, ISE Rule 705(d)(3)—*Limitation of Liability*, which provides that all claims for compensation must be made in writing and submitted no later than the opening of trading on the next business day following the event that gave rise to such claim.

such claims arising on a single trading day or during a single calendar month, as applicable, written notice of which has been given to the Exchange no later than the opening of trading on the next business day following the day on which the use or enjoyment of Exchange facilities giving rise to the claim occurred, based upon the proportion that each claim bears to the sum of all such claims. The Exchange proposes to amend existing Rule 6.42(c), which would be renumbered to Rule 6.42(d), to state that, "if all of the timely requests submitted pursuant to paragraph (c) [of Rule 6.42] that are granted cannot be fully satisfied because in the aggregate they exceed the applicable maximum amount of payments authorized in paragraph (b) [of Rule 6.42], then such maximum amount shall be allocated among all such requests arising on a single trading day or during a single calendar month, as applicable, based upon the proportion that each such request bears to the sum of all such requests." The Exchange notes that it is proposing to replace the term "claim" with the term "request", as well as replace the reference to "liability" with "payments authorized" to eliminate any implication of liability with respect to the Exchange and other Covered Person resulting from the use or enjoyment of the facilities offered by the Exchange, any interruption in or failure or unavailability or any such facilities, or any action taken or omitted to be taken in respect of the business of the Exchange.

Additionally, the Exchange notes that proposed Rule 6.42(d) would continue to provide a fair way of allocating the limited payment that the rule would permit the Exchange to make when the total amount of eligible requests exceed that maximum amount. The proposal would also revise the timeframe in which requests for payment must be made by a Permit Holder.

Exchange Review of Timely Requests

Proposed new Rule 6.42(e) would provide that the Exchange, in determining whether to make payment in response to a request for compensation, may determine whether the amount requested should be reduced based on the actions or inactions of the requesting Permit Holder. The proposed rule change would permit the Exchange to consider, without limitation, whether the actions or inactions of the Permit Holder contributed to the Loss Event; whether the Permit Holder made appropriate efforts to mitigate its loss; whether the Permit Holder realized any gains as a result of a Loss Event; whether the

losses of the Permit Holder, if any, were offset by hedges of positions either on the Exchange or on another affiliated or unaffiliated market; and whether the Permit Holder provided sufficient information to document the request and as demanded by the Exchange. Proposed Rule 6.42(e) would therefore provide reasonable factors that the Exchange may consider in determining whether to pay compensation in response to a request and in determining the amount of any such compensation.¹¹

The Exchange represents that the determination to compensate a Permit Holder will be made on an equitable and non-discriminatory basis and without regard to the Exchange capacity of the Permit Holder, such as whether the Permit Holder is a Designated Primary Market-Maker. Additionally, the Exchange represents that the Exchange will maintain a record of Permit Holder requests including documentation detailing the Exchange's findings and details for approving or denying requests in accordance with its obligations under Section 17 of the Act.

Finality of Exchange Determinations Under Rule

Proposed new Rule 6.42(f) would provide that all determinations by the Exchange pursuant to Rule 6.42 shall be final and not subject to appeal under Chapter XIX of the Exchange Rules.¹² The proposed rule would also provide that nothing in Rule 6.42, nor any payment made pursuant to Rule 6.42, shall in any way limit, waive, or proscribe any defenses a Covered Person may have to any claim, demand, liability, action or cause of action, whether such defense arises in law or equity, or whether such defense is asserted in a judicial, administrative, or other proceeding.¹³ These proposed

¹¹ Another exchange considered similar factors in determining whether to pay compensation and in determining the amount of any such compensation. See, NYSE Rule 18, which provides in relevant part that the NYSE Compensation Review Panel in its review will determine whether the amount should be reduced based on the actions or inactions of the member organization, including whether the member organization made appropriate efforts to mitigate its loss.

¹² The Exchange notes that another exchange has a similar provision indicating that all determinations are final. See, NYSE Rule 18, which provides in relevant part that all determinations made pursuant to NYSE Rule 18 by NYSE's Compensation Review Panel, CEO or his or her designee are final.

¹³ Another exchange has a similar provision. See e.g., NASDAQ Stock Market LLC ("Nasdaq") Rule 4626(b)(6), which provides that nothing in its Limitation of Liability rule shall waive Nasdaq's limitations on, or immunities from, liability as set forth in its Rules or agreements, or that otherwise apply as a matter of law.

changes are consistent with the discretionary nature of any payments that would be made under proposed Rule 6.42(b).

Treatment of Losses Occurring Prior to Effective Date of Rule

Proposed new paragraph 6.42(g) would establish July 1, 2105, as the Effective Date of revised Rule 6.42. Under proposed paragraph 6.42(g), claims for liability under prior versions of Rule 6.42 would not be considered valid if brought with respect to any acts, omissions or transactions occurring more than one year prior to the Effective Date, or if brought more than one month after the Effective Date. Proposed Rule 6.42(g) would thereby provide certainty to the Exchange as to any expense it might incur due to losses arising due to Loss Events that occurred prior to the Effective Date of the proposed rule change, while also putting Permit Holders on notice that they must file any claims for such losses by a date certain.

Deletion of Existing Interpretation Under Rule 6.42

The proposed rule change would delete existing interpretation .01 under Rule 6.42. Interpretation .01 disclaims The Options Clearing Corporation liability to Permit Holders and their associated persons with respect to their use, non-use or inability to use the linkage that was part of the old Options Intermarket Linkage Plan (the "Old Linkage"). Because the Old Linkage is no longer operable, interpretation .01 is no longer necessary.¹⁴

Conforming Changes to Other Rules

The proposed rule change would make conforming changes to Exchange Rules 2.2 and 6.44. Rule 2.2 requires a Permit Holder who fails to prevail in lawsuit or other legal proceeding instituted against the Exchange or certain related parties to pay for the Exchange's reasonable costs of defending such lawsuit or proceeding if those costs exceed \$50,000. Rule 6.44 limits the legal proceedings a Permit Holder may bring against the Exchange and certain related persons for actions or omissions.

Under the proposed amendments to Rule 2.2, contractors would be included within the list of related parties protected by that rule, just as they would be included as Covered Persons under proposed Rule 6.42. As stated

¹⁴ The old Options Intermarket Linkage Plan was replaced by the Options Order Protection and Locked/Crossed Markets Plan in 2009. See Securities Exchange Act Release No. 60405 (July 30, 2009), 74 FR 39362 (August 6, 2009).

above, this proposed change is necessary because the Exchange at times contracts with outside firms to provide products or services to Permit Holders in connection with regulated business conducted on or through the Exchange and that arise out of the use or enjoyment of the facilities afforded by the Exchange and/or the calculation or dissemination of specified values, or quotes or transaction reports for options or other securities.

In addition, under the proposed amendments to Rule 2.2, other officials and contractors of the Exchange and any subsidiaries and affiliates of the Exchange and any such subsidiaries' and affiliates' directors, officers, committee members, other officials, employees, contractors, or agents would be explicitly identified/included within the list of related parties protected by the rule,¹⁵ just as they are proposed to be specifically identified/included within the list of Covered Persons under Rule 6.42. Committee members and affiliates of the Exchange and any subsidiaries' and affiliates' directors, officers, committee members, other officials, employees, contractors and agents would also be explicitly identified/included within the list of related parties under Rule 6.44.¹⁶ These changes are intended to conform the text of the three rules and to include affiliates within all three rules.¹⁷ Moreover, under the proposed amendments to Rule 6.44, committee members would be explicitly identified/included within the list of related parties protected by the rule, just as they are already specifically identified/included within the list of Covered

¹⁵ Specifically, the phrase "the Exchange or any of its directors, officers, committee members, employees or agents" is proposed to be replaced with the phrase "the Exchange or any of its directors, officers, committee members, other officials, employees, contractors, or agents, or any subsidiaries or affiliates of the Exchange or any of their directors, officers, committee members, other officials, employees, contractors, or agents" in Rule 2.2.

¹⁶ Specifically, the phrase "the Exchange or any director, officer, employee, contractor, agent or other official of the Exchange or any subsidiary of the Exchange" is proposed to be replaced with the phrase "the Exchange or any of its directors, officers, committee members, other officials, employees, contractors, or agents, or any subsidiaries or affiliates of the Exchange or any of their directors, officers, committee members, other officials, employees, contractors, or agents" in Rule 6.44.

¹⁷ The Commission notes C2's statement of the purpose of its proposed rule change is to eliminate any implication of liability for losses arising out of the use or enjoyment of Exchange facilities consistent with existing law where courts have recognized the importance of protecting exchanges from liability in the context of matters arising out of the SRO function. See *supra* note 4 and accompanying text.

Persons under existing Rule 6.42 and the similar provision in Rule 2.2. This change is intended to conform the rule text of the three rules. Finally, under the proposed amendments to Rule 6.44, the title to the rule will be revised.¹⁸

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the "Act")¹⁹ in general and furthers the objectives of Section 6(b)(5) of the Act²⁰ in particular, which requires that the rules of an exchange be designed to promote just and equitable principles of trade, to remove impediments to and to perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. In particular, the proposal would amend Exchange Rule 6.42 to eliminate any implication of liability with respect to the Exchange and other Covered Person resulting from the use or enjoyment of the facilities offered by the Exchange, any interruption in or failure or unavailability or any such facilities, or any action taken or omitted to be taken in respect of the business of the Exchange. The proposed rule change is consistent with and supplements existing law, and would assist the Exchange in fulfilling its role as a national securities exchange by avoiding the risk of tempering this critical regulatory function to avoid the disruption and expense of unnecessary litigation or potential catastrophic loss.

The proposal would also permit the Exchange to compensate Permit Holders for their losses incurred due to a Loss Event, even though the Exchange would not have legal liability for those losses. The proposed rule change would therefore facilitate the ability of the Exchange to make discretionary payments to redress a situation in which Permit Holders suffer losses due to a Loss Event. As stated above, the Exchange represents that the determination to compensate a Permit Holder will be made on an equitable and non-discriminatory basis without regard to the Exchange capacity of the Permit Holder, such as whether the Permit Holder is a Designated Primary Market-Maker. The Exchange therefore believes the proposed rule change is consistent with the Act, and Section 6(b)(5) of the Act in particular, in that

it is designed to promote just and equitable principles of trade, to remove impediments to and to 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 also believes these policies would promote fairness in the national market system. The proposed rule change would allow C2 to address Permit Holder requests for compensation under various circumstances and would allow C2 to act in a fashion similar to many of its competitors. As stated above, several exchanges have substantially similar rules to those proposed here, and the Exchange believes that the proposed rule change would place C2 in a similar position to address Permit Holder requests.²¹ The Exchange believes that to the extent there are any differences, such differences are not substantive and are still consistent with the scope of prior self-regulatory organization rulemaking.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that this proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. As stated above, the Exchange believes that these policies would promote fairness in the national market system. The proposed rule change would allow C2 to address Permit Holder requests for compensation under various circumstances and would allow C2 to act in a fashion similar to many of its competitors. In addition, as stated above, several exchanges have substantially similar rules to those proposed here, except as otherwise noted, and the Exchange believes that the proposed rule change would place C2 in a similar position to address Permit Holder requests.²²

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

Because the foregoing proposed rule change does not: (i) Significantly affect

the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act²³ and Rule 19b-4(f)(6)²⁴ thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form <http://www.sec.gov/rules/sro.shtml>; or
- Send an email to rule-comments@sec.gov. Please include File Number SR-C2-2015-010 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090.

All submissions should refer to File Number SR-C2-2015-010. 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

²³ 15 U.S.C. 78s(b)(3)(A).

²⁴ 17 CFR 240.19b-4(f)(6). As required under Rule 19b-4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

¹⁸ Specifically, the title "Legal Proceedings Against the Exchange and its Directors, Officers, Employees, Contractors or Agents" is proposed to be changed to simply "Legal Proceedings Against the Exchange."

¹⁹ 15 U.S.C. 78f(b).

²⁰ 15 U.S.C. 78f(b)(5).

²¹ See BOX Rule 7230 and EDGA Rule 11.14; see also Nasdaq Rule 4626, ISE Rule 705, and BATS Exchange, Inc. Rule 11.16.

²² *Id.*

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-C2-2015-010, and should be submitted on or before June 10, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²⁵

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015-12144 Filed 5-19-15; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-74957; File No. SR-BOX-2015-17]

Self-Regulatory Organizations; BOX Options Exchange, LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend the Fee Schedule on the BOX Market, LLC Options Facility

May 13, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on April 30, 2015, BOX Options Exchange LLC (the "Exchange") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Exchange filed the proposed rule change pursuant to Section 19(b)(3)(A)(ii) of the Act,³ and Rule 19b-4(f)(2) thereunder,⁴ which renders the proposal effective upon filing with the Commission. 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 the Substance of the Proposed Rule Change

The Exchange is filing with the Securities and Exchange Commission ("Commission") a proposed rule change to amend the Fee Schedule on the BOX Market LLC ("BOX") options facility. While changes to the fee schedule pursuant to this proposal will be effective upon filing, the changes will become operative on May 1, 2015. The text of the proposed rule change is available from the principal office of the Exchange, at the Commission's Public Reference Room and also on the Exchange's Internet Web site at <http://boxexchange.com>.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to make a number of changes to Section I of the BOX Fee Schedule (Exchange Fees).

Non-Auction Transactions

First, the Exchange proposes to amend certain fees and credits in the pricing model outlined in Section I.A. (Non-Auction Transactions).⁵ In this section, fees and credits are assessed depending on upon three factors: (i) The account type of the Participant submitting the order; (ii) whether the Participant is a liquidity provider or liquidity taker; and (iii) the account type of the contra party. Non-Auction Transactions in Penny Pilot Classes are assessed different fees or credits than Non-Auction Transactions in Non-Penny Pilot Classes. The Exchange

recently adopted this pricing model⁶ and now proposes to amend certain fees and credits in this section.

Specifically, the Exchange proposes to lower the Maker and Taker credits for Public Customers interacting with Professional Customers/Broker Dealers or Market Makers in both Penny Pilot and Non-Penny Pilot Classes. Here, the Exchange proposes to lower the credit Public Customers receive when interacting with Professional Customers, Broker Dealers or Market Makers, regardless of whether they are adding or removing liquidity to \$0.10 from \$0.22 (Penny Pilot Classes) and to \$0.45 from \$0.57 (Non-Penny Pilot Classes).

The Exchange also proposes to raise the Maker and Taker fees for Professional Customers or Broker Dealers in both Penny Pilot and Non-Penny Pilot Classes. Specifically, when a Professional Customer or Broker Dealer interacts with a Public Customer in a Penny Pilot Class, the Exchange proposes to raise this fee to \$0.60 from \$0.55 (making liquidity) and to \$0.64 from \$0.59 (taking liquidity). For Non-Penny Pilot Classes the Exchange proposes to raise the fees in this same type of interaction to \$0.95 from \$0.90 (making liquidity) and to \$0.99 from \$0.94 (taking liquidity). For when a Professional Customer or Broker Dealer interacts with another Professional Customer or Broker Dealer in Penny Pilot Classes, the Exchange proposes to raise these fees to \$0.25 from \$0.20 (making liquidity) and to \$0.40 from \$0.35 (taking liquidity). For Non-Penny Pilot Classes the Exchange proposes to raise the fees in this same type of interaction to \$0.35 from \$0.30 (making liquidity) and to \$0.40 from \$0.35 (taking liquidity). For when a Professional Customer or Broker Dealer interacts with a Market Maker in Penny Pilot Classes, the Exchange proposes to raise these fees to \$0.25 from \$0.20 (making liquidity) and to \$0.44 from \$0.39 (taking liquidity). For Non-Penny Pilot Classes the Exchange proposes to raise the fees in this same type of interaction to \$0.35 from \$0.30 (making liquidity) and \$0.44 from \$0.39 (taking liquidity).

Finally, the Exchange proposes to lower fees to \$0.00 from \$0.10 for Market Makers interacting with other Market Makers in both Penny Pilot Classes and Non-Penny Pilot Classes.

These transactions will remain exempt from the Liquidity Fees and Credits outlined in Section II of the BOX

²⁵ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A)(ii).

⁴ 17 CFR 240.19b-4(f)(2).

⁵ Non-Auction Transactions are those transactions executed on the BOX Book.

⁶ See Securities Exchange Act Release No. 73547 (November 6, 2014), 79 FR 67520 (November 13, 2014)(Notice of Filing and Immediate Effectiveness of SR-BOX-2014-25).

Fee Schedule. The revised fee structure for Non-Auction Transactions will be as follows:

Account type	Contra party	Penny pilot classes		Non-penny pilot classes	
		Maker fee/credit	Taker fee/credit	Maker fee/credit	Taker fee/credit
Public Customer	Public Customer	\$0.00	\$0.00	\$0.00	\$0.00
	Professional Customer/Broker Dealer	(\$0.10)	(\$0.10)	(\$0.45)	(\$0.45)
	Market Maker	(\$0.10)	(\$0.10)	(\$0.45)	(\$0.45)
Professional Customer or Broker Dealer	Public Customer	\$0.60	\$0.64	\$0.95	\$0.99
	Professional Customer/Broker Dealer	\$0.25	\$0.40	\$0.35	\$0.40
	Market Maker	\$0.25	\$0.44	\$0.35	\$0.44
Market Maker	Public Customer	\$0.51	\$0.55	\$0.85	\$0.90
	Professional Customer/Broker Dealer	\$0.00	\$0.05	\$0.00	\$0.10
	Market Maker	\$0.00	\$0.29	\$0.00	\$0.29

For example, if a Public Customer submitted an order to the BOX Book in a Penny Pilot Class (making liquidity), the Public Customer would now be credited \$0.10 if the order interacted with a Market Maker's order and the Market Maker (taking liquidity) would be charged \$0.55. To expand on this example, if the Market Maker instead submitted an order to the BOX Book in a Penny Pilot Class (making liquidity), the Market Maker would be charged \$0.51 if the order interacted with a Public Customer's order and the Public Customer (taking liquidity) would again be credited \$0.10.

In Section I.A.1., the Tiered Volume Rebate for Non-Auction Transactions, the Exchange gives a per contract rebate to Market Makers and Public Customers based on their average daily volume ("ADV") considering all transactions executed on BOX by the Market Maker or Public Customer, respectively, as calculated at the end of each month. Specifically, the Exchange proposes to adjust the volume tiers and contract rebates in the Market Maker Monthly ADV section, as well certain contract rebates in the Public Customer Monthly ADV section. The new per contract rebate for Market Makers and Public Customers in Non-Auction Transactions as set forth in Section I.A.1. of the BOX Fee Schedule will now be as follows:

Market maker monthly ADV	Per contract rebate
40,001 contracts and greater	(\$0.10)
25,001 contracts to 40,000 contracts	(\$0.05)
10,001 contracts to 25,000 contracts	(\$0.03)
1 contract to 10,000 contracts	\$0.00
Public customer monthly ADV	Per contract rebate
35,001 contracts and greater	(\$0.22)
15,001 contracts to 35,000 contracts	(\$0.12)
5,001 contracts to 15,000 contracts	(\$0.06)
1 contract to 5,000 contracts	\$0.00

Auction Transactions

The Exchange then proposes to amend Section I.B. (Auction Transactions)⁷ and establish separate fees for Facilitation and Solicitation Orders.⁸ The Exchange currently assesses per contract execution fee on all Primary Improvement Orders, Solicitation Orders and Facilitation Orders in Section I.B.1. based upon the Initiating Participant's monthly average daily volume (ADV) in the total contract quantity submitted for these orders. These fees range from \$0.25 to \$0.03 per contract depending on the ADV.

The Exchange now proposes to adopt a flat \$0.25 fee for Facilitation and Solicitation Orders⁹ and remove these Orders from the tiered fee schedule for Initiating Participants. The Exchange also proposes to specify that the fees for these Orders will be capped at \$25,000 per month.

With this, the Exchange then proposes to amend the language in the Section I.B.1. tiered fee schedule to remove all references to the Facilitation and Solicitation Orders and specify that the tiered fee schedule will now only be applicable to Initiating Participants submitting Primary Improvement Orders through the PIP. Additionally, each Initiating Participant's monthly ADV will now only be based on the total contract quantity of Primary Improvement Orders submitted to the PIP as calculated at the end of each month.

Other

Finally, the Exchange is proposing to make additional non-substantive changes to the Fee Schedule.

⁷ Auction Transactions are those transactions executed through the Price Improvement Period ("PIP"), the Complex Order Price Improvement Period ("COPIP"), the Solicitation Auction mechanism, and the Facilitation Auction mechanism.

⁸ Facilitation and Solicitation Orders are the matching contra orders submitted on the opposite side of the Agency Order.

⁹ Public Customers are unable to submit Facilitation and Solicitation Orders on BOX.

Specifically, the Exchange is renumbering certain footnotes, headings and internal references to accommodate the above proposed changes to the Fee Schedule.

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Act, in general, and Section 6(b)(4) and 6(b)(5) of the Act,¹⁰ in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among BOX Participants and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers. The proposed changes will allow the Exchange to be competitive with other exchanges and to apply fees and credits in a manner that is equitable among all BOX Participants. Further, the Exchange operates within a highly competitive market in which market participants can readily direct order flow to any other competing exchange if they determine fees at a particular exchange to be excessive.

Exchange Fees

Non-Auction Transactions

The Exchange believes amending the Non-Auction Transaction fees and credits is reasonable, equitable and not unfairly discriminatory. The fee structure for Non-Auction Transactions has been well received by Participants and the industry since it was adopted last year,¹¹ and the Exchange believes it is now appropriate to adjust certain fees and credits. The proposed fee structure is intended to attract order flow to the Exchange by offering all market participants incentives to submit their Non-Auction orders to the Exchange. The practice of providing additional incentives to increase order flow is, and has been, a common practice in the

¹⁰ 15 U.S.C. 78f(b)(4) and (5).

¹¹ See *supra*, note 6.

options markets.¹² Further, the Exchange believes it is appropriate to provide incentives for market participants which will result in greater liquidity and ultimately benefit all Participants trading on the Exchange.

The Exchange also believes it is equitable, reasonable and not unfairly discriminatory to assess fees and credits according to the account type of the Participant originating the order and the contra party. This fee structure has been in place on the Exchange since last year and the Exchange is simply adjusting certain fees and credits within the structure.¹³ The result of this structure is that a Participant does not know the fee it will be charged when submitting certain orders. Therefore, the Participant must recognize that it could be charged the highest applicable fee on the Exchange's schedule, which may, instead, be lowered or changed to a credit depending upon how the order interacts.

The Exchange believes that the proposed fees and credits for Public Customers in Non-Auction Transactions are reasonable. Under the proposed fee structure Public Customers will either pay a Maker fee of \$0.00 (when interacting with another Public Customer) or receive a Maker/Taker credit of \$0.10 for Penny Pilot classes and \$0.45 for Non-Penny Pilot classes when interacting with a Professional Customer, Broker Dealer or Market Maker. The Exchange believes the credits listed above are reasonable as they are in line with the current fees assessed by other competing exchanges.¹⁴

¹² See BATS Exchange, Inc. ("BATS") BATS Options Exchange Fee Schedule "Standard Rates"; Chicago Board Options Exchange, Inc. ("CBOE") Fee Schedule "Volume Incentive Program" (page 4); ISE Gemini, LLC ("Gemini") Schedule of Fees, Section I. Regular Order Fees and Rebates "Penny Symbols and SPY, and Non-Penny Symbols" (page 4); Miami International Securities Exchange, LLC ("MIAX") Fee Schedule Section I(a)(i) "Market Maker Transaction Fees" and "Market Maker Sliding Scale", and Section I(a)(iii) "Priority Customer Rebate Program"; NASDAQ OMX BX, Inc. ("BX Options") Chapter XV, Section 2 BX Options Market—Fees and Rebates; NASDAQ OMX PHLX, ("PHLX"), Pricing Schedule Section B, "Customer Rebate Program"; NASDAQ Stock Market LLC ("NOM") Chapter XV, Section 2 NASDAQ Options Market—Fees and Rebates; NYSE Amex, Inc. ("AMEX") Fee Schedule Section I.C. NYSE Amex Options Market Maker Sliding Scale—Electronic; and NYSE Arca, Inc. ("Arca") Options Fees and Charges, "Customer and Professional Customer Monthly Posting Credit Tiers and Qualifications for Executions in Penny Pilot Issues" (page 4).

¹³ See *supra*, note 6.

¹⁴ Many U.S. Options Exchanges do not differentiate their fees between auction and non-auction transactions. However, Public Customers are charged anywhere from \$0.00 to \$0.85 within the following options exchange fee schedules. See NASDAQ OMX BX ("BX") Options Pricing, Chapter

The Exchange believes it is reasonable, equitable and not unfairly discriminatory to give Public Customers a credit when their orders execute against a non-Public Customer and, accordingly, charge non-Public Customers a higher fee when their orders execute against a Public Customer. The securities markets generally, and BOX in particular, have historically aimed to improve markets for investors and develop various features within the market structure for Public Customer benefit. Similar to the payment for order flow and other pricing models that have been adopted by the Exchange and other exchanges to attract Public Customer order flow, the Exchange increases fees to non-Public Customers in order to provide incentives for Public Customers. The Exchange believes that providing incentives for Non-Auction Transactions by Public Customers is reasonable and, ultimately, will benefit all Participants trading on the Exchange by attracting Public Customer order flow.

The Exchange believes that charging Professional Customers and Broker Dealers higher fees than Public Customers for Non-Auction Transactions is equitable and not unfairly discriminatory. Professional Customers, while Public Customers by virtue of not being Broker Dealers, generally engage in trading activity more similar to Broker Dealer proprietary trading accounts. The Exchange believes that the higher level of trading activity from these Participants will draw a greater amount of BOX system resources, which the Exchange aims to recover its costs by assessing Professional Customers and Broker Dealers higher fees for transactions.

The Exchange also believes it is equitable and not unfairly discriminatory for BOX Market Makers to be assessed lower fees than Professional Customers and Broker Dealers for Non-Auction Transactions because of the significant contributions to overall market quality that Market Makers provide. Specifically, Market Makers can provide higher volumes of liquidity and lowering their fees will help attract a higher level of Market Maker order flow to the BOX Book and create liquidity, which the Exchange believes will ultimately benefit all Participants trading on BOX.

The Exchange believes that the proposed fees and credits for

XV, Sec. 2; NYSE Arca Options ("Arca") Fees and Charges page 3; International Securities Exchange ("ISE") Schedule of Fees, Section I.

Professional Customers, Broker Dealers and Market Makers in Non-Auction Transactions are reasonable. Under the proposed fee structure, a Professional Customer or Broker Dealer making liquidity and interacting with a Professional Customer, Broker Dealer or Market Maker will either be charged a fee of \$0.25 for Penny Pilot Classes or \$0.35 for Non-Penny Pilot Classes. If the Professional Customer or Broker Dealer is instead taking liquidity in either Penny Pilot or Non-Penny Pilot Classes, it will be charged \$0.40 if it interacts with a Professional Customer or Broker Dealer and \$0.44 if it interacts with a Market Maker. The Exchange believes the fees listed above are reasonable as they are in line with the current fees assessed by other competing exchanges.¹⁵

Similarly, in the proposed fee structure a Market Maker making liquidity in both Penny Pilot and Non-Penny Pilot Classes will now always be charged a fee of \$0.00 for interacting with a Professional Customer/Broker Dealer or Market Maker. The Exchange believes the fees listed above are reasonable as they are in line with what is currently charged by the industry.¹⁶

The Exchange believes it is reasonable, equitable and not unfairly discriminatory for Professional Customers and Broker Dealers to be charged higher fees for both making and taking liquidity when interacting with Public Customers. A Professional Customer or Broker Dealer interacting with a Public Customer will now be charged a \$0.60 Maker fee or \$0.64 Taker fee for Penny Pilot Classes and a \$0.95 Maker fee or \$0.99 Taker fee for Non-Penny Pilot Classes. The Exchange believes they are reasonable as they are in line when compared to similar fees in the options industry.¹⁷ Further, as stated above, the Exchange believes charging a higher fee for interactions with a Public Customer is equitable and not unfairly discriminatory because it allows the Exchange to incentivize Public Customer order flow by offering credits to Public Customers in Non-Auction Transactions. The Exchange believes that providing incentives for Non-Auction Transactions by Public Customers will benefit all Participants trading on the Exchange by attracting this Public Customer order flow.

¹⁵ *Id.* Professional Customer and Broker Dealers are charged anywhere from \$0.10 to \$0.94 within the option exchange fee schedules referenced above.

¹⁶ See *supra*, note 13 [sic]. The general range for Market Maker fees is between \$0.10 and \$0.92 within the fee schedules referenced above.

¹⁷ See *supra*, note 14.

The Exchange believes it is reasonable, equitable and not unfairly discriminatory for Professional Customers, Broker Dealers and Market Makers to be charged a higher fee for orders removing liquidity when compared to the fee they receive for orders that add liquidity. Charging a lower fee for orders that add liquidity will promote liquidity on the Exchange and ultimately benefit all participants on BOX. Further, the concept of incentivizing orders that add liquidity over orders that remove liquidity is commonly accepted within the industry as part of the "Make/Take" liquidity model.¹⁸

The Exchange believes it is equitable and not unfairly discriminatory to charge the Professional Customer or Broker Dealer more for taking liquidity against a Market Maker than they are charged for taking liquidity against other Professional Customers or Broker Dealers. As stated above, the Exchange proposes to provide certain incentives to Market Makers because of the high volumes of liquidity they can provide and increasing fees for Professional Customers and Broker Dealers taking liquidity will allow the Exchange to offer these incentives, ultimately benefiting all Participants trading on BOX.

Finally, the Exchange also believes it is reasonable to charge Professional Customers and Broker Dealers less for certain executions in Penny Pilot issues compared to Non-Penny Pilot issues because these classes are typically more actively traded; assessing lower fees will further incentivize order flow in Penny Pilot issues on the Exchange, ultimately benefiting all Participants trading on BOX. Additionally, the Exchange believes it is reasonable to give a greater credit to Public Customers for Non-Auction Transactions in Non-Penny Pilot issues as compared to Penny Pilot issues. Since these classes have wider spreads and are less actively traded, giving a larger credit will further incentivize Public Customers to trade in these classes, ultimately benefitting all Participants trading on BOX.

Tiered Volume Rebate for Non-Auction Transactions

BOX believes it is reasonable, equitable and not unfairly discriminatory to adjust the tiered volume based rebates for Market Makers and Public Customers in all Non-Auction Transactions. The volume thresholds and applicable rebates are

meant to incentivize Public Customers and Market Makers to direct order flow to the Exchange to obtain the benefit of the rebate, which will in turn benefit all market participants by increasing liquidity on the Exchange. Other exchanges employ similar incentive programs;¹⁹ and the Exchange believes that the proposed changes to the volume thresholds and rebates are reasonable and competitive when compared to incentive structures at other exchanges.

The Exchange continues to believe it is equitable and not unfairly discriminatory to only have these rebate structures for Public Customers and Market Makers in Non-Auction transactions. The practice of incentivizing increased Public Customer order flow is common in the options markets. With this proposal, Public Customers benefit from the opportunity to obtain a higher rebate. Further, Market Makers can provide high volumes of liquidity and lowering their Non-Auction Transaction fees will potentially help attract a higher level of Market Maker order flow and create liquidity, which the Exchange believes will ultimately benefit all Participants trading on BOX.

Auction Transactions

The Exchange believes that establishing a flat \$0.25 fee for all Facilitation and Solicitation Orders is reasonable, equitable and not unfairly discriminatory. While the proposal will potentially raise the fees for certain Participants submitting Facilitation and Solicitation Orders, the Exchange believes the fee is reasonable as it is equal to highest fee that Participants are currently charged for these Orders under the volume based tier schedule in Section I.B.1., and will also be capped at \$25,000 for each Participant per month. Further, the fee cap will act as a volume based discount for any Participants who meet the cap each month. The Exchange believes the fee cap is reasonable as it is lower than similar fee caps at other options exchanges.²⁰ Finally, the Exchange

¹⁹ See Section B of the PHLX Pricing Schedule entitled "Customer Rebate Program;" ISE Gemini's Qualifying Tier Thresholds (page 6 of the ISE Gemini Fee Schedule); and CBOE's Volume Incentive Program (VIP). CBOE's Volume Incentive Program ("VIP") pays certain tiered rebates to Trading Permit Holders for electronically executed multiply-listed option orders which include AIM orders. Note that some of these exchanges base these rebate programs on the percentage of total national Public Customer volume traded on their respective exchanges, which the Exchange is not proposing to do.

²⁰ See Section H of the ISE Fee Schedule "Crossing Fee Caps." Transactions that are part of the origination or contra side of a Crossing Order (contracts that are submitted as part of a

believes that a \$0.25 fee for Facilitation and Solicitation Orders is equitable and not unfairly discriminatory as all Participants will be charged the same fee with the exception of Public Customers, who are not able to submit these Orders in the BOX trading system.

Finally, the Exchange believes that removing references to Facilitation and Solicitation Orders in the Tiered Fee Schedule in Section I.B.1. is reasonable, equitable and not unfairly discriminatory. The Exchange believes it is reasonable because Facilitation and Solicitation Orders will no longer be charged according to this section of the fee schedule, and therefore it is appropriate to both remove these references and specify that the monthly ADV will be now only be based on the total Primary Improvement Order contract quantity submitted to the PIP as calculated at the end of the month. The Exchange believes it is equitable and not unfairly discriminatory to remove these references as they apply equally to all Participants on BOX.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange 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.

The Exchange believes that the proposed adjustments to fees and rebates in the Non-Auction Transactions fee structure will not impose a burden on competition among various Exchange Participants. Rather, BOX believes that the changes will result in the Participants being charged appropriately for these transactions and are designed to enhance competition in Non-Auction transactions on BOX. Submitting an order is entirely voluntary and Participants can determine which type of order they wish to submit, if any, to the Exchange. Further, the Exchange believes that this proposal will enhance competition between exchanges because it is designed to allow the Exchange to better compete with other exchanges for order flow.

The Exchange believes that adopting a flat fee for Facilitation and Solicitation Orders will not impose a burden on competition because all Participants will be affected to the same extent, with the exception of Public Customers who cannot submit these Orders in the BOX trading system.

Finally, the Exchange notes that it operates in a highly competitive market in which market participants can

Facilitation, Solicitation, PIM, Block or QCC order) are capped at \$75,000 per month.

¹⁸ The "Make/Take" model is currently used by the International Securities Exchange LLC ("ISE") and NASDAQ OMX PHLX LLC ("PHLX").

readily favor competing exchanges. In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Exchange Act²¹ and Rule 19b-4(f)(2) thereunder,²² because it establishes or changes a due, or fee.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend the rule change if it appears to the Commission that the action is necessary or appropriate in the public interest, for the protection of investors, or would otherwise further the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-BOX-2015-17 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-BOX-2015-17. 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-BOX-2015-17, and should be submitted on or before June 10, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²³

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015-12173 Filed 5-19-15; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-74962; File No. SR-BX-2015-026]

Self-Regulatory Organizations; NASDAQ OMX BX, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Update the Public Disclosure of Sources of Data BX Utilizes

May 14, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934

(“Act”),¹ and Rule 19b-4 thereunder,² notice is hereby given that on May 6, 2015, NASDAQ OMX BX, Inc. (“BX” or “Exchange”) filed with the Securities and Exchange Commission (“SEC” or “Commission”) the proposed rule change as described in Items I and II, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to update the public disclosure of the sources of data that BX utilizes when performing (1) order handling and execution; (2) order routing; and (3) related compliance processes.

The text of the proposed rule change is below. Proposed new language is italicized; proposed deletions are bracketed.

* * * * *

4759. Data Feeds Utilized

[BX shall publicly disclose the proprietary and network processor feeds utilized by the System for the handling, routing, and execution of orders, as well as for the regulatory compliance processes related to those functions. This information shall be displayed on www.nasdaqtrader.com, and it shall be updated promptly each time BX determines to add, subtract, or otherwise modify a data source.]

The BX System utilizes the below proprietary and network processor feeds utilized by the System for the handling, routing, and execution of orders, as well as for the regulatory compliance processes related to those functions. The Secondary Source of data is utilized only in emergency market conditions and only until those emergency conditions are resolved.

²¹ 15 U.S.C. 78s(b)(3)(A)(ii).

²² 17 CFR 240.19b-4(f)(2).

²³ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

Market center	Primary source	Secondary source
A—NYSE MKT (AMEX)	CQS/UQDF	n/a
B—NASDAQ OMX BX	BX ITCH 5.0	CQS/UQDF
D—FINRA ADF	CQS/UQDF	n/a
J—DirectEdge A	EdgeBook	CQS/UQDF
K—DirectEdge X	EdgeBook	CQS/UQDF
M—CSX	CQS/UQDF	n/a
N—NYSE	NYSE OpenBook Ultra	CQS/UQDF
P—NYSE Arca	ArcaBook Binary uncompactd	CQS/UQDF
T/Q—NASDAQ	ITCH 5.0	CQS/UQDF
X—NASDAQ OMX PSX	PSX ITCH 5.0	CQS/UQDF
Y—BATS Y-Exchange	BATS PITCH	CQS/UQDF
Z—BATS Exchange	BATS PITCH	CQS/UQDF

* * * * *

- (b) Not applicable.
- (c) Not applicable.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

In her June 5, 2014 market structure speech, the Chair requested that all national securities exchanges review and disclose their policies and procedures governing the market data used when performing important exchange functions.³ In a letter dated June 20, 2014, the Director of the Division of Trading and Markets codified this request:

We believe there is a need for clarity regarding whether (1) the SIP data feeds, (2) proprietary data feeds, or (3) a combination thereof, are used by the exchanges for purposes of (1) order handling and execution (e.g., with pegged or midpoint orders), (2) order routing, and (3) regulatory compliance, as applicable. . . . Accordingly, we ask that proposed rule changes be filed that disclose the particular market data feeds that are used

for each of these purposes. Consistent with your recent discussions with Commission staff, we ask that each SRO file these proposed rule changes with the Commission by July 15, 2014.⁴

BX fully supports the Commission’s efforts to provide more clarity in this area. Through this proposed rule change, BX is publicly clarifying on a market-by-market basis the specific network processor and proprietary data feeds that BX utilizes for the handling, routing, and execution of orders, and for performing the regulatory compliance checks related to each of those functions. These complex practices are governed by a few, simple principles that are designed to ensure that BX has the most accurate view of the trading interest available across multiple markets, and to maximize the synchronization of the many exchange functions that depend upon the calculation of an accurate NBBO and top-of-book for each market. These principles are:

1. BX uses a proprietary data feed from each exchange that provides a reliable proprietary data feed. Where no reliable proprietary data feed is available, BX uses the network processor feed;
2. Where BX uses a proprietary data feed for an exchange quote, it also maintains access to the network processor feed as a back-up in the event a specific proprietary feed become [sic] unavailable or unusable for any reason;
3. BX uses the same proprietary data feed when performing order handling, routing, and execution functions, and also when the execution and routing system performs internal compliance checks related to those functions; and
4. BX acquires and processes all proprietary and network processor feeds

via the same technological configuration (i.e., telecommunication circuitry, switches, and feed handlers) to the greatest extent possible.

5. BX calculates the National Best Bid and Offer (“NBBO”) and top-of-book for each exchange at a single point within the BX System, and then distributes that data simultaneously to numerous applications performing order handling, routing, execution, and internal compliance functions throughout the BX System.

6. BX aggregates odd-lot orders, including those in its own and affiliated markets, when calculating the NBBO based upon a direct feed from an away exchange. BX processes odd-lot orders from each exchange direct feed in the same manner that that exchange aggregates odd-lots when reporting its own quotations to the SIP.

7. BX utilizes the NBBO and top-of-book calculations described above for the handling of orders that use those reference points, including all variations of midpoint orders, pegged orders, and price-to-comply orders described in BX Rule 4751(f), as well as Retail Price Improving Orders described in BX Rule 4780(a).

8. When calculating the NBBO, the BX System does not utilize feedback from other venues when calculating the NBBO. The BX System assumes that a protected quotation to which it has routed an order has been executed and can be removed from the NBBO; it does not await or respond to execution reports from such routing activity.

As of the date of this filing, BX utilizes the following data feeds for the handling, execution and routing of orders, as well as for performing related compliance checks:

³ See Mary Jo White, Chair, Securities and Exchange Commission, Speech at the Sandler O’Neill & Partners L.P. Global Exchange and Brokerage Conference (June 5, 2014).

⁴ See Letter from Steven Luparello, Director, SEC Division of Trading and Markets, to Robert Greinfeld, Chief Executive Officer, NASDAQ OMX Group, Inc., dated June 20, 2014.

Market center	Primary source	Secondary source
A—NYSE MKT (AMEX)	CQS/UQDF	n/a
B—NASDAQ OMX BX	BX ITCH 5.0	CQS/UQDF
D—FINRA ADF	CQS/UQDF	n/a
J—DirectEdge A	EdgeBook	CQS/UQDF
K—DirectEdge X	EdgeBook	CQS/UQDF
M—CSX	CQS/UQDF	n/a
N—NYSE	NYSE OpenBook Ultra	CQS/UQDF
P—NYSE Arca	ArcaBook Binary uncompactd	CQS/UQDF
T/Q—NASDAQ	ITCH 5.0	CQS/UQDF
X—NASDAQ OMX PSX	PSX ITCH 5.0	CQS/UQDF
Y—BATS Y-Exchange	BATS PITCH	CQS/UQDF
Z—BATS Exchange	BATS PITCH	CQS/UQDF

BX uses these feeds to calculate the NBBO via an application called the “NMSFeed.” The NMSFeed consumes the BX Protected Quote Service (“NPQS”), which provides an internal view of that exchange’s own market data as BX ITCH, plus the proprietary and network processor market data feeds listed above. The NMSFeed calculates a Regulation NMS-Compliant “Best Bid or Offer” (“Compliant BBO”), and then delivers that information throughout the BX System, including to the “OUCH” order entry ports,⁵ the routing system, and various compliance applications described below.

Upon receipt of an update to a protected quote for a specific venue, the NMSFeed updates its quote for that venue, recalculates the consolidated BBO based upon the update, and recalculates the Compliant BBO after applying BX’s own BBO. Any portion of a quote that crosses BX’s BBO is ignored for purposes of calculating the NBBO. BX odd lot orders at the same price are aggregated and considered in the NBBO calculation if the sum is greater than or equal to a round lot. Otherwise, they are not considered in the NBBO calculation. Out of the remaining quotes, the most aggressive remaining bid and offer (excluding BX⁶ and any destination which has been excluded from the NBBO in compliance with the self-help procedures under Regulation NMS) is selected and reported as the best quote. If away markets are crossing the market after applying BX’s BBO, orders will be accepted as originally priced and have the potential to execute. Any order sent to BX that is not an Intermarket Sweep

⁵ OUCH is a protocol that allows BX participants to enter, replace and cancel orders and receive executions. In addition to OUCH, BX offers the FLITE protocol as an option for participants. In this document, references to OUCH also include FLITE because they are interchangeable for these purposes.

⁶ Deletion of BX’s quote at this stage of the process is necessary because otherwise the system would prevent valid executions on BX in the erroneous belief that such executions would be “trade throughs” in violation of Regulation NMS.

Order (“ISO”) will have the Compliant BBO check enforced by the system.⁷

The BX Routing and Special Handling System (“RASH”) utilizes the Compliant BBO to determine if and when an order with special processing directives is marketable either against one or more orders in either the Core Matching System or a remote trading venue. RASH also receives market data feeds from certain venues not displaying protected quotes in the national market system for use in “BDRK” and “BCST” routing strategies set forth in BX Rule 4758(a)(1)(A)(xiii) [sic] and (xiv) [sic], respectively. RASH maintains a number of routing processes, or Routers, unique to each venue that the System accesses. These Routers maintain a limited set of details for orders that are configured as routable by the user, while also monitoring the current best bid and best offer prices on each exchange.

The BX System includes internal compliance applications related to locked and crossed markets, trade throughs, limit-up/limit-down, and Regulation SHO compliance. Each of these applications utilizes the Compliant BBO to ensure compliance with applicable regulations. BX operates a separate real-time surveillance system that is external to the execution systems and that monitors the execution system’s compliance with applicable rules and regulations. The real-time surveillance system utilizes a “mirrored” version of the internal NMSFeed in various realtime surveillance patterns, including (1) Lock/Cross, which detects lock/cross events across all markets, regardless of whether or not BX is a participant in the

⁷ In general, any order that is sent to BX with an ISO flag is not re-priced and will be processed at its original price. There are a limited number of circumstances in which an order marked as an ISO will be determined not to be executable at its original price and will be re-priced. These include re-pricing under the Plan to Address Extraordinary Market Volatility, re-pricing to comply with Regulation SHO, and the re-pricing of an order with a post-only condition if BX has an order at that price at the time the order is accepted.

event; (2) Trade Through, which detects potential trade through events for all three NASDAQ equity markets; and (3) RegSho, which detects potential RegSho violations, alerting when a trade executes at or below the NBB at the time of order entry while the stock is in a RegSho restricted state.

2. Statutory Basis

BX believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,⁸ in general and with Sections [sic] 6(b)(5) of the Act,⁹ 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 regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, 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 its proposal to describe the Exchange’s use of data feeds removes impediments to and perfects the mechanism of a free and open market and protects investors and the public interest because it provides additional specificity and transparency. The Exchange’s proposal will enable investors to better assess the quality of the Exchange’s execution and routing services. The proposal does not change the operation of the Exchange or its use of data feeds; rather it describes how, and for what purposes, the Exchange uses the quotes disseminated from data feeds to calculate the NBBO for a security for purposes of Regulation NMS, Regulation SHO and various order types that update based on changes to the applicable NBBO. The Exchange believes the additional transparency into the operation of the Exchange as described in the proposal will remove

⁸ 15 U.S.C. 78f.

⁹ 15 U.S.C. 78f(b)(5).

impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange 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, as amended. To the contrary, the Exchange believes the proposal would enhance competition because describing the Exchange's use of data feeds enhances transparency and enables investors to better assess the quality of the Exchange's execution and routing services.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁰ and Rule 19b-4(f)(6) thereunder.¹¹

A proposed rule change filed pursuant to Rule 19b-4(f)(6) under the Act¹² normally does not become operative for 30 days after the date of its filing. However, Rule 19b-4(f)(6)(iii)¹³ permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing, noting that waiver of the operative delay would permit the Exchange to immediately enhance

transparency. The Commission believes the waiver of the operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal operative upon filing.¹⁴

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-BX-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-BX-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 will also 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-BX-2015-026 and should be submitted on or before June 10, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁵

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015-12142 Filed 5-19-15; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-74969; File No. SR-CBOE-2015-042]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Regarding Limitation of Liability

May 14, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on May 5, 2015, Chicago Board Options Exchange, Incorporated (the "Exchange" or "CBOE") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the Exchange. The Exchange filed the proposal as a "non-controversial" proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act³ and Rule 19b-4(f)(6) thereunder.⁴ The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

¹⁵ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ 15 U.S.C. 78s(b)(3)(A)(iii).

⁴ 17 CFR 240.19b-4(f)(6).

¹⁰ 15 U.S.C. 78s(b)(3)(A).

¹¹ 17 CFR 240.19b-4(f)(6). As required under Rule 19b-4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

¹² 17 CFR 240.19b-4(f)(6).

¹³ 17 CFR 240.19b-4(f)(6)(iii).

¹⁴ For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend its Rule 6.7 governing Exchange liability and payments to Trading Permit Holders in connection with certain types of losses that Trading Permit Holders may allege arose out of business conducted on or through the Exchange or in connection with the use of the Exchange's facilities. The Exchange also proposes conforming changes to Rules 2.24 and 6.7A, and the elimination of Rule 7.11. The text of the proposed rule change is available on the Exchange's Web site (<http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx>), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

CBOE proposes to amend Rule 6.7 to eliminate any implication of liability with respect to the Exchange and its subsidiaries or affiliates, or any of their directors, officers, committee members, other officials, employees, contractors, or agents, (including the Exchange, collectively, "Covered Persons") for losses arising out of the use or enjoyment of Exchange facilities. The proposed rule change is consistent with and supplements existing law, and would ensure that self-regulatory organizations ("SROs") can operate within the sphere of their regulatory duties without fear of endless, costly litigation and potential catastrophic loss.⁵ As discussed below, the proposed

⁵ Courts have recognized the importance of protecting exchanges from such loss in deciding that SROs must be absolutely immune from civil actions for losses arising out of the SRO function. See *Dexter v. Depository Trust & Clearing Corp.*,

rule change is also consistent with the rules of other exchanges limiting exchange liability (*see, e.g.*, EDGA Exchange, Inc. ("EDGA") Rule 11.14, BOX Options Exchange, LLC ("BOX") Rule 7230, International Securities Exchange, LLC ("ISE") Rule 705, and New York Stock Exchange LLC ("NYSE") Rule 18).

Under CBOE's proposal, although the Exchange would not be liable for losses, it would have the discretion to compensate Trading Permit Holders for losses alleged to have resulted from the Exchange's failure to correctly process an order or quote due to the acts or omissions of the Exchange or due to the failure of its systems or facilities (each, a "Loss Event"), up to specified limits. The proposed rule change would also establish timeframes within which Trading Permit Holders would be required to bring requests for compensation (and provide supporting documentation), provide factors the Exchange may consider in determining whether to provide compensation in response to such requests, and establish that the Exchange's determinations on compensation are final and not appealable. The proposed rule change would also provide that claims arising under a previous version of Rule 6.7 for losses occurring more than one year prior July 1, 2015 (the "Effective Date") would not be considered valid, and that claims for any losses occurring prior to the Effective Date must be brought within one month of the Effective Date to be considered valid. Specific changes to Exchange Rules are discussed below.⁶

406 F. Supp. 2d 260, 263 (S.D.N.Y. 2005) (absolute immunity possessed by SROs "is an integral part of the American system of self-regulation"), *aff'd* 219 F. App'x 91 (2d Cir. 2007). Without such protection, an SRO's "exercise of its quasi-governmental functions would be unduly hampered by disruptive and recriminatory lawsuits." *D'Alessio v. NYSE*, 258 F.3d 93, 105 (2d Cir. 2001). It is critical that SROs, which stand in the shoes of the SEC in performing their quasi-governmental regulatory function, be free from "the fear of burdensome damage suits that would inhibit the exercise of their independent judgment." *Dexter*, 406 F.Supp. 2d at 263.

⁶ The Exchange notes that Rule 6.7 is cross-referenced in several places throughout the Exchange Rules including, for example, in Rules 20.5, *Limitation of Liability of Exchange and of Reporting Authority*, 22.5, *Limitation of Liability of Exchange and of Reporting Authority*, and 50.6, *Liability and Legal Proceedings*, as well as Appendix A of Chapters XLVII–XLIX and Appendix A of Chapters L–LIV, and generally as part of the Chapter VI cross-references contained in the Introductions to Chapters XX–XXIX. The Exchange also notes that, in accordance with Rule 50.6, the provisions of Rules 2.24, 6.7, and 6.7A apply to the CBOE Stock Exchange, LLC ("CBSX," CBOE's stock execution facility) to the same extent that they apply to CBOE and references in those rules to the Exchange are also deemed to be references to CBSX.

Proposed Amendment to Rule Title

The proposed rule change would change the title of Rule 6.7 from "Exchange Liability" to "Exchange Liability Disclaimers and Limitations." The proposed amendment to the Rule title would clarify that the Rule does not impose liability on the Exchange, but rather disclaims Exchange liability for any losses that arise out of the use or enjoyment of the facilities afforded by the Exchange, any interruption in or failure or unavailability of any such facilities, or any action taken or omitted to be taken in respect to the business of the Exchange, the calculation or dissemination of specified values, or quotes or transaction reports for options or other securities (the "General Disclaimer").⁷

Proposed Amendments to Scope of General Disclaimer

Proposed amendments to Rule 6.7(a) would clarify that "contractors" are included within the term "Covered Persons," and are therefore included within the General Disclaimer. This proposed change is needed because the Exchange at times contracts with outside firms to provide products and services to the Exchange for use by Trading Permit Holders in connection with regulated business conducted on or through the Exchange and that arise out of the use or enjoyment of the facilities afforded by the Exchange and/or the calculation or dissemination of specified values, or quotes or transaction reports for options or other securities. The Exchange notes that this proposed rule change is consistent with the exclusion from liability for contractors found in EDGA Rule 11.14, BOX Rule 7230 and ISE Rule 705. Proposed amendments to Rule 6.7(a) would also clarify that "other officials" of the Exchange or "any subsidiaries or affiliates of the Exchange" are included within the term "Covered Persons," and are therefore included within the General Disclaimer. We note that this proposed rule change to include other officials and subsidiaries is consistent with the existing provisions of Rule 6.7A.⁸ The term "Covered Persons"

⁷ Cross-references to Rule 6.7 contained in Appendix A of Chapters XLVII–XLIX and Appendix A of Chapters L–LIV are also proposed to be updated to reflect the new title. In addition Appendix A of Chapters L–LIV is proposed to be updated to delete an unnecessary reference to Rule 24.4 and to include a cross-reference to Rule 50.6.

⁸ Exchange Rule 6.7A currently limits the rights of any Trading Permit Holder or any person associated with a Trading Permit Holder to institute a lawsuit or other legal proceeding against the Exchange or any director, officer, employee, agent or contractor, or other official of the Exchange, or any subsidiary of the Exchange, for any actions

would also include such subsidiaries' and affiliates' directors, officers, committee members, other officials, employees, contractors, or agents.

The proposed rule change would also clarify that implicit in the General Disclaimer is the Exchange's disclaimer of any warranties, express or implied, with respect to the use or enjoyment of facilities afforded by the Exchange, including without limitation, of any data provided by the Exchange. The current language of the rule states that the Exchange does not warrant "the use of any data transmitted or disseminated by or on behalf of the Exchange or any reporting authority designated by the Exchange, including but not limited to reports of transactions in or quotations for securities traded on the Exchange or underlying securities, or reports of interest rate measures or index values or related data." Under the proposed rule change, the Exchange would make explicit that the General Disclaimer is intended to contain within it a disclaimer of any warranties as to the use or enjoyment of the facilities offered by the Exchange. The proposed rule change would thereby clarify that such use or enjoyment of Exchange facilities by Trading Permit Holders is provided "as is," without specific warranties of merchantability or of fitness for a particular purpose. For the avoidance of doubt, the explicit list of the types of data for which the Exchange disclaims any warranties would also include, without limitation, "any current or closing index value, any current or closing value of interest rate options, or any report of transactions in or quotations for options or other securities, including underlying securities."⁹

The proposed rule change would also clarify that all limitations on liability and disclaimers within paragraph (a) of Rule 6.7 are in addition to, and not in limitation of, any limitations on liability otherwise existing under law. This proposed rule change is intended to ensure that the protection of Rule 6.7 does not circumscribe protections that otherwise would exist under the

taken or omitted to be taken in connection with the official business of the Exchange or any subsidiary, except to the extent such actions or omissions constitute violations of the federal securities laws for which a private right of action exist. The rule also permits appeals of Exchange disciplinary actions as provided in Exchange Rule. Proposed amendments to Rule 6.7A (discussed below) would clarify that this limitation applies to committee members and affiliates of the Exchange.

⁹ The Exchange also proposes to replace the phrase "facilities or services" with simply "facilities" in two locations within the existing text of Rule 6.7(a). The Exchange believes use of the term "services" is duplicative of the term "facilities" and is therefore unnecessary.

principles of law.¹⁰ This and other limitations on liability operate independently from, and in addition to, both the current and proposed amended versions of Rule 6.7 and CBOE's other rules.

Proposed Limits on Discretionary Payments for Alleged Losses

Currently, Rule 6.7(b) provides that whenever custody of an unexecuted order is transmitted by a Trading Permit Holder to or through the Exchange's systems or to any other automated facility of the Exchange whereby the Exchange assumes responsibility for the transmission or execution of the order, and provided that the Exchange has acknowledged receipt of such order, the Exchange's liability for the negligent acts or omissions of its employees or for the failure of its systems or facilities shall not exceed certain limits set forth in Rule 6.7(b). The Exchange first proposes to provide that Rule 6.42(b) applies to quotes as well as unexecuted orders. Additionally, the Exchange proposes to eliminate the word "automated" from "automated facility of the Exchange", as not all facilities of the Exchange may be considered automated and the Exchange did not intend to restrict the scope of rule as such. The Exchange also seeks to amend Rule 6.7(b) to explicitly provide that, although the Exchange would not be liable with respect to regulated Exchange business for losses that arise out of the use or enjoyment of the facilities afforded by the Exchange and/or the calculation or dissemination of specified values, or quotes or transaction reports for options or other securities, as provided in Rule 6.7(a),¹¹

¹⁰ For example, as CBOE is organized under Delaware law, the principals of Delaware law also apply.

¹¹ Specifically, Rule 6.7(a), as proposed to be amended, would provide as follows:

Neither the Exchange nor any of its directors, officers, committee members, other officials, employees, contractors, or agents, nor any subsidiaries or affiliates of the Exchange or any of their directors, officers, committee members, other officials, employees, contractors, or agents ("Covered Persons") shall be liable to the Trading Permit Holders or to persons associated therewith for any loss, expense, damages or claims that arise out of the use or enjoyment of the facilities afforded by the Exchange, any interruption in or failure or unavailability of any such facilities, or any action taken or omitted to be taken in respect to the business of the Exchange except to the extent such loss, expense, damages or claims are attributable to the willful misconduct, gross negligence, bad faith or fraudulent or criminal acts of the Exchange or its officers, employees or agents acting within the scope of their authority. Without limiting the generality of the foregoing, and subject to the same exception, no Covered Person shall have any liability to any person or entity for any loss, expense, damages or claims that result from any error, omission or delay in calculating or

the Exchange may make discretionary payments to Trading Permit Holders for certain losses alleged to have occurred due to Loss Events. Specifically, the proposed rule change would permit the Exchange to make discretionary payments to Trading Permit Holders for their losses alleged to have resulted from Loss Events up to the following limits. As to any one or more requests for compensation made by a single Trading Permit Holder that arose out of one or more Loss Events occurring on a single trading day, the Exchange could compensate the Trading Permit Holder up to but not exceeding the larger of \$100,000 or the amount of any recovery obtained by the Exchange under applicable insurance maintained by the Exchange. As to the aggregate of all requests for compensation made by all Trading Permit Holders that arose out of one or more Loss Events occurring: (i) On a single trading day, the Exchange could compensate the Trading Permit Holders, in the aggregate, up to but not exceeding the larger of \$250,000 or the amount of recovery obtained by the Exchange under any applicable insurance policy; and (ii) during a single calendar month, the Exchange could compensate the Trading Permit Holders, in the aggregate, up to but not exceeding the larger of \$500,000 or the amount of the recovery obtained by the Exchange under any applicable insurance maintained by the Exchange. The proposed rule change would also state that no request for compensation by a Trading Permit Holder may be in an amount less than \$100. Losses incurred on the same trading day and arising out of the same underlying act or omission of the Exchange or failure of the Exchange's systems or facilities may be aggregated to meet the \$100 minimum.¹²

disseminating any current or closing index value, any current or closing value of interest rate options, or any reports of transactions in or quotations for options or other securities, including underlying securities. The Exchange makes no warranty, express or implied, as to results to be obtained by any person or entity from the use or enjoyment of the facilities afforded by the Exchange, including without limitation, of any data transmitted or disseminated by or on behalf of the Exchange or any reporting authority designated by the Exchange, including but not limited to any data described in the preceding sentence, and the Exchange makes no express or implied warranties of merchantability or fitness for a particular purpose or use with respect to any such data. The foregoing limitations of liability and disclaimers shall be in addition to, and not in limitation of, the provisions of Article Eighth of the Exchange's Certificate of Incorporation or any limitations otherwise available under law.

¹² For example, if a TPH incurs a loss of \$30 on one day due to a certain glitch in the Exchange's systems and a loss of \$75 on the same day due to a separate unrelated glitch in the Exchange's systems, the TPH could not request compensation for either loss. However, if for example, the TPH

This is intended as a de minimis threshold to avoid requiring the Exchange to devote the resources to considering relatively small requests for payment. The proposed rule change also would state that nothing in Rule 6.7 would obligate the Exchange to seek recovery under any applicable insurance policy. The proposed changes to Rule 6.7(b) would therefore, consistent with Rule 6.7(a), permit the Exchange to make discretionary payments to Trading Permit Holders to compensate them for such losses, up to specified limits, even though the Exchange would not be legally liable to pay for such losses.

Timeframes Within Which To Notify Exchange and Submit Requests

Proposed new Rule 6.7(c) would establish timeframes within which a valid request for compensation must be brought under the Rule. Under the proposed rule change, notice of all requests would be required to be in writing and to be submitted to the Exchange no later than 12:00 p.m. Central Time on the next business day following the Loss Event giving rise to such request. All requests would be required to be in writing and to be submitted, along with supporting documentation, by 5:00 p.m. Central Time on the third business day following the Loss Event giving rise to each such request.¹³ Additional information related to the request as demanded by the Exchange is also required to be provided. The proposed rule change would also specify that the Exchange would not consider requests for which timely notice and submission had not been provided as required under amended Rule 6.7(c).

The proposed provisions of new Rule 6.7(c) would benefit Trading Permit Holders by providing them with clear timeframes within which to submit notices of requests, requests for compensation, and supporting

incurs a loss of \$105 on one day due to a certain glitch in the Exchange's system, the TPH may request compensation. In this second example, the TPH may request compensation even if such losses were incurred over a number of different transactions so long as it was the result of the same systems issue.

¹³ Other exchanges have similar submission requirements. See, e.g., NYSE Rule 18—*Compensation in Relation to Exchange System Failure*, which provides in relevant part that NYSE members provide oral notice to NYSE's Division of Floor Operations by the market opening on the next business day following the system failure and written notice by the end of the third business day following the system failure (T+3). See also, ISE Rule 705(d)(3)—*Limitation of Liability*, which provides that all claims for compensation must be made in writing and submitted no later than the opening of trading on the next business day following the event that gave rise to such claim.

documentation. The proposed changes would also provide the Exchange with certainty as to the deadlines by which notices of requests and completed requests would be required to be submitted in order for the Exchange to consider them for compensation under Rule 6.7.

Exchange Treatment of Aggregate Requests Exceeding Maximum Amount Permitted To Be Paid

Currently, Rule 6.7(c) provides that if all of the claims cannot be fully satisfied because in the aggregate they exceed the applicable maximum amount of liability provided for in paragraph (b) [of Rule 6.7] [sic], then such maximum amount would be allocated among all such claims arising on a single trading day or during a single calendar month, as applicable, written notice of which has been given to the Exchange no later than the opening of trading on the next business day following the day on which the use or enjoyment of Exchange facilities giving rise to the claim occurred, based upon the proportion that each claim bears to the sum of all such claims. The Exchange proposes to amend existing Rule 6.7(c), which would be renumbered to Rule 6.7(d), to state that, "if all of the timely requests submitted pursuant to paragraph (c) [of Rule 6.7] that are granted cannot be fully satisfied because in the aggregate they exceed the applicable maximum amount of payments authorized in paragraph (b) [of Rule 6.7], then such maximum amount shall be allocated among all such requests arising on a single trading day or during a single calendar month, as applicable, based upon the proportion that each such request bears to the sum of all such requests."

The Exchange notes that it is proposing to replace the term "claim" with the term "request", as well as replace the reference to "liability" with "payments authorized" to eliminate any implication of liability with respect to the Exchange and other Covered Person resulting from the use or enjoyment of the facilities offered by the Exchange, any interruption in or failure or unavailability or any such facilities, or any action taken or omitted to be taken in respect of the business of the Exchange.

Additionally, the Exchange notes that proposed Rule 6.7(d) would continue to provide a fair way of allocating the limited payment that the rule would permit the Exchange to make when the total amount of eligible requests exceed that maximum amount. The proposal would also revise the timeframe in

which requests for payment must be made by a Trading Permit Holder.

Exchange Review of Timely Requests

Proposed new Rule 6.7(e) would provide that the Exchange, in determining whether to make payment in response to a request for compensation, may determine whether the amount requested should be reduced based on the actions or inactions of the requesting Trading Permit Holder. The proposed rule change would permit the Exchange to consider, without limitation, whether the actions or inactions of the Trading Permit Holder contributed to the Loss Event; whether the Trading Permit Holder made appropriate efforts to mitigate its loss; whether the Trading Permit Holder realized any gains as a result of a Loss Event; whether the losses of the Trading Permit Holder, if any, were offset by hedges of positions either on the Exchange or on another affiliated or unaffiliated market; and whether the Trading Permit Holder provided sufficient information to document the request and as demanded by the Exchange. Proposed Rule 6.7(e) would therefore provide reasonable factors that the Exchange may consider in determining whether to pay compensation in response to a request and in determining the amount of any such compensation.¹⁴

The Exchange represents that the determination to compensate a Trading Permit Holder will be made on an equitable and non-discriminatory basis and without regard to the Exchange capacity of the Trading Permit Holder (including whether the Trading Permit Holder is a Designated Primary Market-Maker). Additionally, the Exchange represents that the Exchange will maintain a record of Trading Permit Holder requests including documentation detailing the Exchange's findings and details for approving or denying requests in accordance with its obligations under Section 17 of the Act.

Finality of Exchange Determinations Under Rule

Proposed new Rule 6.7(f) would provide that all determinations by the Exchange pursuant to Rule 6.7 shall be final and not subject to appeal under

¹⁴ Another exchange considered similar factors in determining whether to pay compensation and in determining the amount of any such compensation. See NYSE Rule 18, which provides in relevant part that the NYSE Compensation Review Panel in its review will determine whether the amount should be reduced based on the actions or inactions of the member organization, including whether the member organization made appropriate efforts to mitigate its loss.

Chapter XIX of the Exchange Rules.¹⁵ The proposed rule would also provide that nothing in Rule 6.7, nor any payment made pursuant to Rule 6.7, shall in any way limit, waive or proscribe any defenses a Covered Person may have to any claim, demand, liability, action or cause of action, whether such defense arises in law or equity, or whether such defense is asserted in a judicial, administrative, or other proceeding.¹⁶ These proposed changes are consistent with the discretionary nature of any payments that would be made under proposed Rule 6.7(b).

Treatment of Losses Occurring Prior to Effective Date of Rule

Proposed new paragraph 6.7(g) would establish July 1, 2015 as the Effective Date of revised Rule 6.7. Under proposed paragraph 6.7(g), claims for liability under prior versions of Rule 6.7 would not be considered valid if brought with respect to any acts, omissions or transactions occurring more than one year prior to the Effective Date, or if brought more than one month after the Effective Date. Proposed Rule 6.7(g) would thereby provide certainty to the Exchange as to any expense it might incur due to Loss Events that occurred prior to the Effective Date of the proposed rule change, while also putting Trading Permit Holders on notice that they must file any claims for such losses by a date certain.

Deletion of Existing Interpretations Under Rule 6.7

The proposed rule change would delete existing Interpretations .01–.04 under Rule 6.7. Interpretation .01 states that Rule 7.11 governs the liability of the Exchange for claims arising out of the errors or omissions of an Order Book Official or his or her assistants or clerks or a PAR Official or his or her assistants or clerks. Under the proposed rule change, Rule 7.11 (as well as cross-references to Rule 7.11)¹⁷ would be

¹⁵ The Exchange notes that another exchange has a similar provision indicating that all determinations are final. See, NYSE Rule 18, which provides in relevant part that all determinations made pursuant to NYSE Rule 18 by NYSE's Compensation Review Panel, CEO or his or her designee are final.

¹⁶ Another exchange has a similar provision. See e.g., Nasdaq Rule 4626(b)(6), which provides that nothing in its Limitation of Liability rule shall waive Nasdaq's limitations on, or immunities from, liability as set forth in its Rules or agreements, or that otherwise apply as a matter of law.

¹⁷ Specifically, Rules 6.7, 7.12 and 21.18 are proposed to be amended to delete cross-references to Rule 7.11. In addition, the Exchange is proposing to amend Rule 21.18 to delete an outdated reference to Board Brokers, a floor function that no longer exists on the Exchange.

eliminated, making the interpretation unnecessary.

Interpretation .02 is reserved and would therefore be deleted. Interpretation .03 states that the provision of Exchange liability in paragraph (b) of current Rule 6.7 for certain orders routed through the Exchange's Order Routing System or E-Book shall not apply. Because the proposed rule change would eliminate Exchange liability under paragraph (b), the interpretation would no longer be necessary.

Interpretation .04 disclaims The Options Clearing Corporation liability to Trading Permit Holders and their associated persons with respect to their use, non-use or inability to use the linkage that was part of the old Options Intermarket Linkage Plan (the "Old Linkage"). Because the Old Linkage is no longer operable, interpretation .04 is no longer necessary.¹⁸

Conforming Changes to Other Rules

The proposed rule change would make conforming changes to Exchange Rules 2.24 and 6.7A. Rule 2.24 requires a Trading Permit Holder who fails to prevail in a lawsuit or other legal proceeding instituted against the Exchange or certain related parties to pay for the Exchange's reasonable costs of defending such lawsuit or proceeding if those costs exceed \$50,000. Rule 6.7A limits the legal proceedings a Trading Permit Holder may bring against the Exchange and certain related persons for actions or omissions.

Under the proposed amendments to Rules 2.24, contractors would be included within the list of related parties protected by that rule, just as they would be included as Covered Persons under proposed Rule 6.7. As stated above, this proposed change is necessary because the Exchange at times contracts with outside firms to provide products or services to Trading Permit Holders in connection with regulated business conducted on or through the Exchange and that arise out of the use or enjoyment of the facilities afforded by the Exchange and/or the calculation or dissemination of specified values, or quotes or transaction reports for options or other securities.

In addition, under the proposed amendments to Rule 2.24, other officials and contractors of the Exchange and any subsidiaries and affiliates of the Exchange and any such subsidiaries' and affiliates' directors, officers,

¹⁸ The old Options Intermarket Linkage Plan was replaced by the Options Order Protection and Locked/Crossed Markets Plan in 2009. See Securities Exchange Act Release No. 60405 (July 30, 2009), 74 FR 39362 (August 6, 2009).

committee members, other officials, employees, contractors, or agents would be explicitly identified/included within the list of related parties protected by the rule,¹⁹ just as they are proposed to be specifically identified/included within the list of Covered Persons under Rule 6.7. Committee members and affiliates of the Exchange and any subsidiaries' and affiliates' directors, officers, committee members, other officials, employees, contractors and agents would also be explicitly identified/included within the list of related parties under Rule 6.7A.²⁰ These changes are intended to conform the text of the three rules and to include affiliates within all three rules.²¹ Moreover, under the proposed amendments to Rule 6.7A, committee members would be explicitly identified/included within the list of related parties protected by the rule, just as they are already specifically identified/included within the list of Covered Persons under existing Rule 6.7 and the similar provision in Rule 2.24. This is also intended to conform the text of the three rules. Finally, under the proposed amendments to Rule 6.7A, the title to the rule will be revised.²²

The proposed rule change would also delete Rule 7.11 in its entirety. Rule

¹⁹ Specifically, the phrase "the Exchange or any of its directors, officers, committee members, employees or agents" is proposed to be replaced with the phrase "the Exchange or any of its directors, officers, committee members, other officials, employees, contractors, or agents, or any subsidiaries or affiliates of the Exchange or any of their directors, officers, committee members, other officials, employees, contractors, or agents" in Rule 2.24.

²⁰ Specifically, the phrase "the Exchange or any director, officer, employee, contractor, agent or other official of the Exchange or any subsidiary of the Exchange" is proposed to be replaced with the phrase "the Exchange or any of its directors, officers, committee members, other officials, employees, contractors, or agents, or any subsidiaries or affiliates of the Exchange or any of their directors, officers, committee members, other officials, employees, contractors, or agents" in Rule 6.7A.

²¹ The Commission notes CBOE's statement of the purpose of its proposed rule change is to eliminate any implication of liability for losses arising out of the use or enjoyment of Exchange facilities consistent with existing law where courts have recognized the importance of protecting exchanges from liability in the context of matters arising out of the SRO function. See *supra* note 5 and accompanying text.

²² Specifically, the title "Legal Proceedings Against the Exchange and its Directors, Officers, Employees, Contractors or Agents" is proposed to be changed to simply "Legal Proceedings Against the Exchange." Cross-references to Rule 6.7A contained in Appendix A of Chapters XLVII–XLIX and Appendix A of Chapters L–LIV Appendix A are also proposed to be updated to reflect the new title. Additionally, cross-references to Rule 2.24 contained in Appendix A of Chapters XLVII–XLIX and Appendix A of Chapters L–LIV Appendix A are proposed to be updated to include consistent capitalization of words in the Rule's title.

7.11 currently governs the liability of the Exchange relating to losses resulting from the errors or omissions of Exchange Order Book Officials and PAR Officials. Rule 7.11 provides that the Exchange's liability arising out of any errors or omissions of an Order Book Official or PAR Official (or their assistants or clerks) shall be subject to the limitations set forth in paragraph (a) of existing Rule 6.7, and to further limitations set forth in paragraph (b) and (c) of Rule 7.11. Under paragraph (b) of Rule 7.11, absent reasonable justification or excuse, any single claim²³ by a Trading Permit Holder or person associated with a Trading Permit Holder for losses arising from errors or omissions of an Order Book Official or PAR Official, and any claim by the Exchange made pursuant to paragraph (d) of the Rule,²⁴ must be presented in writing to the opposing party within ten business days following the transaction giving rise to the claim.²⁵ All disputed

²³ Under paragraph (b), the term "transaction" means any single order or instruction which is placed with an Order Book Official or PAR Official, or any series of orders or instructions which is placed with an Order Book Official or a PAR Official at substantially the same time by the same Trading Permit Holder and which relates to any one or more series of options of the same class. All errors and omissions made by an Order Book Official or PAR Official with respect to or arising out of any transaction shall give rise to a "single claim" against the Exchange for losses resulting therefrom as provided in paragraph (b) and in paragraph (c), and the Exchange is free to assert any defense to such claim it may have. No claim shall arise as to errors or omissions which are found to have resulted from any failure by a Trading Permit Holder (whether or not the Trading Permit Holder is claiming against the Exchange pursuant to paragraph (b)), or by any person acting on behalf of a Trading Permit Holder, to enter or cancel an order with such Order Book Official or PAR Official on a timely basis or clearly and accurately to communicate to such Order Book Official or PAR Official: (i) The description or symbol of the security involved; (ii) the exercise price or option contract price; (iii) the type of option; (iv) the number of trading units; (v) the expiration month; or (vi) any other information or data which is material to the transaction. In addition, no claim shall be allowed if, in the opinion of the arbitration panel, the Trading Permit Holder or other person making such claim did not take promptly, upon discovery of the errors or omissions, all proper steps to correct such errors or omissions and to establish the loss resulting therefrom. See Rule 7.11(b)(1).

²⁴ Under paragraph (d), if any damage is caused by an error or omission of an Order Book Official or PAR Official which is the result of any error or omission of a TPH organization, then such TPH organization shall indemnify the Exchange and hold it harmless from any claim of liability resulting from or relating to such damage. See Rule 7.11(d).

²⁵ Provided, that if an error or omission has resulted in an unmatched trade, then any claim based thereon shall be presented after the unmatched trade has been closed out in accordance with Rule 10.1, *Disagreement on Unmatched Trades*, but within ten business days following such resolution of the unmatched trade. See Rule 7.11(b)(2).

claims shall be referred to binding arbitration before an arbitration panel whose resolution of the dispute shall be final, and there shall be no appeal to the Board of Directors from a decision of such panel. Under paragraph (c), liability under Rule 7.11 is limited as follows: Should a Trading Permit Holder, TPH organization or the Exchange fail to close out an uncomparated trade in the period of time provided by Rule 10.1, then the opposing party's liability with respect to any claims arising from such trade shall be limited to the lesser of (i) the loss which would have been experienced by the claimant if the uncomparated trade had been closed out at the opening of trading on the day provided in Rule 10.1 for the closing out of such uncomparated trade; or (ii) the actual loss realized by the claimant.

Under the proposed rule change, Rule 6.7 would govern the liability of the Exchange for claims arising out of any errors or omissions by agents of the Exchange, which would include Order Book Officials, PAR Officials and their respective assistants or clerks. Rule 7.11 therefore would be rendered superfluous. The Exchange does note that, with the elimination of Rule 7.11, both the Exchange's reciprocal right to bring a claim against Trading Permit Holders and the arbitration process for disputed claims will be eliminated. The Exchange no longer believes it is necessary to single out the errors or omissions of Order Book Officials and PAR Officials in the manner described under Rule 7.11 as compared to other errors and omissions that are subject to Rule 6.7.²⁶ As simplified and revised, Rule 6.7 would apply equally to all types of claims by Trading Permit Holders against Covered Persons, including Order Book Officials and PAR Officials.

2. Statutory Basis

The proposed rule change is consistent with Section 6(b) of the Securities Exchange Act of 1934 (the "Act")²⁷ in general and furthers the objectives of Section 6(b)(5) of the Act²⁸ in particular, which requires that the rules of an exchange be designed to promote just and equitable principles of trade, to remove impediments to and to perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. In

²⁶ The Exchange also notes that, in practice, there have not been any disputed claims submitted to the arbitration process under Rule 7.11 for several years.

²⁷ 15 U.S.C. 78f(b).

²⁸ 15 U.S.C. 78f(b)(5).

particular, the proposal would amend Exchange Rule 6.7 to eliminate any implication of liability with respect to the Exchange and other Covered Person resulting from the use or enjoyment of the facilities offered by the Exchange, any interruption in or failure or unavailability or any such facilities, or any action taken or omitted to be taken in respect of the business of the Exchange. The proposed rule change is consistent with and supplements existing law, and would assist the Exchange in fulfilling its role as a national securities exchange by avoiding the risk of tempering this critical regulatory function to avoid the disruption and expense of unnecessary litigation or potential catastrophic loss.

The proposal would also permit the Exchange to compensate Trading Permit Holders for their losses incurred due to a Loss Event, even though the Exchange would not have legal liability for those losses. The proposed rule change would therefore facilitate the Exchange's ability to make discretionary payments to redress a situation in which Trading Permit Holders suffer losses due to a Loss Event. As stated above, the Exchange represents that the determination to compensate a Trading Permit Holder will be made on an equitable and non-discriminatory basis without regard to the Exchange capacity of the Trading Permit Holder, including whether the Trading Permit Holder is a Designated Primary Market-Maker. The Exchange therefore believes the proposed rule change is consistent with the Act, and Section 6(b)(5) of the Act in particular, in that it is designed to promote just and equitable principles of trade, to remove impediments to and to 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 also believes that these policies would promote fairness in the national market system. The proposed rule change would allow CBOE to address Trading Permit Holder requests for compensation under various circumstances and would allow CBOE to act in a fashion similar to many of its competitors. As stated above, several exchanges have substantially similar rules to those proposed here, and the Exchange believes that the proposed rule change would place CBOE in a similar position to address Trading Permit Holder requests.²⁹ The Exchange believes that to the extent there are any

²⁹ See BOX Rule 7230 and EDGA Rule 11.14; see also NASDAQ Stock Market LLC ("Nasdaq") Rule 4626, ISE Rule 705, BATS Exchange, Inc. Rule 11.16, and NYSE Rule 18.

differences, such differences are not substantive and are still consistent with the scope of prior self-regulatory organization rulemaking.

Finally, the Exchange believes that as Rule 6.7 will now govern the liability of the Exchange for claims arising out of any errors or omissions by agents of the Exchange (which would include Order Book Officials, PAR Officials and their respective assistants or clerks), Rule 7.11 is superfluous and unnecessary to maintain in the rules. Additionally, the Exchange no longer believes it is necessary to single out the errors or omissions of Order Book Officials and PAR Officials in the manner described under Rule 7.11 as compared to other errors and omissions that are subject to Rule 6.7. The Exchange notes that although the Exchange's reciprocal right to bring a claim against Trading Permit Holders and the arbitration process for disputed claims will be eliminated, such language is no longer necessary.³⁰ As such, the Exchange believes that eliminating Rule 7.11 maintains clarity in the rules and avoids potential confusion, which removes impediments and perfects the mechanism of a free and open market and a national market system, and, in general, protects investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that this proposed rule change does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. As stated above, the Exchange believes that these policies would promote fairness in the national market system. The proposed rule change would allow CBOE to address Trading Permit Holder requests for compensation under various circumstances and would allow CBOE to act in a fashion similar to many of its competitors. In addition, as stated above, several exchanges have substantially similar rules to those proposed here, except as otherwise noted, and the Exchange believes that the proposed rule change would place CBOE in a similar position to address Trading Permit Holder requests.³¹

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

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, it has become effective pursuant to Section 19(b)(3)(A) of the Act³² and Rule 19b-4(f)(6)³³ thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-CBOE-2015-042 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090. All submissions should refer to File Number SR-CBOE-2015-042. This file

³² 15 U.S.C. 78s(b)(3)(A).

³³ 17 CFR 240.19b-4(f)(6). As required under Rule 19b-4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

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 St. 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-CBOE-2015-042, and should be submitted on or before June 10, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.³⁴

Robert W. Errett,
Deputy Secretary.

[FR Doc. 2015-12148 Filed 5-19-15; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-74967; File No. SR-Phlx-2015-39]

Self-Regulatory Organizations; NASDAQ OMX PHLX, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Update the Public Disclosure of Sources of Data Utilized by PSX

May 14, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on May 5, 2015, NASDAQ OMX PHLX LLC ("Phlx" or "Exchange") filed with the

³⁴ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³⁰ In practice, there have not been any disputed claims submitted to the arbitration process under Rule 7.11 for several years.

³¹ *Id.*

Securities and Exchange Commission (“SEC” or “Commission”) the proposed rule change as described in Items I and II, below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to update the public disclosure of the sources of data that PSX, the PHLX equities facility, utilizes when performing (1) order

handling and execution; (2) order routing; and (3) related compliance processes.

The text of the proposed rule change is below. Proposed new language is italicized; proposed deletions are bracketed.

* * * * *

3304. Data Feeds Utilized

[Phlx shall publicly disclose the proprietary and network processor feeds utilized by the System for the handling, routing, and execution of orders, as well as for the regulatory compliance processes related to those functions.

This information shall be displayed on www.nasdaqtrader.com, and it shall be updated promptly each time Phlx determines to add, subtract, or otherwise modify a data source.]

The PSX System utilizes the below proprietary and network processor feeds utilized by the System for the handling, routing, and execution of orders, as well as for the regulatory compliance processes related to those functions. The Secondary Source of data is utilized only in emergency market conditions and only until those emergency conditions are resolved.

Market center	Primary source	Secondary source
A—NYSE MKT (AMEX)	CQS/UQDF	n/a
B—NASDAQ OMX BX	BX ITCH 5.0	CQS/UQDF
D—FINRA ADF	CQS/UQDF	n/a
J—DirectEdge A	EdgeBook	CQS/UQDF
K—DirectEdge X	EdgeBook	CQS/UQDF
M—CSX	CQS/UQDF	n/a
N—NYSE	NYSE OpenBook Ultra	CQS/UQDF
P—NYSE Arca	ArcaBook Binary uncompactd	CQS/UQDF
T/Q—NASDAQ	ITCH 5.0	CQS/UQDF
X—NASDAQ OMX PSX	PSX ITCH 5.0	CQS/UQDF
Y—BATS Y-Exchange	BATS PITCH	CQS/UQDF
Z—BATS Exchange	BATS PITCH	CQS/UQDF

* * * * *

- (b) Not applicable.
- (c) Not applicable.

The text of the proposed rule change is available on the Exchange’s Web site at <http://nasdaqomxphlx.cchwallstreet.com/>, at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

In her June 5, 2014 market structure speech, the Chair requested that all national securities exchanges review

and disclose their policies and procedures governing the market data used when performing important exchange functions.³ In a letter dated June 20, 2014, the Director of the Division of Trading and Markets codified this request:

We believe there is a need for clarity regarding whether (1) the SIP data feeds, (2) proprietary data feeds, or (3) a combination thereof, are used by the exchanges for purposes of (1) order handling and execution (e.g., with pegged or midpoint orders), (2) order routing, and (3) regulatory compliance, as applicable. . . . Accordingly, we ask that proposed rule changes be filed that disclose the particular market data feeds that are used for each of these purposes. Consistent with your recent discussions with Commission staff, we ask that each SRO file these proposed rule changes with the Commission by July 15, 2014.⁴

PHLX fully supports the Commission’s efforts to provide more clarity in this area. Through this proposed rule change, PHLX is publicly clarifying on a market-by-market basis the specific network processor and proprietary data feeds that PHLX

utilizes for the handling, routing, and execution of orders, and for performing the regulatory compliance checks related to each of those functions. These complex practices are governed by a few, simple principles that are designed to ensure that PHLX has the most accurate view of the trading interest available across multiple markets, and to maximize the synchronization of the many exchange functions that depend upon the calculation of an accurate NBBO and top-of-book for each market. These principles are:

1. PHLX uses a proprietary data feed from each exchange that provides a reliable proprietary data feed. Where no reliable proprietary data feed is available, PHLX uses the network processor feed;
2. Where PHLX uses a proprietary data feed for an exchange quote, it also maintains access to the network processor feed as a back-up in the event a specific proprietary feed become [sic] unavailable or unusable for any reason;
3. PHLX uses the same proprietary data feed when performing order handling, routing, and execution functions, and also when the execution and routing system performs internal compliance checks related to those functions; and
4. PHLX acquires and processes all proprietary and network processor feeds via the same technological configuration

³ See Mary Jo White, Chair, Securities and Exchange Commission, Speech at the Sandler O’Neill & Partners L.P. Global Exchange and Brokerage Conference (June 5, 2014).

⁴ See Letter from Steven Luparello, Director, SEC Division of Trading and Markets, to Robert Greinfeld, Chief Executive Officer, NASDAQ OMX Group, Inc., dated June 20, 2014.

(i.e., telecommunication circuitry, switches, and feed handlers) to the greatest extent possible.

5. PHLX calculates the National Best Bid and Offer (“NBBO”) and top-of-book for each exchange at a single point within the PHLX System, and then distributes that data simultaneously to numerous applications performing order handling, routing, execution, and internal compliance functions throughout the PHLX System.

6. PHLX aggregates odd-lot orders, including those in its own and affiliated

markets, when calculating the NBBO based upon a direct feed from an away exchange. PHLX processes odd-lot orders from each exchange direct feed in the same manner that that exchange aggregates odd-lots when reporting its own quotations to the SIP.

7. PHLX utilizes the NBBO and top-of-book calculations described above for the handling of orders that use those reference points, including all variations of midpoint orders, pegged orders, and price-to-comply orders described in PHLX Rule 3301(f).

8. When calculating the NBBO, the PHLX System does not utilize feedback from other venues when calculating the NBBO. The PHLX System assumes that a protected quotation to which it has routed an order has been executed and can be removed from the NBBO; it does not await or respond to execution reports from such routing activity. As of the date of this filing, PHLX utilizes the following data feeds for the handling, execution and routing of orders, as well as for performing related compliance checks:

Market center	Primary source	Secondary source
A—NYSE MKT (AMEX)	CQS/UQDF	n/a
B—NASDAQ OMX BX	BX ITCH 5.0	CQS/UQDF
D—FINRA ADF	CQS/UQDF	n/a
J—DirectEdge A	EdgeBook	CQS/UQDF
K—DirectEdge X	EdgeBook	CQS/UQDF
M—CSX	CQS/UQDF	n/a
N—NYSE	NYSE OpenBook Ultra	CQS/UQDF
P—NYSE Arca	ArcaBook Binary uncompactd	CQS/UQDF
T/Q—NASDAQ	ITCH 5.0	CQS/UQDF
X—NASDAQ OMX PSX	PSX ITCH 5.0	CQS/UQDF
Y—BATS Y-Exchange	BATS PITCH	CQS/UQDF
Z—BATS Exchange	BATS PITCH	CQS/UQDF

PHLX uses these feeds to calculate the NBBO via an application called the “NMSFeed.” The NMSFeed consumes the PHLX Protected Quote Service (“NPQS”), which provides an internal view of that exchange’s own market data as PHLX ITCH, plus the proprietary and network processor market data feeds listed above. The NMSFeed calculates a Regulation NMS-Compliant “Best Bid or Offer” (“Compliant BBO”), and then delivers that information throughout the PHLX System, including to the “OUCH” order entry ports,⁵ the routing system, and various compliance applications described below.

Upon receipt of an update to a protected quote for a specific venue, the NMSFeed updates its quote for that venue, recalculates the consolidated BBO based upon the update, and recalculates the Compliant BBO after applying PHLX’s own BBO. Any portion of a quote that crosses PHLX’s BBO is ignored for purposes of calculating the NBBO. PHLX odd lot orders at the same price are aggregated and considered in the NBBO calculation if the sum is greater than or equal to a round lot. Otherwise, they are not considered in the NBBO calculation. Out of the

remaining quotes, the most aggressive remaining bid and offer (excluding PHLX⁶ and any destination which has been excluded from the NBBO in compliance with the self-help procedures under Regulation NMS) is selected and reported as the best quote. If away markets are crossing the market after applying PHLX’s BBO, orders will be accepted as originally priced and have the potential to execute. Any order sent to PHLX that is not an Intermarket Sweep Order (“ISO”) will have the Compliant BBO check enforced by the system.⁷

The PHLX Routing and Special Handling System (“RASH”) utilizes the Compliant BBO to determine if and when an order with special processing directives is marketable either against one or more orders in either the Core Matching System or a remote trading venue. RASH also receives market data feeds from certain venues not displaying

protected quotes in the national market system for use in “XDRK” and “XCST” routing strategies set forth in PHLX Rule 3308(a)(1)(A)(xiii) [sic] and (xiv) [sic], respectively. RASH maintains a number of routing processes, or Routers, unique to each venue that the System accesses. These Routers maintain a limited set of details for orders that are configured as routable by the user, while also monitoring the current best bid and best offer prices on each exchange.

The PHLX System includes internal compliance applications related to locked and crossed markets, trade throughs, limit-up/limit-down, and Regulation SHO compliance. Each of these applications utilizes the Compliant BBO to ensure compliance with applicable regulations.

PHLX operates a separate real-time surveillance system that is external to the execution systems and that monitors the execution system’s compliance with applicable rules and regulations. The real-time surveillance system utilizes a “mirrored” version of the internal NMSFeed in various realtime surveillance patterns, including (1) Lock/Cross, which detects lock/cross events across all markets, regardless of whether or not PHLX is a participant in the event; (2) Trade Through, which detects potential trade through events for all three NASDAQ equity markets; and (3) RegSho, which detects potential RegSho violations, alerting when a trade executes at or below the NBB at the time

⁵ OUCH is a protocol that allows PHLX participants to enter, replace and cancel orders and receive executions. In addition to OUCH, PHLX offers the FLITE protocol as an option for participants. In this document, references to OUCH also include FLITE because they are interchangeable for these purposes.

⁶ Deletion of PHLX’s quote at this stage of the process is necessary because otherwise the system would prevent valid executions on PHLX in the erroneous belief that such executions would be “trade throughs” in violation of Regulation NMS.

⁷ In general, any order that is sent to PHLX with an ISO flag is not re-priced and will be processed at its original price. There are a limited number of circumstances in which an order marked as an ISO will be determined not to be executable at its original price and will be re-priced. These include re-pricing under the Plan to Address Extraordinary Market Volatility, re-pricing to comply with Regulation SHO, and the re-pricing of an order with a post-only condition if PHLX has an order at that price at the time the order is accepted.

of order entry while the stock is in a RegSho restricted state.

2. Statutory Basis

PHLX believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,⁸ in general and with Sections [sic] 6(b)(5) of the Act,⁹ 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 regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, 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 its proposal to describe the Exchange's use of data feeds removes impediments to and perfects the mechanism of a free and open market and protects investors and the public interest because it provides additional specificity and transparency. The Exchange's proposal will enable investors to better assess the quality of the Exchange's execution and routing services. The proposal does not change the operation of the Exchange or its use of data feeds; rather it describes how, and for what purposes, the Exchange uses the quotes disseminated from data feeds to calculate the NBBO for a security for purposes of Regulation NMS, Regulation SHO and various order types that update based on changes to the applicable NBBO. The Exchange believes the additional transparency into the operation of the Exchange as described in the proposal will remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange 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, as amended. To the contrary, the Exchange believes the proposal would enhance competition because describing the Exchange's use of data feeds enhances transparency and enables investors to better assess the quality of the Exchange's execution and routing services.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were either solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁰ and Rule 19b-4(f)(6) thereunder.¹¹

A proposed rule change filed pursuant to Rule 19b-4(f)(6) under the Act¹² normally does not become operative for 30 days after the date of its filing. However, Rule 19b-4(f)(6)(iii)¹³ permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the proposal may become operative immediately upon filing, noting that waiver of the operative delay would permit the Exchange to immediately enhance transparency. The Commission believes the waiver of the operative delay is consistent with the protection of investors and the public interest. Therefore, the Commission hereby waives the operative delay and designates the proposal operative upon filing.¹⁴

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the

¹⁰ 15 U.S.C. 78s(b)(3)(A).

¹¹ 17 CFR 240.19b-4(f)(6). As required under Rule 19b-4(f)(6)(iii), the Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and the text of the proposed rule change, at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission.

¹² 17 CFR 240.19b-4(f)(6).

¹³ 17 CFR 240.19b-4(f)(6)(iii).

¹⁴ For purposes only of waiving the 30-day operative delay, the Commission has also considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-Phlx-2015-39 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-Phlx-2015-39. 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 will also 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-Phlx-2015-39 and should be submitted on or before June 10, 2015.

⁸ 15 U.S.C. 78f.

⁹ 15 U.S.C. 78f(b)(5).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁵

Robert W. Errett, Deputy Secretary.

[FR Doc. 2015-12146 Filed 5-19-15; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-74963; File No. SR-CBOE-2015-012]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing of a Proposed Rule Change Relating to Trading Permit Holder Qualifications

May 14, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on May 4, 2015, Chicago Board Options Exchange, Incorporated (the "Exchange" or "CBOE") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposed to amend its rules related to Trading Permit Holder requirements and direct access to the Exchange's Hybrid Trading System (the "System"). The text of the proposed rule change is provided below.

(Additions Are Italicized; Deletions Are [Bracketed])

* * * * *

Chicago Board Options Exchange, Incorporated Rules

* * * * *

Rule 3.4. Foreign Trading Permit Holders

[(a)]A Trading Permit Holder that does not maintain an office in the United States responsible for preparing and maintaining financial and other reports required to be filed with the Securities and Exchange Commission and the Exchange must:

[(i)a] prepare all such reports, and maintain a general ledger chart of

account and any description thereof, in English and U.S. dollars;

[(ii)b] reimburse the Exchange for any expense incurred in connection with examination of the Trading Permit Holder to the extent that such expenses exceed the cost of examining a Trading Permit Holder located within the continental United States; and

[(iii)c] ensure the availability of an individual fluent in English knowledgeable in securities and financial matters to assist the representatives of the Exchange during examinations.

Rule 3.4A. Additional Trading Permit Holder Qualifications

(a) In addition to the qualifications set forth in Rules 3.2 through 3.4, a Trading Permit Holder applicant:

(i) must be domiciled in (with respect to individuals), or organized under the laws of (with respect to organizations), a jurisdiction expressly approved by the Exchange. When determining whether to approve a jurisdiction, the Exchange will consider whether:

(A) The applicant will be able to supply the Exchange with such information with respect to its dealings with the Exchange as set forth in the Rules;

(B) the Exchange will be able to examine the applicant's books and records to verify the accuracy of any information so supplied;

(C) approval of the applicant as a Trading Permit Holder will comply with all applicable laws, rules and regulations; and

(D) other factors that the Exchange reasonably and objectively determines may impact the applicant's ability to comply with the Rules and the Act or the Exchange's ability to accept Trading Permit Holders from the applicable jurisdiction.

This approval may be limited to one or more specified categories of Trading Permit Holders or Trading Permit Holder activities in a jurisdiction or be contingent upon the satisfaction of specified conditions by all applicants from a jurisdiction to the extent such limits or conditions are necessary to satisfy clauses (A) through (D);

(ii) will be subject to the jurisdiction of the federal courts of the United States and the courts of the state of Illinois; and

(iii) prior to acting as agent for a customer, must be able to provide information regarding the customer and the customer's trading activities to the Exchange in response to a regulatory request for information pursuant to the Rules. To the extent an individual or organization is required by an

applicable law, rule or regulation to obtain written consent from a customer to permit the provision of this information to the Exchange, the applicant must obtain such consent.

(b) The Exchange may at any time determine that a Trading Permit Holder can no longer comply with this Rule 3.4A. In that event, the Trading Permit Holder will have three months following the date of that determination to come into compliance with this Rule 3.4A. If a Trading Permit Holder does not come into compliance during that time period, the Exchange may terminate the Trading Permit Holder's status as a Trading Permit Holder.

* * * * *

Rule 6.20A. Sponsored Users

(a)-(b) No change.

(c) A Sponsoring Trading Permit Holder must ensure that a Sponsored User satisfies the requirements set forth in Rule 3.4A(a) and only directly accesses the System from an approved jurisdiction as set forth in Rule 6.23A(d).

. . . Interpretations and Policies:

.01 No change.

* * * * *

Rule 6.23A. Trading Permit Holder Connectivity

(a)-(c) No change.

(d) The Hybrid Trading System shall be available for entry and execution of orders only to Trading Permit Holders, [and]persons associated with Trading Permit Holders, and Sponsored Users (pursuant to Rule 6.20A) with authorized access. Such persons may only directly access the System from a jurisdiction expressly approved by the Exchange pursuant to Rule 3.4A(a). The Exchange will require a Trading Permit Holder to enter into a software user or license agreement with the Exchange in such form or forms as the Exchange may prescribe in order to obtain authorized access to the Hybrid Trading System, if the Trading Permit Holder elects to use an API for which the Exchange has determined such an agreement is necessary.

(e)-(f) No change.

* * * * *

The text of the proposed rule change is also available on the Exchange's Web site (<http://www.cboe.com/AboutCBOE/CBOELegalRegulatoryHome.aspx>), at the Exchange's Office of the Secretary, and at the Commission's Public Reference Room.

¹⁵ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its rules related to Trading Permit Holder requirements and direct access to the System. The Exchange recently launched Extended Trading Hours.³ To accommodate the potential interest of non-U.S. persons or organizations to become Trading Permit Holders or Trading Permits Holders to access the System from other jurisdictions in connection with the launch of Extended Trading Hours, the proposed rule change adds Rule 3.4A to set forth additional qualifications applicable to all Trading Permit Holder applicants, amends Rule 6.20A to add a requirement regarding access by Sponsored Users and amends Rule 6.23A to add a requirement regarding access to the System.

Rules 3.2 and 3.3 set forth qualifications for individuals and organizations, respectively, to become Trading Permit Holders. For an individual to be a Trading Permit Holder, Rule 3.2 requires the individual to (i) be at least 21 years of age, (ii) be registered as a broker or dealer pursuant to Section 15 of the Act or be associated with a Trading Permit Holder organization that is registered as a broker or dealer pursuant to Section 15 of the Act, and (iii) meet the other qualification requirements for being a Trading Permit Holder under the Exchange's bylaws and rules. Similarly, for an organization to be a Trading Permit Holder, Rule 3.3 requires the organization to (i) be a corporation, partnership, or limited liability company, (ii) be registered as a broker or dealer pursuant to Section 15 of the

Act, and (iii) meet the other qualification requirements for being a Trading Permit Holder under the Exchange's bylaws and rules. Each individual and organization must be approved to engage in an authorized trading function.

Rule 3.4 imposes additional qualifications on Trading Permit Holders that do not maintain an office in the United States responsible for preparing and maintaining financial and other reports required to be filed with the Commission and the Exchange. Under Rule 3.4, these foreign Trading Permit Holders must (i) prepare all such reports, and maintain a general ledger chart of account and any description thereof, in English and U.S. dollars, (ii) reimburse the Exchange for any expense incurred in connection with examination of the Trading Permit Holder to the extent that such expenses exceed the cost of examining a Trading Permit Holder located within the United States, and (iii) ensure the availability of an individual fluent in English knowledgeable in securities and financial matters to assist the representatives of the Exchange during examinations.⁴

Proposed Rule 3.4A(a) provides that in addition to the qualifications set forth in Rules 3.2 through 3.4, a Trading Permit Holder applicant:

- Must be domiciled in (with respect to individuals), or organized under the laws of (with respect to organizations), a jurisdiction expressly approved by the Exchange.⁵ When determining whether to approve a jurisdiction, the Exchange will consider whether: (i) The applicant will be able to supply the Exchange with such information with respect to the applicant's dealings with the

⁴ The proposed rule change makes nonsubstantive changes to Rule 3.4. It deletes the paragraph letter (a) from the introductory paragraph, as there is no paragraph (b). The proposed rule change then revises the paragraph markings of subparagraphs (i) through (iii) to (a) through (c) to be consistent with the lettering and numbering system generally used throughout the Rules.

⁵ Proposed Rule 3.4A(b) allows the Exchange to determine at any time that a Trading Permit Holder can no longer comply with proposed Rule 3.4A (for example, if the laws in an applicable jurisdiction change). In that event, the Trading Permit Holder will have three months following the date of this determination to come into compliance with Rule 3.4A. If the Trading Permit Holder does not come into compliance during that time period, the Exchange may terminate the Trading Permit Holder's status as a Trading Permit Holder. This proposed rule change is consistent with Rule 3.5(d), which, among other things, permits the Exchange to determine not to permit a Trading Permit Holder to continue being a Trading Permit Holder if it fails to meet any qualification requirements for being a Trading Permit Holder after approval as a Trading Permit Holder.

Exchange as set forth in the Rules,⁶ (ii) the Exchange will be able to examine the applicant's books and records to verify the accuracy of any information so supplied, (iii) approval of such application will comply with all applicable laws, rules and regulations, and (iv) other factors that the Exchange reasonably and objectively determines may impact the applicant's ability to comply with the Rules and the Act or the Exchange's ability to accept Trading Permit Holders from the applicable jurisdiction. This approval may be limited to one or more specified categories of Trading Permit Holders or Trading Permit Holder activities in a jurisdiction or be contingent upon the satisfaction of specified conditions by all applicants from a jurisdiction to the extent such limits or conditions are necessary to satisfy clauses (i) through (iv);

- will be subject to the jurisdiction of the federal courts of the United States and the courts of the state of Illinois; and

- prior to acting as agent for a customer, must be able to provide information regarding the customer and the customer's trading activities to the Exchange in response to a regulatory request for information pursuant to the Rules. To the extent an individual or organization is required by an applicable law, rule or regulation to obtain written consent from a customer to permit the provision of this information to the Exchange, the applicant must obtain such consent.⁷

CBOE intends to initially notify market participants of approved jurisdictions by Regulatory Circular (which are publicly available on CBOE's Web site). CBOE also intends to have a Web page that lists then-currently approved jurisdictions. To the extent CBOE no longer intends to issue Regulatory Circulars to announce changes to the list of approved jurisdictions and only update the Web page, CBOE will issue a Regulatory Circular stating that fact.⁸

The Exchange believes the proposed Trading Permit Holder qualifications in

⁶ Rule 1.1(c) defines the term "Rules" to mean the Rules of CBOE.

⁷ The proposed rule change makes a corresponding change to Rule 6.20A to provide that Sponsoring Trading Permit Holders must ensure that Sponsored Users also satisfy these requirements, as Sponsored Users may enter orders, and the Exchange would similarly need the same information from Sponsored Users as it would from Trading Permit Holders.

⁸ See Regulatory Circular RG15-014 (question #5 includes a current list of approved jurisdictions (British Virgin Islands, Cayman Islands, Gibraltar, Ireland, Isle of Jersey, Luxembourg, Poland, United Kingdom and United States), subject to approval of this proposed rule change).

³ See Securities Exchange Act Release No. 34-73704 (November 28, 2014), 79 FR 72044 (December 4, 2014) (SR-CBOE-2014-062) (approval of rules adopting Extended Trading Hours).

proposed Rule 3.4A are reasonable for the following reasons:

- Proposed Rule 3.4A(a)(i) is intended to ensure that the Exchange can comply with applicable regulatory requirements in jurisdictions in which Trading Permit Holders are located and obtain the information necessary to perform its self-regulatory obligations. With respect to the factors the Exchange will consider when determining whether to approve a jurisdiction, the Exchange needs sufficient information to monitor Trading Permit Holders' compliance with the Rules and the Act.

- The Exchange understands that laws in certain jurisdictions may limit market participants' ability to share, or a foreign entity's ability to access, certain information. In order to perform its self-regulatory obligations, CBOE needs to ensure it has a complete audit trail and sufficient access to information with respect to all Trading Permit Holders. Proposed paragraphs (a)(i)(A) and (B) are intended to ensure that CBOE will be able to obtain this information regarding a Trading Permit Holder to properly conduct its surveillances and other regulatory functions.

- Additionally, the Exchange understands that certain jurisdictions require a foreign exchange to receive certain authorization to permit direct access (including exchange membership) to an exchange. Proposed paragraph (a)(i)(C) is intended to ensure CBOE's compliance with all applicable laws, rules and regulations, including such restrictions on exchange membership.

- Legal and regulatory requirements related to the securities industry, including exchanges, and international business relationships are constantly changing, which changes could impact a Trading Permit Holder applicant's ability to comply with the Rules and the Act or the Exchange's ability to permit Trading Permit Holders from a particular jurisdiction. For example, a country may adopt telecommunication laws that restrict market participants from complying with Exchange system requirements to establish a connection. A jurisdiction may also impose obligations on CBOE as a foreign exchange that may conflict with its self-regulatory obligations under the Act or may not have a regulatory framework in place that the Exchange believes provides sufficient local oversight and protection over market participants. Additionally, the Exchange believes it may be reasonable to consider other factors when determining whether to approve a jurisdiction, such as if necessary to maintain a fair and orderly

market or to address other circumstances. For example, the U.S. government may restrict U.S. businesses from doing business in a jurisdiction, or may not officially recognize the government of another jurisdiction. CBOE believes it is reasonable to comply with these governmental restrictions and not approve any such jurisdiction. Proposed paragraph (a)(i)(D) provides CBOE with the flexibility to consider these changes or circumstances when determining whether to approve a jurisdiction.

- The proposed rule change that permits CBOE to limit the categories or activities of a Trading Permit Holder from a jurisdiction or impose conditions will allow the Exchange to comply with any laws, rules or regulations in a jurisdiction that may permit only certain activities on the Exchange by market participants in that jurisdiction. For example, local laws or regulations may restrict market participants from quoting as market-makers or from submitting orders as agent for customers. In such a case, this rule change permits the Exchange to comply with such laws or regulations while permitting Trading Permit Holders from a jurisdiction on a restricted basis.

- Proposed Rule 3.4A(a)(ii) will ensure CBOE can enforce the Rules and any agreements it has with Trading Permit Holders in U.S. and Illinois courts.

- The Exchange understands that certain jurisdictions have privacy laws that restrict broker-dealers from sharing certain information regarding their customers. CBOE believes such information is necessary to regulate its market. Similar to proposed Rule 3.4A(a)(i)(A) and (B), proposed Rule 3.4A(a)(iii) is intended to ensure CBOE has a complete audit trail and sufficient access to information with respect to all Trading Permit Holders and the orders they represent on the Exchange (including those from customers) in order to properly conduct its surveillances and other regulatory functions.

These requirements will ultimately enhance the Exchange's regulatory oversight of its Trading Permit Holders' trading activity.

The Exchange also believes these additional requirements for all Trading Permit Holders are objective and nondiscriminatory. Proposed Rule 3.4A(a) sets forth explicit requirements that all Trading Permit Holder applicants must satisfy. With respect to approved jurisdictions, the Exchange will consider all of the factors included in proposed Rule 3.4A(a)(i) for all

jurisdictions in the same manner. The Exchange's consideration of the factors in subparagraph (A) through (C) generally will include reviews of the applicable laws, rules and regulations of a jurisdiction in consideration to determine whether those factors can be satisfied in that jurisdiction. Proposed Rule 3.4A(a)(i)(D) explicitly states that the Exchange will determine "other factors" objectively, and CBOE will consider them in the same manner for all jurisdictions it considers. The proposed rule change that indicates the Exchange may limit approval to categories of Trading Permit Holders or activities in a jurisdiction or impose other conditions specifies that such limits or conditions will be imposed on all applicants from the same jurisdiction, and the Exchange represents it will determine in the same manner for all jurisdictions whether to impose any such limits or conditions on Trading Permit Holders from a jurisdiction.⁹

The proposed change to Rule 6.23A provides that persons with authorized access to the System (Trading Permit Holders, persons associated with Trading Permit Holders and Sponsored Users)¹⁰ only directly access the System from an approved jurisdiction. The Exchange has determined that laws, rules and regulations related to exchange membership (that may restrict persons or entities domiciled in or organized under the laws of, as applicable, a specific jurisdiction from, for example, supplying an exchange with certain trading information or providing an exchange with access to its books and records) apply in the same manner to persons or entities accessing an exchange from the applicable jurisdiction.¹¹ For example, if an office

⁹ The Exchange notes that this does not prevent the Exchange from imposing conditions or restrictions on individual Trading Permit Holders pursuant to other Rules. *See, e.g.*, Rules 3.5(c) (permits the Exchange to condition a person from becoming a Trading Permit Holder on satisfaction of requirements set forth in that paragraph); Rule 8.2(b) (permits the Exchange to suspend or terminate a Trading Permit Holder's registration as a Market-Maker); and Rule 8.90 (permits the Exchange to terminate, place conditions upon or otherwise limit a TPH organization's approval to act as Designated Primary Market-Maker under certain circumstances).

¹⁰ Rule 6.20A provides that Sponsored Users may be authorized to electronically access the System subject to the requirements set forth in that Rule. The proposed rule change adds Sponsored Users to the list of persons that may have authorized access to the System pursuant to Rule 6.23A to be consistent with Rule 6.20A, which were inadvertently omitted from that list.

¹¹ The proposed rule change makes a corresponding change to Rule 6.20A to provide that Sponsoring Trading Permit Holders must ensure that Sponsored Users directly access the System

of a Trading Permit Holder organization that is organized in the United States is located in a foreign jurisdiction, as a Trading Permit Holder (organized in an approved jurisdiction) it is authorized to directly access the System for trading purposes. However, the laws of that jurisdiction may prevent the Exchange from obtaining necessary information related to the trading activity on the Exchange originating in such office (in accordance with proposed Rule 3.4A(a)). Therefore, the Exchange would not permit this direct System access from such jurisdiction for the same purposes as it would not approve a Trading Permit Holder applicant domiciled in or organized under the laws of such jurisdiction. Currently, the Exchange has authority under Rule 6.23A(e) to prescribe technical specifications regarding the establishment of an electronic connection to the System. While the proposed rule change is not a technical, system specification, the Exchange believes that imposing requirements on the location of the connection is similar to a "specification," because this location requirement will be part of the same process that otherwise imposes these technical specifications with which the Trading Permit Holder must comply when establishing a connection with the Exchange.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Act and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.¹² Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹³ requirements that the rules of an exchange be 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 regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, 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. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5)¹⁴ requirement that

the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, proposed Rule 3.4A, which imposes additional qualifications on Trading Permit Holder applicants, including the requirement that the Exchange may determine in which jurisdiction Trading Permit Holder applicants may be domiciled in or organized under (and the ability of the Exchange to determine that a Trading Permit Holder no longer complies with this proposed requirement), is similar to Section 6(c)(3)(C) of the Act. That section of the Act allows the Exchange to deny persons from becoming associated with Trading Permit Holders if they are unable to supply the Exchange with such information with respect to its relationship and dealings with such persons or entities and unable to permit the Exchange to examine their books and records due to the jurisdiction (and any applicable laws, rules and regulations of that jurisdiction) in which they are domiciled or under the laws of which they are organized. While that Section of the Act applies to associated persons and not Trading Permit Holders, the Exchange believes it is appropriate to impose those requirements on Trading Permit Holders as well to ensure it has access to sufficient information to perform its self-regulatory obligations. Additionally, the Rules (which have been approved by the Commission and deemed to be in accordance with the Act) currently provide that an applicant must meet the qualification requirements under the Exchange's Bylaws and Rules (including obtaining a Trading Permit)¹⁵ and deny a person from becoming (or condition being) a Trading Permit Holder for such other cause as the Exchange reasonably may decide.¹⁶

The Exchange believes the additional qualifications set forth in proposed Rule 3.4A are reasonable and consistent with these current rules. Please see the "Purpose" section above (beginning on page 29) for a discussion regarding the reasonability of these qualifications. The Exchange notes that the membership qualifications, and reasons an exchange may deny membership to a party, set forth in Section 6(b) and (c) of the Act are not meant to be exhaustive, and that it is reasonable for an Exchange to have requirements for exchange membership beyond those contained in the Act.¹⁷

The Commission has previously approved rules that impose additional membership requirements, including additional qualifications for foreign organizations.¹⁸

The proposed changes to Rules 6.20A and 6.23A regarding access are similar to current Rule 6.23A(e) (previously approved by the Commission as consistent with the Act), which permits the Exchange to impose specific requirements related to connectivity to the Exchange. As discussed above, while the proposed rule change is not a technical specification, the access location requirement is part of the entire process a Trading Permit Holder must satisfy in order to establish a connection with the Exchange. Additionally, requiring Sponsored Users to satisfy the requirements in proposed Rule 3.4A(a) is consistent with Rule 6.20A(b)(1)(C), which provides that a Sponsored User will be bound by and comply with Exchange Rules as if the Sponsored User were a Trading Permit Holder. The proposed rule change makes explicit in the Rules that proposed Rule 3.4A(a) is one of those rules to which the Sponsored User must agree to be bound. Additionally, the proposed rule change to require the Sponsoring Trading

proposed rule change to require Trading Permit Holders of the CBOE Stock Exchange, LLC (CBSX), a stock trading facility of CBOE, to be members of a national securities association). In that approval order, the Commission stated that "the proposed rule change is consistent with Section 6(b)(2) and Section 6(c) of the Act. While Section 6(c) specifies certain bases upon which a national securities exchange can deny membership to, among other entities, a broker or a dealer, Section 6(c) is not intended to provide an exclusive list of reasons a national securities exchange can deny membership to a party. National securities exchanges may have requirements for exchange membership beyond those contained in the Act so long as they are consistent with the Act." *Id.* at 8772.

¹⁸ See, e.g., Securities Exchange Act Release No. 34-43056 (July 19, 2000), 65 FR 46524 (July 28, 2000) (SR-CBOE-1999-15) (order approving proposed rule change to, among other things, impose additional membership qualifications on foreign organizations (including that such organizations must be organized under laws of a country that satisfies certain criteria set forth by the Exchange in the proposed rule)). In that approval order, the Commission stated that it "believes that it is reasonable for the CBOE to clarify that, in addition to satisfying the requirements of CBOE Rule 3.4, a foreign organization must satisfy the other membership qualification requirements under the CBOE's rules and Constitution, as well [as] any additional requirements that the CBOE reasonably deems appropriate. The Commission believes that these provisions will clarify that a foreign organization, like a U.S. applicant for membership, must satisfy all of the CBOE's membership qualification requirements and provide the CBOE with flexibility to impose additional requirements that the CBOE reasonably believes are necessary with respect to foreign members." *Id.* at 46534. The Exchange notes that SR-CBOE-1999-15 imposed more restrictive membership requirements on foreign organizations than the proposed rule change in this filing.

only from an approved jurisdiction, as these laws, rules and regulations apply to any persons that directly access the Exchange from the applicable jurisdiction.

¹² 15 U.S.C. 78f(b).

¹³ 15 U.S.C. 78f(b)(5).

¹⁴ *Id.*

¹⁵ See Rules 3.2(a)(iii) and 3.3(a)(iii).

¹⁶ See Rule 3.5(c)(iv).

¹⁷ See, e.g., Securities Exchange Act Release No. 34-71513 (February 7, 2014), 79 FR 8771 (February 13, 2014) (SR-CBOE-2013-100) (order approving

Permit Holder to ensure the Sponsored Users satisfaction of the proposed jurisdiction requirements is consistent with Rule 6.20A, which generally makes the Sponsoring Trading Permit Holder responsible for the Sponsored User's actions. Rule 6.20A currently sets forth a number of requirements with respect to the Sponsoring Trading Permit Holder/Sponsored User relationship, and this rule filing imposes proposed requirements applicable to all Trading Permit Holders on that relationship as well.

This proposed rule change will promote compliance by the Exchange with regulatory requirements of governments and regulatory authorities outside of the United States related to exchange memberships and access, which promotes just and equitable principles of trade and fosters cooperation and coordinates with other regulatory authorities. The proposed rule change enhances the Exchange's ability to satisfy its self-regulatory obligations by ensuring it is able to receive sufficient information to conduct its surveillances and investigations, which prevents fraudulent and manipulative acts and practices and removes impediments to and perfects the mechanism of a free and open market and a national market system, which ultimately protects investors.

Additionally, this proposed rule change is not unfairly discriminatory, as the proposed additional qualifications and access requirements will apply to all Trading Permit Holders and applicants. When determining whether to approve a jurisdiction, the Exchange will consider the proposed factors in the same manner for each jurisdiction. The Exchange believes that individuals or organizations within a specific jurisdiction are similarly situated, and thus it may allow individuals or organizations from one jurisdiction to become Trading Permit Holders but not from another based on the objective criteria set forth in the proposed rule. The objective criteria will ensure that the Exchange determines approved jurisdictions in a fair, reasonable manner that is not unfairly discriminatory. Please see the "Purpose" section above (beginning on page 32) for additional discussion regarding how the proposed qualifications, including factors to be considered when the Exchange is determining whether to approve a jurisdiction, will be applied in an objective and nondiscriminatory manner.

The proposed changes to Rule 3.4 are nonsubstantive and merely intended to

eliminate any potential confusion resulting from the mislettering of the paragraphs of that rule.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposed rule change imposes additional Trading Permit Holder qualifications and access requirements for CBOE, and thus does not raise any competitive issues. The proposed Trading Permit Holder qualifications and access requirements apply equally to all Trading Permit Holders and individuals and organizations seeking to become Trading Permit Holders. As discussed above, the Exchange will consider all factors in an objective and nondiscriminatory manner. The proposed rule change is intended to promote compliance by the Exchange with regulatory requirements of governments and regulatory authorities outside of the United States and enhance the Exchange's ability to satisfy its self-regulatory obligations and regulate its markets.

The Exchange notes that current Trading Permit Holders are all domiciled in or organized under the laws of the United States and satisfy these requirements (and thus need to take no additional action). Any potential burden that these qualifications and requirements may impose on Trading Permit Holders and applicants are far outweighed the Exchange's need to receive sufficient information to conduct its surveillances and investigations in order to ensure it can continue to effectively regulate its markets, which enhanced regulation will ultimately benefit all market participants. Please see the "Purpose" and "Statutory Basis" sections above (beginning on pages 29 and 35, respectively) for additional discussion regarding the reasonableness and objectivity of the proposed rule change.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

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

up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the Exchange consents, the Commission will:

A. By order approve or disapprove such proposed rule change, or

B. institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-CBOE-2015-012 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549.

All submissions should refer to File Number SR-CBOE-2015-012. 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-CBOE-2015-012 and should be submitted on or before June 10, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁹

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015-12143 Filed 5-19-15; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-74971; File No. SR-ISE Gemini-2015-09]

Self-Regulatory Organizations; ISE Gemini, LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the Schedule of Fees To Introduce a New “Retail” Designation for Priority Customer Orders

May 14, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the “Act”),¹ and Rule 19b-4 thereunder,² notice is hereby given that on April 29, 2015, ISE Gemini, LLC (the “Exchange” or the “ISE Gemini”) filed with the Securities and Exchange Commission (the “Commission”) the proposed rule change, as described in Items I, II, and III below, which items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization’s Statement of the Terms of Substance of the Proposed Rule Change

ISE Gemini proposes to amend the Schedule of Fees to introduce a new “Retail” designation for Priority Customer orders. The text of the proposed rule change is available on the Exchange’s Web site (<http://www.ise.com>), at the principal office of the Exchange, and at the Commission’s Public Reference Room.

II. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received

on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections A, B and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Schedule of Fees to introduce a new “Retail” designation for Priority Customer orders. A “Priority Customer” is a person or entity that is not a broker/dealer in securities, and does not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s), as defined in Rule 100(a)(37A). This market participant type is one of six currently recognized for purposes of determining applicable fees and rebates, along with: Market Maker,³ Non-ISE Gemini Market Maker,⁴ Firm Proprietary,⁵ Broker-Dealer,⁶ and Professional Customer.⁷ The Priority Customer designation was adopted by the Exchange to provide competitive pricing and market structure advantages to retail investors, and to level the playing field between retail investors and market professionals. As such, Priority Customer orders executed on the Exchange are generally afforded more favorable fees and rebates than other market participants, including Professional Customers. The Exchange now believes that it is appropriate to introduce a further distinction between market participants that fall within the definition of Priority Customer.

In particular, the Exchange proposes to introduce a new “Retail” designation for Priority Customer orders for the purpose of determining applicable fees and rebates. As proposed, a Retail order is a Priority Customer order that originates from a natural person,

³ The term “Market Makers” refers to “Competitive Market Makers” and “Primary Market Makers” collectively. See Rule 100(a)(25).

⁴ A “Non-ISE Gemini Market Maker” is a market maker as defined in Section 3(a)(38) of the Securities Exchange Act of 1934, as amended, registered in the same options class on another options exchange. See Schedule of Fees, Preface.

⁵ A “Firm Proprietary” order is an order submitted by a member for its own proprietary account. See Schedule of Fees, Preface.

⁶ A “Broker-Dealer” order is an order submitted by a member for a broker-dealer account that is not its own proprietary account. See Schedule of Fees, Preface.

⁷ A “Professional Customer” is a person or entity that is not a broker/dealer and is not a Priority Customer. See Schedule of Fees, Preface.

provided that no change is made to the terms of the order with respect to price or side of market and the order does not originate from a trading algorithm or any other computerized methodology. The proposed definition of a Retail order is designed to mirror a similar concept introduced by the New York Stock Exchange (“NYSE”), NYSE Amex (“Amex”), and other equities exchanges to promote price improvement for orders submitted by retail investors.⁸ The proposed rule change, however, is intended to provide benefits to retail options investors in the form of more favorable pricing rather than market structure changes.⁹ While the Exchange is not amending fees and rebates applicable to Priority Customer orders that are designated Retail at this time, the Exchange intends to introduce special fees and rebates for Retail orders at a later date, such that Retail orders will potentially be entitled to the most favorable fees and rebates available on the Exchange. Until such time, Retail orders will be charged the same fees and provided the same rebates as other Priority Customer orders.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6(b) of the Act.¹⁰ In particular, the proposal is consistent with Section 6(b)(5) of the Act,¹¹ because is designed to promote just and equitable principles of trade, remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

Specifically, the proposed rule change will allow the Exchange to potentially offer more favorable fees and rebates to Retail orders that originate from natural

⁸ See Securities Exchange Act Release No. 67347 (July 3, 2012), 77 FR 40673 (July 10, 2012) (SR-NYSE-2011-55; SR-NYSEAmex-2011-84) (Approval Order). See also NYSE and Amex Rule 107C(a)(3).

NYSE and Amex define a “Retail Order” as an agency order or a riskless principal order that meets the criteria of FINRA Rule 5320.03 that originates from a natural person and is submitted to the Exchange by a Retail Member Organization, provided that no change is made to the terms of the order with respect to price or side of market and the order does not originate from a trading algorithm or any other computerized methodology.

⁹ In addition, the Exchange notes that unlike the related equities programs, all members will be eligible to mark orders as Retail provided that the orders meet the requirements discussed above.

¹⁰ 15 U.S.C. 78f(b).

¹¹ 15 U.S.C. 78f(b)(5).

¹⁹ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

persons. Currently, the Exchange distinguishes between orders executed for two categories of Public Customer:¹² Priority and Professional Customers. Priority Customers are distinguished from Professional Customers by the requirement that they not place more than 390 orders in listed options per day on average during a calendar month for its own beneficial account(s). Because of this limitation, Priority Customer orders are generally afforded more favorable fees and rebates than market professionals, including Professional Customers. The Exchange now believes that it is appropriate to distinguish further between orders that originate from a natural person (*i.e.*, Retail orders) and other Priority Customer orders.

The equities markets already provide benefits to order flow that originates from a natural person and not a trading algorithm or any other computerized methodology. The Exchange believes that the proposed definition of a Retail order is appropriate as it is substantially similar to the definition already used in the equities context, and is therefore already familiar to market participants. The Exchange notes, however, that unlike equities exchanges such as NYSE and Amex, it is not proposing any market structure changes at this time to accompany the introduction of a Retail designation for Priority Customer orders. All Priority Customer orders will continue to benefit from the current market structure benefits that they receive on the Exchange. In addition, Priority Customer orders other than Retail orders will continue to benefit from pricing that is generally more favorable than pricing adopted for Professional Customer and non-Customer orders.

By adopting a definition of Retail order, the Exchange hopes to be able to offer potentially more favorable fees and rebates to retail investors. The Exchange believes that this will advance the goals identified when the Exchange first introduced the Priority Customer designation, by providing genuine retail investors with the best prices available on the Exchange. In this regard, the Exchange notes that the fees and rebates for Retail orders will initially be the same as fees and rebates for other Priority Customer orders; however, the Exchange will introduce additional pricing advantages for Retail orders at a later date pursuant to a proposed rule change filed with the Commission.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with Section 6(b)(8) of the Act,¹³ the Exchange does not believe that the proposed rule change will impose any burden on intermarket or intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the Exchange believes the proposed Retail designation is an innovative change that evidences strong competition between options markets. In particular, the proposed rule change is designed to allow the Exchange to potentially offer the most favorable fees and rebates available to Retail orders that originate from natural persons. The Exchange operates in a highly competitive market in which market participants can readily direct their order flow to competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and rebates to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed changes reflect this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any unsolicited written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange believes that the foregoing proposed rule change may take effect upon filing with the Commission pursuant to Section 19(b)(3)(A)¹⁴ of the Act and Rule 19b-4(f)(6) thereunder¹⁵ because the foregoing proposed rule change does not (i) significantly affect the protection of investors or the public interest, (ii) impose any significant burden on competition, and (iii) become operative for 30 days after its filing date, or such shorter time as the Commission may designate. The Exchange provided the Commission with written notice of its intent to file the proposed rule change, along with a brief description and text of the proposed rule change, at least five

business days prior to the date of filing the proposed rule change.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is: (i) Necessary or appropriate in the public interest; (ii) for the protection of investors; or (iii) otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an Email to rule-comments@sec.gov. Please include File Number SR-ISE Gemini-2015-09 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-ISE Gemini-2015-09. 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 ISE Gemini. All comments received will be posted without change;

¹² A "Public Customer" is a person or entity that is not a broker or dealer in securities. See Rule 100(a)(38).

¹³ 15 U.S.C. 78f(b)(8).

¹⁴ 15 U.S.C. 78s(b)(3)(A).

¹⁵ 17 CFR 240.19b-4(f)(6).

the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–ISE Gemini–2015–09 and should be submitted by June 10, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁶

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–12150 Filed 5–19–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–74965; File No. SR–NSCC–2015–002]

Self-Regulatory Organizations; National Securities Clearing Corporation; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Clarify NSCC’s Rules & Procedures Relating to the Process by Which NSCC Members Submit Buy-Ins Within NSCC’s Continuous Net Settlement System

May 14, 2015.

Pursuant to Section 19(b)(1)¹ of the Securities Exchange Act of 1934 (“Act”) and Rule 19b–4² thereunder, notice is hereby given that on May 4, 2015, National Securities Clearing Corporation (“NSCC”) 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 NSCC. NSCC filed the proposed rule change pursuant to Section 19(b)(3)(A)³ of the Act and Rule 19b–4(f)(1)⁴ thereunder. The proposed rule change was effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Clearing Agency’s Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of amendments to NSCC’s Rules & Procedures (“Rules”) in order to clarify those Rules relating to the process by which NSCC Members submit buy-ins within NSCC’s Continuous Net Settlement (“CNS”) system, as more fully described below.

II. Clearing Agency’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NSCC 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. NSCC has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

(A) Clearing Agency’s Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

One of NSCC’s core services as a central counterparty is trade clearance and settlement through CNS, where compared and recorded transactions in eligible securities for a particular settlement date are netted by issue into one net long (buy) or net short (sell) position. As a continuous net system, those positions are further netted with positions of the same issue that remain open after their originally scheduled settlement date, so that trades or miscellaneous activity scheduled to settle on any day are netted with fail positions to result in a single deliver or receive obligation for each Member for each issue in which it has activity. Currently, under NSCC’s Rules, a Member with a long position at the end of the day may submit to NSCC a Notice of Intention to Buy-In (“Buy-In Notice”) specifying a quantity of securities (not exceeding such long position) (“Buy-In Position”) that it intends to purchase to satisfy the fail that resulted in that long position, or “buy-in”.⁵ Typically, the day the Buy-In Notice is submitted is referred to as N, and N+1 and N+2 refer to the succeeding days (N through N+2 is referred to as the “Buy-In Period”).⁶ The Buy-In Position is given high priority for allocation from the CNS night cycle on N+1 through completion of the CNS day cycle on N+2.

The CNS position of a long Member that submits a Buy-In Notice can change during the Buy-In Period as a result of settling trades or miscellaneous activity.⁷ Settling trades or miscellaneous activity that reduce a

Member’s CNS long position is first applied to the Member’s current CNS position that is not represented by the Buy-In Position, and then that activity may be applied to reduce the Member’s Buy-In Position. If a Member’s Buy-In Position is reduced as a result of settling trades or miscellaneous activity, its Buy-In Position is adjusted to reflect the new amount. If, at any time during the Buy-In Period, settling trades or miscellaneous activity reduce the Member’s long position such that the Member becomes either short or flat in that position, or causes the Member’s CNS long position to be reduced to less than its outstanding Buy-In Position in that security, NSCC will consider that Member’s Buy-In Position with respect to that security complete and satisfied. NSCC will update the Buy-In Notice to reflect the reduced Buy-In Position if only a portion of the Buy-In Position is satisfied, or the Buy-In Notice will be cancelled if the entire Buy-In Position is satisfied by the settling trades or miscellaneous activity.

This process by which a Buy-In Notice would be updated to reflect settling trades or miscellaneous activity is not currently described in NSCC’s Rules. As such, NSCC is proposing to update Rule 11, Section 7 of its Rules in order to describe the effect of settling trades or miscellaneous activity on a Member’s Buy-In Position. Pursuant to this proposed rule change, NSCC’s Rules will make clear that any portion of a Member’s Buy-In Position would be considered complete and satisfied if, at any time during the Buy-in Period that Member’s CNS long position is reduced to less than the outstanding Buy-In Position, or its Buy-In Position is reduced such that the Member is either flat or short in that security. If the entire Buy-In Position is considered complete and satisfied, it will be removed from the system. The proposed rule change would also make a technical correction to Procedure X, as marked on Exhibit 5 hereto.

2. Statutory Basis

The proposed rule change is consistent with the Act and the rules and regulations thereunder, in particular Section 17A(b)(3)(F)⁸ because it will promote the prompt and accurate clearance and settlement of securities transactions in that it will provide clarity to NSCC’s Members regarding the process by which a Buy-In Notice would be updated to reflect settling trades or miscellaneous activity. Additionally, the proposed rule change constitutes a stated policy, practice, or interpretation

¹⁶ 17 CFR 200.30–3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b–4.

³ 15 U.S.C. 78s(b)(3)(A).

⁴ 17 CFR 240.19b–4(f)(1).

⁵ Members are not permitted to submit a Buy-In Notice with respect to securities that are subject to a voluntary corporate reorganization.

⁶ NSCC’s Rules provide that Members may also submit Buy-in Retransmittal Notices on N+1. This proposed rule clarification would apply to these Buy-in Retransmittal Notices as well.

⁷ Miscellaneous activity processed by CNS that updates the net position of a security could include, for example, corporate actions and stock dividends.

⁸ 15 U.S.C. 78q–1(b)(3)(F).

with respect to the meaning, administration, or enforcement of an existing rule.

(B) Clearing Agency's Statement on Burden on Competition

The proposed rule change will not have any impact, or impose any burden, on competition.

(C) Clearing Agency's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments relating to the proposed rule change have not yet been solicited or received. NSCC will notify the Commission of any written comments received by NSCC.

III. Date of Effectiveness of the Proposed Rule Change, and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A)⁹ of the Act and paragraph (f) of Rule 19b-4¹⁰ thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-NSCC-2015-002 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549-1090. All submissions should refer to File Number SR-NSCC-2015-002. 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 NSCC and on DTCC's Web site (<http://dtcc.com/legal/sec-rule-filings.aspx>). 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-NSCC-2015-002 and should be submitted on or before June 10, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹¹

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015-12145 Filed 5-19-15; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-74968; File No. SR-BATS-2015-38]

Self-Regulatory Organizations; BATS Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Related to Fees for Use of BATS Exchange, Inc.

May 14, 2015.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),¹ and Rule 19b-4 thereunder,² notice is hereby given that on May 6, 2015, BATS Exchange, Inc. (the "Exchange" or "BATS") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been

prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act³ and Rule 19b-4(f)(2) thereunder,⁴ which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to amend the fee schedule applicable to Members⁵ and non-members of the Exchange pursuant to BATS Rules 15.1(a) and (c). Changes to the fee schedule pursuant to this proposal are effective upon filing.

The text of the proposed rule change is available at the Exchange's Web site at www.batstrading.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to modify the "Options Pricing" section of its fee schedule, effective immediately, in order to modify pricing charged by the Exchange's options platform ("BATS Options") including: (i) add a new standard rate and a fee code NM

³ 15 U.S.C. 78s(b)(3)(A)(ii).

⁴ 17 CFR 240.19b-4(f)(2).

⁵ The term "Member" is defined as "any registered broker or dealer that has been admitted to membership in the Exchange." See Exchange Rule 1.5(n).

⁹ 15 U.S.C. 78s(b)(3)(A).

¹⁰ 17 CFR 240.19b-4(f).

¹¹ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

associated with Market Maker⁶ orders that add liquidity in non-Penny Pilot Securities;⁷ (ii) add a new footnote 7 entitled “Market Maker Non-Penny Pilot Add Volume Tiers”; (iii) simplifying the Exchange’s physical connection fees; (iv) certain corresponding changes associated with the new rebates associated with Market Maker orders in non-Penny Pilot Securities; and (v) a non-substantive, clarifying change in footnote 5.

Standard Rate in Market Maker Orders in Non-Penny Pilot Securities

Currently, the Exchange offers a rebate of \$0.65 per contract for Market Maker orders that add liquidity in non-Penny Pilot Securities. The Exchange is proposing to create a new fee code NM and to change the standard rate for Market Maker orders that add liquidity in non-Penny Pilot Securities to a rebate of \$0.42 per contract. Such orders will be eligible for the enhanced rebates available under the NBBO Setter Tiers, the Quoting Incentive Program Tiers, and the new Market Maker Non-Penny Pilot Add Volume Tiers proposed below. The Exchange is not proposing to change pricing for Professional⁸ or Firm⁹ orders or for any Market Maker orders that do not add liquidity non-Penny Pilot Securities.

Market Maker Non-Penny Pilot Add Volume Tiers

As described above, the Exchange currently provides a rebate of \$0.65 per contract for Market Maker orders that add liquidity in non-Penny Pilot Securities, which it proposes to change to \$0.42 per contract. The Exchange is also proposing to add new footnote 7 to its fee schedule entitled “Market Maker Non-Penny Pilot Add Volume Tiers” in order to offer enhanced rebates for Market Maker orders in non-Penny Pilot Securities to Members that meet certain thresholds. Specifically, the Exchange is proposing to: (i) Provide a rebate of \$0.45 per contract where the Member has an ADV¹⁰ equal to or greater than 0.30% of average TCV;¹¹ and (ii)

provide a rebate of \$0.52 where the Member has an ADV equal to or greater than 1.00% of average TCV. Where a Member does not meet either of these thresholds, they would receive the standard rebate of \$0.42 per contract, as proposed above.

Physical Connection Fees

The Exchange currently maintains a presence in two third-party data centers: (i) The primary data center where the Exchange’s business is primarily conducted on a daily basis, and (ii) a secondary data center, which is predominantly maintained for business continuity purposes. The Exchange currently assesses fees to Members and non-Members of \$1,000 for any 1G physical port connection at either data center and of \$2,500 for any 10G physical port connection at either data center. The Exchange also provides market participants with the ability to access the Exchange’s network through another data center entry point, or Point of Presence (“PoP”), at a data center other than the Exchange’s primary or secondary data center.¹² The Exchange currently charges \$2,000 for any 1G physical port to connect to the Exchange in any data center where the Exchange maintains a PoP other than the Exchange’s primary or secondary data center and \$5,000 per month for each single physical 10G port provided by the Exchange to any Member or non-member in any data center where the Exchange maintains a PoP other than the Exchange’s primary or secondary data center.

The Exchange proposes to simplify its pricing structure by imposing a uniform rate for physical ports regardless of the data center in which the port connection is made. Specifically, the Exchange proposes to charge \$1,000 per month for all 1G physical port connections and \$2,500 per month for all 10G physical ports in any location where the Exchange offers the ability to connect to Exchange systems, including the secondary data center and any PoP location.

Corresponding Changes

In conjunction with the changes proposed above, the Exchange is proposing to make certain corresponding changes, including: (i)

to the consolidated transaction reporting plan for the month for which the fees apply, excluding volume on any day that the Exchange experiences an Exchange System Disruption and on any day with a scheduled early market close.

¹² See Securities Exchange Act Release No. 70199 (August 14, 2013), 78 FR 51250 (August 20, 2013) (SR-BATS-2013-036) (Order Approving a Proposed Rule Change to Introduce a Connectivity Option Through Points of Presence).

Add fee code NM references in footnotes 4 and 5; (ii) removing the reference to “MM” (short for Market Maker) from the description in fee code NA; and (iii) remove the words “Market Maker Add Volume” from both Market Maker Add Volume Tier 1 and Tier 2 in footnote 6.

Clarifying Change

The Exchange is proposing to add references to the fee codes PA and PF in footnote 5. While the Fee Codes and Associated Fees table indicates that footnote 5 applies to both fee codes PA and PF, the fee codes are not included in the footnote itself as fee codes to which the footnote is applicable.

Effectiveness Date

As noted above, the Exchange proposes to implement the amendments to its fee schedule effective immediately.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6 of the Act.¹³ Specifically, the Exchange believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,¹⁴ in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and other persons using any facility or system which the Exchange operates or controls. The Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels to be excessive.

The Exchange believes the proposed reduction of the standard rebate for Market Maker orders in non-Penny Pilot Securities that add liquidity is a reasonable, fair and equitable allocation of fees and rebates because it will provide Members with a greater incentive to increase their participation on BATS Options in order to receive a higher rebate by meeting any of the enhanced rebate tiers for which the orders are eligible, including the NBBO Setter Tiers, the Quoting Incentive Program Tiers, and the Market Maker Non-Penny Pilot Add Volume Tiers proposed herein. Finally, while adjusting the standard rebate of \$0.65 per contract to remove liquidity to \$0.42 per share will obviously result in a

⁶ “Market Maker” applies to any transaction identified by a Member for clearing in the Market Maker range at the OCC.

⁷ “Penny Pilot Securities” are those issues quoted pursuant to Exchange Rule 21.5, Interpretation and Policy .01.

⁸ “Professional” applies to any transaction identified by a Member as such pursuant to Exchange Rule 16.1.

⁹ “Firm” applies to any transaction identified by a Member for clearing in the Firm range at the OCC.

¹⁰ “ADV” means average daily volume calculated as the number of contracts added or removed, combined, per day.

¹¹ “TCV” means total consolidated volume calculated as the volume reported by all exchanges

¹³ 15 U.S.C. 78f.

¹⁴ 15 U.S.C. 78f(b)(4).

reduction in rebates paid per contract to Members, the Exchange believes that any potential negative impact of this change will be outweighed by the Exchange's ability to apply the cost savings to other areas of the business, including enhanced rebates, reduced fees, and improved technology on the BATS Options. The Exchange also believes that the proposed fee change is non-discriminatory because it would apply uniformly to all Members [sic].

Volume-based rebates and fees such as the ones currently maintained on BATS Options have been widely adopted by equities and options exchanges and are equitable because they are open to all Members on an equal basis and provide additional benefits or discounts that are reasonably related to the value to an exchange's market quality associated with higher levels of market activity, such as higher levels of liquidity provision and/or growth patterns, and introduction of higher volumes of orders into the price and volume discovery processes. The Exchange believes that the proposed addition of Market Maker Non-Penny Pilot Add Volume Tiers is a reasonable, fair and equitable allocation of fees and rebates because it will provide Members with a greater incentive to increase their participation on BATS Options in order to receive a higher rebate, which will result in enhanced market quality for all Members.

The Exchange reiterates that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if they deem fee levels to be excessive.

Physical Connection Fees

The Exchange believes that providing uniform rates for all 1G and 10G physical connections to Exchange is reasonable because such change represents a reduction in fees for any Member that connects to the Exchange at a PoP location and no change to fees for any Member located in the Exchange's primary or secondary data center. The Exchange also believes that the proposal is equitably allocated and not unreasonably discriminatory because, as proposed, market participants will be able to access the Exchange at uniform rates regardless of whether such access is at the Exchange's primary or secondary data center location or another location where the Exchange offers access.

Corresponding and Clarifying Changes

Finally, the Exchange believes that the corresponding and clarifying changes discussed above are non-

substantive and would contribute to the protection of investors and the public interest by helping to avoid confusion with respect the Exchange fee schedule.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange 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. With respect to the proposed new rebates for Market Maker orders that add liquidity in non-Penny Pilot Securities, particularly the enhanced rebates available under the Market Maker Non-Penny Pilot Add Volume Tiers, the Exchange does not believe that any such changes burden competition, but instead, that they enhance competition, as they are intended to increase the competitiveness of BATS Options. As stated above, the Exchange notes that it operates in a highly competitive market in which market participants can readily direct order flow to competing venues if the deem fee structures to be unreasonable or excessive.

The Exchange does not believe that the proposed change to physical port fees represents a significant departure from previous pricing offered by the Exchange or pricing offered by the Exchange's competitors. Rather, as described above, the Exchange is simply normalizing its fees for physical access to the Exchange regardless of the location where a physical connection is made. The offering is consistent with the Exchange's own economic incentives to facilitate as many market participants as possible in connecting to its market. Accordingly, the Exchange does not believe that the proposed change will impair the ability of Members or competing venues to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act¹⁵ and paragraph (f)(2) of Rule

19b-4 thereunder.¹⁶ At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (<http://www.sec.gov/rules/sro.shtml>); or
- Send an email to rule-comments@sec.gov. Please include File Number SR-BATS-2015-38 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-BATS-2015-38. 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 will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change;

¹⁵ 15 U.S.C. 78s(b)(3)(A).

¹⁶ 17 CFR 240.19b-4(f)(2).

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-BATS-2015-38 and should be submitted on or before June 10, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.¹⁷

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015-12147 Filed 5-19-15; 8:45 am]

BILLING CODE 8011-01-P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-74960; File No. SR-CBOE-2015-029]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Order Granting Approval of a Proposed Rule Change Relating to Stock-Option Order Handling

May 14, 2015.

I. Introduction

On March 16, 2015, Chicago Board Options Exchange, Incorporated (“CBOE” or the “Exchange”) filed with the Securities and Exchange Commission (“Commission”), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (“Act” or “Exchange Act”) ¹ and Rule 19b-4 thereunder, ² a proposed rule change to amend its rules regarding the handling and processing of stock-option orders on the Exchange. The proposed rule change was published for comment in the **Federal Register** on April 1, 2015. ³ The Commission received no comments on the proposal. This order grants approval of the proposed rule change.

II. Description of the Proposed Rule Change

The Exchange proposes to amend its rules regarding the handling and processing of stock-option orders represented in open outcry on the floor of the Exchange. As described in more detail below, the Exchange proposes to amend CBOE Rule 6.48 to allow Trading Permit Holders (“TPHs”) or PAR Officials ⁴ to electronically route the stock component of a stock-option order represented in open outcry on the floor

of the CBOE directly from a Public Automated Routing (“PAR”) workstation ⁵ to an Exchange-designated broker-dealer for electronic execution on a stock venue. In addition, the Exchange proposes to amend Interpretation .06 to Rule 6.53C to require that the Clearing Trading Permit Holder (“CTPH”) ⁶ identified as the Designated Give Up by the executing TPH in accordance with CBOE Rule 6.21 on a stock-option order enter into a brokerage agreement with the non-affiliated Exchange-designated broker-dealers before the TPH electronically routes the stock component of the stock-option order to that Exchange-designated broker-dealer for execution on a stock venue.

Routing Stock Component of a Stock-Option Order via PAR. Currently, the stock component of stock-option orders handled and processed on the Exchange in open outcry are manually transmitted (*e.g.*, via telephone) by the PAR user (*i.e.*, a floor broker or PAR Official) on the floor to a broker on a stock trading venue for execution. The Exchange proposes to adopt subparagraph (d) to Exchange Rule 6.48 (Contract Made on Acceptance of Bid or Offer) to allow TPHs or PAR Officials to electronically route the stock component of such stock-option orders to an Exchange-designated broker-dealer not affiliated with the Exchange for electronic execution at a stock trading venue directly from PAR. ⁷ Proposed Rule 6.48(d) also provides that the stock component of a stock-option order represented in open outcry may be routed to an Exchange-designated broker-dealer not affiliated with the Exchange for electronic execution at a stock trading venue as single orders or as paired orders (including with orders transmitted from separate PAR workstations), and that the stock-option order must comply with the Qualified Contingent Trade (“QCT”) Exemption of Rule 611(a) of Regulation NMS. ⁸ Finally, Rule 6.48(d) would require TPHs who route the stock component of a stock-option order represented in open outcry through PAR to comply with Rule 6.53C.06, which governs the trading of complex orders, including stock-option orders, on the CBOE Hybrid System. ⁹

The Exchange represents that for any order whose stock component is routed via PAR to an Exchange-designated

broker-dealer for execution at a stock trading venue, the Exchange-designated broker-dealer would be responsible for the proper execution, trade reporting, and submission to clearing of the stock trade that is part of the stock-option order. ¹⁰ The Exchange also represents that once the stock component of a stock-option order is transmitted to the Exchange-designated broker-dealer, the Exchange-designated broker-dealers is responsible for determining whether the orders may be executed in accordance with all of the rules applicable to the execution of equity orders, including compliance with applicable short sale, trade-through, and reporting rules. ¹¹

The Exchange believes that the proposed rule change will support more efficient stock-option order execution, streamline the steps required for open-outcry stock-option order trading, and enhance the Exchange’s audit trail by creating a more robust record of the stock component of stock-option order executions on the floor of the Exchange. ¹² The Exchange also believes that the proposed rule change will promote liquidity on the national market system by allowing TPHs to more easily use stock-option orders and more quickly send the stock component of a stock-option order to a stock trading venue. ¹³

Brokerage Agreement between the Clearing Trading Permit Holder and the Exchange-designated Broker-Dealer. Under current Interpretation and Policy .06(a) to CBOE Rule 6.53C, the stock component of a stock-option order cannot be processed automatically unless the executing TPH has entered into a brokerage agreement with one or more Exchange-designated broker-dealer(s) not affiliated with the Exchange that can electronically execute the equity order on a stock trading venue. ¹⁴ Under the proposed rule change, Interpretation and Policy .06 to CBOE Rule 6.53C would instead require the CTPH that was previously identified by the TPH as the “Designated Give Up” pursuant to CBOE Rule 6.21 to enter into a brokerage agreement with the non-affiliated Exchange-designated broker-dealer(s) before the TPH electronically routes the stock component of a stock-option order to the Exchange-designated broker-dealer for execution at a stock-trading venue. ¹⁵ The Exchange notes that it is the CTPH, not the order entry TPH that guarantees

¹⁷ 17 CFR 200.30-3(a)(12).

¹ 15 U.S.C. 78s(b)(1).

² 17 CFR 240.19b-4.

³ See Securities Exchange Act Release No. 74590 (March 26, 2015), 80 FR 17528 (“Notice”).

⁴ See Notice, *supra* note 3 at 17529, defining “PAR Officials.”

⁵ *Id.*, defining “PAR workstations.”

⁶ *Id.* at footnote 5, discussing the obligations of TPHs and CTPHs.

⁷ See Notice, *supra* note 3 at 17530.

⁸ *Id.*

⁹ See Proposed Rule 6.48(d).

¹⁰ See Notice, *supra* note 3 at 17530.

¹¹ *Id.*

¹² *Id.*

¹³ See Notice, *supra* note 3 at 17532.

¹⁴ *Id.* at 17531.

¹⁵ *Id.*

authorization of a trade and accepts financial responsibility for all Exchange transactions made by the execution TPH. Accordingly, the Exchange believes that, consistent with CBOE Rule 6.21 (relating to give-ups), the CTPH should be responsible for order handling and processing requirements for trades that it guarantees.¹⁶ In connection with the Exchange's proposal to amend Interpretation and Policy .06 to Rule 6.53C, the Exchange also clarified that the stock component of a stock-option order represented in open outcry shall be routed from PAR to the Exchange-designated broker-dealer for automated processing in accordance with the order's terms.¹⁷

Conforming and Clarifying Changes. Finally, the Exchange also proposes conforming changes to Exchange Rules 6.45A (Priority and Allocation of Equity Option Trades on the CBOE Hybrid System) and 6.45B (Priority and Allocation of Trades in Index Options and Options on ETFs on the CBOE Hybrid System) to reference the revised functionality set forth in this proposal.¹⁸ The Exchange also proposes to specify that stock-option orders may be executed against other electronic stock-option orders in general, rather than state that such orders may be executed against other stock-option orders specifically through either the COB or COA.¹⁹

III. Discussion and Commission Findings

After careful review, the Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange.²⁰ In particular, the Commission finds that the proposed rule change is consistent with the requirements of Section 6(b)(5) of the Act,²¹ which requires, among other things, that the Exchange's rules be 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 regulating, clearing, settling, processing

information with respect to, and facilitation transactions in securities, 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; and are not designed to permit unfair discrimination between customers, issuers, brokers or dealers. The Commission believes that the proposed change to extend electronic stock component routing functionality to PAR users will create another method for processing stock-option orders entered into on the Exchange that is designed to facilitate transactions in stock-option orders on the Exchange. The Commission also believes that it is reasonable for the CTPH that guarantees a stock-option order transaction to enter into a brokerage agreement with the Exchange-designated broker-dealer that will execute the stock component of the stock-option order on a stock trading venue.

IV. Conclusion

It is therefore ordered, pursuant to Section 19(b)(2) of the Act,²² that the proposed rule change (SR-CBOE-2015-029) be, and it hereby is, approved.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.²³

Robert W. Errett,
Deputy Secretary.

[FR Doc. 2015-12141 Filed 5-19-15; 8:45 am]

BILLING CODE 8011-01-P

SMALL BUSINESS ADMINISTRATION

Data Collection Available for Public Comments

ACTION: 60-day notice and request for comments.

SUMMARY: The Small Business Administration (SBA) intends to request approval, from the Office of Management and Budget (OMB) for the new collection of information described below. The Paperwork Reduction Act (PRA) of 1995, 44 U.S.C. Chapter 35, required federal agencies to publish a notice in the **Federal Register** concerning each proposed collection of information before submission to OMB, and to allow 60 days for public comment in response to the notice. This notice complies with that requirement.

DATES: Submit comments on or before July 20, 2015.

ADDRESSES: Send all comments to Melinda Edwards, Program Analyst,

Office of Business Development, Small Business Administration, 409 3rd Street, 8th Floor, Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Melinda Edwards, Program Analyst, Office of Business Development, Melinda.Edwards@sba.gov, 202-619-1843, or Curtis B. Rich, Management Analyst, 202-205-7030, Curtis.Rich@sba.gov.

SUPPLEMENTARY INFORMATION: In accordance with 13 CFR 124.604, as part of its annual review submission, each Participant owned by a Tribe, ANC, NHO or CDC must submit to SBA information showing how they have provided benefits to their members and communities. This data includes information relating to funded cultural programs, employment assistance, jobs, scholarships, internships, subsistence activities, and other services provided.

Solicitation of Public Comments

SBA is requesting comments on (a) whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

Summary of Information Collection

Title: 8(a) Participant Benefits Report.

Description of Respondents: 8(a) Program Participants—Entity Owned (Indian Tribe, Alaskan Native Corporations, Native Hawaiian Organizations, and Community Development Corporations).

Form Number: N/A.

Total Estimated Annual Responses: 329.

Total Estimated Annual Hour Burden: 165.

Curtis B. Rich,
Management Analyst.

[FR Doc. 2015-12166 Filed 5-19-15; 8:45 am]

BILLING CODE 8025-01-P

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: 30-day notice.

SUMMARY: The Small Business Administration (SBA) is publishing this notice to comply with requirements of the Paperwork Reduction Act (PRA) (44 U.S.C. Chapter 35), which requires

¹⁶ *Id.* at 17532.

¹⁷ See Proposed Interpretation and Policy .06(a) to Rule 6.53C.

¹⁸ See Notice, *supra* note 3 at 17531.

¹⁹ *Id.* According to the Exchange, this latter change reflects the fact that such orders may be subjected to the Automated Improvement Mechanism ("AIM") as well as executed through the COB or COA.

²⁰ In approving this proposed rule change, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. See 15 U.S.C. 78c(f).

²¹ 15 U.S.C. 78f(b)(5).

²² 15 U.S.C. 78s(b)(2).

²³ 17 CFR 200.30-3(a)(12).

agencies to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission. This notice also allows an additional 30 days for public comments.

DATES: Submit comments on or before June 19, 2015.

ADDRESSES: Comments should refer to the information collection by name and/or OMB Control Number and should be sent to: *Agency Clearance Officer*, Curtis Rich, Small Business Administration, 409 3rd Street SW., 5th Floor, Washington, DC 20416; and *SBA Desk Officer*, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Curtis Rich, Agency Clearance Officer, (202) 205-7030, curtis.rich@sba.gov.

Copies: A copy of the Form OMB 83-1, supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

SUPPLEMENTARY INFORMATION: Small Business Administration (SBA) Forms 856 and 856A are used by SBA examiners as part of their examination of licensed small business investment companies (SBICs). This information collection obtains representations from an SBIC's management regarding certain obligations, transactions and relationships of the SBIC and helps SBA to evaluate the SBIC's financial condition and compliance with applicable laws and regulations.

Solicitation of Public Comments

Comments may be submitted on (a) whether the collection of information is necessary for the agency to properly perform its functions; (b) whether the burden estimates are accurate; (c) whether there are ways to minimize the burden, including through the use of automated techniques or other forms of information technology; and (d) whether there are ways to enhance the quality, utility, and clarity of the information.

Summary of Information Collections

Title: Disclosures Statement Leveraged Licenses; Disclosure Non-Leveraged Licensees.

Description of Respondents: SBA Examiners.

Form Numbers: SBA Forms 856 and 856 A.

Estimated Annual Respondents: 298.

Estimated Annual Responses: 298.

Estimated Annual Hour Burden: 138.

Curtis B. Rich,

Management Analyst.

[FR Doc. 2015-12164 Filed 5-19-15; 8:45 am]

BILLING CODE 8025-01-P

SMALL BUSINESS ADMINISTRATION

[Disaster Declaration #14310 and #14311]

Kentucky Disaster #KY-00024

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 Kentucky (FEMA-4218-DR), dated 05/12/2015.

Incident: Severe winter storm, snowstorm, flooding, landslides, and mudslides.

Incident Period: 03/03/2015 through 03/09/2015.

Effective Date: 05/12/2015.

Physical Loan Application Deadline Date: 07/13/2015.

Economic Injury (EIDL) Loan Application Deadline Date: 02/12/2016.

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 05/12/2015, 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:

Anderson, Bell, Bourbon, Boyd, Breathitt, Bullitt, Butler, Calloway, Carter, Casey, Clay, Daviess, Elliott, Estill, Fleming, Floyd, Franklin, Fulton, Gallatin, Grant, Greenup, Hancock, Harrison, Hart, Jackson, Johnson, Knott, Knox, Larue, Lawrence, Lee, Leslie, Letcher, Lewis, Magoffin, Marshall, Martin, Mason, Menifee, Metcalfe, Morgan, Nicholas, Ohio, Owen, Owsley, Perry, Pike, Powell, Robertson, Rockcastle, Rowan, Spencer, Trigg, Washington, Webster, Whitley, Woodford.

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 14310B and for economic injury is 14311B.

(Catalog of Federal Domestic Assistance Numbers 59002 and 59008)

James E. Rivera,

Associate Administrator for Disaster Assistance.

[FR Doc. 2015-12167 Filed 5-19-15; 8:45 am]

BILLING CODE 8025-01-P

DEPARTMENT OF STATE

[Public Notice 9137]

30-Day Notice of Proposed Information Collection: Affidavit of Relationship (AOR) for Minors Who Are Nationals Of El Salvador, Guatemala, and Honduras

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for approval. In accordance with the Paperwork Reduction Act of 1995 we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

DATES: Submit comments directly to the Office of Management and Budget (OMB) up to June 19, 2015.

ADDRESSES: Direct comments to the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB). You may submit comments by the following methods:

- *Email:* oira_submission@omb.eop.gov. You must include the DS form number, information collection title, and the OMB control number in the subject line of your message.
- *Fax:* 202-395-5806. Attention: Desk Officer for Department of State.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests

for copies of the proposed collection instrument and supporting documents, to PRM/Admissions (Sean Hantak PRM/Admissions, 2025 E Street NW, 8th Floor, Washington DC 20520), who may be reached at *Fax*: 202-453-9393 or at *hantaksr@state.gov*.

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection*: DS-7699 Affidavit of Relationship (AOR) for Minors Who Are Nationals Of El Salvador, Guatemala, and Honduras
- *OMB Control Number*: 1405-0217
- *Type of Request*: Extension of a Currently Approved Collection
- *Originating Office*: PRM/A
- *Form Number*: DS-7699
- *Respondents*: Anchor parents in the U.S. with children in El Salvador, Guatemala, and Honduras.
- *Estimated Number of Respondents*: 2,500
- *Estimated Number of Responses*: 2,500
- *Average Time per Response*: 60 minutes per response
- *Total Estimated Burden Time*: 2,500 hours
- *Frequency*: Once per respondent
- *Obligation to Respond*: Required to Obtain or Retain a Benefit

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of proposed collection:

The Department of State Bureau of Population, Refugees, and Migration (PRM) is responsible for coordinating and managing the U.S. Refugee Admissions Program (USRAP). PRM coordinates within the Department of State, as well as with the Department of Homeland Security's U.S. Citizenship and Immigration Services (DHS/USCIS), in carrying out this responsibility. A critical part of the State Department's

responsibility is determining which individuals, from among millions of refugees worldwide, will have access to U.S. resettlement consideration. PRM and DHS/USCIS are now assisting with the preparation of a White House directive to initiate an in-country program to provide a means for certain persons who are lawfully present in the United States to claim a relationship with child(ren) in Honduras, El Salvador, and Guatemala and to assist the U.S. Department of State in determining whether those child(ren) are qualified to apply for access to the USRAP for family reunification purposes. This form also assists DHS/USCIS to verify parent-child relationships during refugee case adjudication. The main purpose of the DS-7699 is for the U.S. based parent to provide biographical information about his/her child(ren) in the qualifying countries who may subsequently seek access to the USRAP for verification by the U.S. government.

Methodology:

This information collection currently involves the limited use of electronic techniques. Parents (respondents) in the United States will work closely with a resettlement agency during the completion of the AOR to ensure that the information is accurate. Anchor parents may visit any resettlement agency to complete an AOR. Sometimes respondents do not have strong English-language skills and benefit from having a face-to-face meeting with resettlement agency staff. The DS-7699 form will be available electronically and responses will be completed electronically. Completed AORs will be printed out for ink signature by the respondents as well. The electronic copy will be submitted electronically to the Refugee Processing Center (RPC) for downloading into the Worldwide Refugee Admissions Processing System (WRAPS), with the signed paper copy remaining with PRM's Reception and Placement Agency partners.

Dated: May 7, 2015.

Simon Henshaw,

Principle Deputy Assistant Secretary, Bureau of Population, Refugees and Migration, Department of State.

[FR Doc. 2015-12233 Filed 5-19-15; 8:45 am]

BILLING CODE 4710-33-P

DEPARTMENT OF STATE

[Public Notice: 9138]

Meetings of the United States-Peru Environmental Affairs Council, Environmental Cooperation Commission, and Sub-Committee on Forest Sector Governance

ACTION: Notice of meetings of the United States-Peru Environmental Affairs Council, Environmental Cooperation Commission, and Sub-Committee on Forest Sector Governance, and request for comments.

SUMMARY: The Department of State and the Office of the United States Trade Representative (USTR) are providing notice that the United States and Peru intend to hold the seventh meeting of the Sub-Committee on Forest Sector Governance (the "Sub-Committee"), the fifth meeting of the Environmental Affairs Council (the "Council"), and the third meeting of the Environmental Cooperation Commission (the "Commission") on June 8-9, 2015. The public sessions for the Council, Commission and Sub-Committee will be held on June 9, at 3:00 p.m. All meetings will take place in Lima, Peru at the Ministry of Foreign Trade and Tourism (MINCETUR), Calle Uno Oeste N 050 Urb. Corpac, San Isidro, Lima, Conference Rooms 1&2.

The purpose of the meetings is to review implementation of: Chapter 18 (Environment) of the United States-Peru Trade Promotion Agreement (PTPA); the PTPA Annex on Forest Sector Governance (Annex 18.3.4); and the United States-Peru Environmental Cooperation Agreement (ECA). The United States and Peru will also approve a new 2015-2018 Environmental Cooperation Work Program under the ECA.

The Department of State and USTR invite interested organizations and members of the public to attend the public session, and to submit written comments or suggestions regarding implementation of Chapter 18, Annex 18.3.4, and the ECA, and any issues that should be discussed at the meetings. If you would like to attend the public sessions, please notify Rachel Kastenberg and Laura Buffo at the email addresses listed below under the heading **ADDRESSES**. Please include your full name and any organization or group you represent.

In preparing comments, submitters are encouraged to refer to:

- Chapter 18 of the PTPA, including Annex 18.3.4, <https://ustr.gov/trade-agreements/free-trade-agreements/peru-tpa/final-text>

• the Final Environmental Review of the PTPA, <https://ustr.gov/sites/default/files/uploads/factsheets/Trade%20Topics/environment/Environmental%20Review%20FINAL%2020071101.pdf>, and

• the ECA <http://www.state.gov/e/oes/eqt/trade/peru/81638.htm>.

These and other useful documents are available at: <http://www.ustr.gov/trade-agreements/free-trade-agreements/peru-tpa> and at <http://www.state.gov/e/oes/eqt/trade/peru/index.htm>

DATES: The public sessions of the Council, Sub-Committee and Commission meetings will be held on June 9, 2015, beginning at 3:00 p.m., at the Ministry of Foreign Trade and Tourism (MINCETUR), Calle Uno Oeste N 050 Urb. Corpac, San Isidro, Lima, Conference Rooms 1&2. Comments and suggestions are requested in writing no later than June 2, 2015.

ADDRESSES: Written comments and suggestions should be submitted to both:

(1) Rachel Kastenberg, Office of Environmental Quality and Transboundary Issues, U.S. Department of State, by electronic mail at KastenbergRL@state.gov with the subject line "U.S.-Peru EAC/ECC/Sub-Committee Meetings"; and

(2) Laura Buffo, Office of Environment and Natural Resources, Office of the United States Trade Representative, by electronic mail at Laura_Buffo@ustr.eop.gov with the subject line "U.S.-Peru EAC/ECC/Sub-Committee Meetings."

If you have access to the Internet, you can view and comment on this notice by going to <http://www.regulations.gov/#!home> and searching on its Public Notice number: 7873.

FOR FURTHER INFORMATION CONTACT: Rachel Kastenberg, Telephone (202) 736-7111 or Laura Buffo, Telephone (202) 395-9424.

SUPPLEMENTARY INFORMATION: The PTPA entered into force on February 1, 2009. Article 18.6 of the PTPA establishes an Environmental Affairs Council, which is required to meet at least once a year or as otherwise agreed by the Parties to discuss the implementation of Chapter 18. Annex 18.3.4 of the PTPA establishes a Sub-Committee on Forest Sector Governance. The Sub-Committee is a specific forum for the Parties to exchange views and share information on any matter arising under the PTPA Annex on Forest Sector Governance. The ECA entered into force on August 23, 2009. Article III of the ECA establishes an Environmental Cooperation Commission and makes the Commission responsible for developing

a Work Program. Chapter 18 of the PTPA and Article VI of the ECA require that meetings of the Council and Commission respectively include a public session, unless the Parties otherwise agree. At its first meeting, the Sub-Committee on Forest Sector Governance committed to hold a public session after each Sub-Committee meeting.

Dated: May 15, 2015.

Deborah Klepp,

Director, Office of Environmental Quality and Transboundary Issues, Department of State.

[FR Doc. 2015-12234 Filed 5-19-15; 8:45 am]

BILLING CODE 4710-09-P

SUSQUEHANNA RIVER BASIN COMMISSION

Projects Approved for Consumptive Uses of Water

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice.

SUMMARY: This notice lists the projects approved by rule by the Susquehanna River Basin Commission during the period set forth in **DATES**.

DATES: April 1-30, 2015.

ADDRESSES: Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, PA 17110-1788.

FOR FURTHER INFORMATION CONTACT:

Jason E. Oyler, Regulatory Counsel, telephone: (717) 238-0423, ext. 1312; fax: (717) 238-2436; email: joyler@srbc.net. Regular mail inquiries may be sent to the above address.

SUPPLEMENTARY INFORMATION: This notice lists the projects, described below, receiving approval for the consumptive use of water pursuant to the Commission's approval by rule process set forth in 18 CFR 806.22(f) for the time period specified above:

Approvals by Rule Issued Under 18 CFR 806.22(f)

1. Chesapeake Appalachia, LLC, Pad ID: Redmond, ABR-201007005.R1, Meshoppen Township, Wyoming County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 3, 2015.

2. Chesapeake Appalachia, LLC, Pad ID: EDF NEW, ABR-201007125.R1, Mehoopany Township, Wyoming County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 3, 2015.

3. Chesapeake Appalachia, LLC, Pad ID: Warren, ABR-201008010.R1, Windham Township, Wyoming County,

Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 3, 2015.

4. Chesapeake Appalachia, LLC, Pad ID: Lambert Farms, ABR-201008011.R1, Forks Township, Sullivan County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 3, 2015.

5. Chesapeake Appalachia, LLC, Pad ID: Joanclark, ABR-201008025.R1, Fox Township, Sullivan County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 3, 2015.

6. Chesapeake Appalachia, LLC, Pad ID: Roundtop, ABR-201008067.R1, Colley Township, Sullivan County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 3, 2015.

7. Chesapeake Appalachia, LLC, Pad ID: George, ABR-201008101.R1, Windham Township, Wyoming County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 3, 2015.

8. Chesapeake Appalachia, LLC, Pad ID: Bedford, ABR-201008139.R1, Elkland Township, Sullivan County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 3, 2015.

9. Chesapeake Appalachia, LLC, Pad ID: Benspond, ABR-201008146.R1, Elkland Township, Sullivan County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 3, 2015.

10. Chesapeake Appalachia, LLC, Pad ID: Fremar, ABR-201008147.R1, Fox Township, Sullivan County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 3, 2015.

11. Chesapeake Appalachia, LLC, Pad ID: Hottenstein, ABR-201008148.R1, Forks Township, Sullivan County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 3, 2015.

12. EXCO Resources (PA), LLC Pad ID: Litke (14H, 15H, 16H), ABR-20090431.R1, Burnside Township, Centre County, Pa.; Consumptive Use of Up to 5.000 mgd; Approval Date: April 3, 2015.

13. EXCO Resources (PA), LLC Pad ID: COP Tract 706 (Pad 8) ABR-201008059.R1, Burnside Township, Centre County, Pa.; Consumptive Use of Up to 8.000 mgd; Approval Date: April 3, 2015.

14. XTO Energy Inc., Pad ID: MARQUARDT UNIT 8517H, ABR-20100417.R1, Penn Township, Lycoming County, Pa.; Consumptive Use of Up to 4.000 mgd; Approval Date: April 3, 2015.

15. XTO Energy Inc., Pad ID: Everbe Farms 8518H, ABR-20100533.R1, Franklin Township, Lycoming County, Pa.; Consumptive Use of Up to 4.000 mgd; Approval Date: April 3, 2015.

16. Anadarko E&P Onshore LLC, Pad ID: COP Tr 685 A, ABR-20100541.R1, Cummings Township, Lycoming County, Pa.; Consumptive Use of Up to

3.000 mgd; Approval Date: April 8, 2015.

17. Anadarko E&P Onshore LLC, Pad ID: COP Tr 728 Pad A, ABR-20100631.R1, Watson Township, Lycoming County, Pa.; Consumptive Use of Up to 3.000 mgd; Approval Date: April 8, 2015.

18. Anadarko E&P Onshore LLC, Pad ID: David C Duncan Pad A, ABR-20100635.R1, Cascade Township, Lycoming County, Pa.; Consumptive Use of Up to 3.000 mgd; Approval Date: April 8, 2015.

19. Chesapeake Appalachia, LLC, Pad ID: Barnes, ABR-201007048.R1, Smithfield Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 8, 2015.

20. Chesapeake Appalachia, LLC, Pad ID: Scheffler, ABR-201007102.R1, Standing Stone Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 8, 2015.

21. Chesapeake Appalachia, LLC, Pad ID: Champluvier, ABR-201007105.R1, Tuscarora Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 8, 2015.

22. Chesapeake Appalachia, LLC, Pad ID: Covington, ABR-201007123.R1, Sheshequin Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 8, 2015.

23. Chesapeake Appalachia, LLC, Pad ID: Felter-NEW, ABR-201008026.R1, Wyalusing Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 8, 2015.

24. Chesapeake Appalachia, LLC, Pad ID: Atgas, ABR-201008066.R1, Leroy Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 8, 2015.

25. Chesapeake Appalachia, LLC, Pad ID: Ammerman, ABR-201008099.R1, Litchfield Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 8, 2015.

26. Chesapeake Appalachia, LLC, Pad ID: Dave, ABR-201008107.R1, Albany Stone Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 8, 2015.

27. Seneca Resources, Pad ID: CRV Pad C09-D, ABR-201504001, Shippen Township, Cameron County, Pa.; Consumptive Use of Up to 4.000 mgd; Approval Date: April 8, 2015.

28. Range Resources—Appalachia, LLC, Pad ID: Cornwall South Unit, ABR-201504002, Lewis Township, Lycoming County, Pa.; Consumptive Use of Up to 5.000 mgd; Approval Date: April 8, 2015.

29. Range Resources—Appalachia, LLC, Pad ID: Cornhill A Well Pad, ABR-

201504003, Cogan House Township, Lycoming County, Pa.; Consumptive Use of Up to 5.000 mgd; Approval Date: April 8, 2015.

30. SWEPI, LP, Pad ID: 808 Thomas, ABR-20100344.R1, Elkland Township, Tioga County, Pa.; Consumptive Use of Up to 4.990 mgd; Approval Date: April 8, 2015.

31. SWEPI, LP, Pad ID: Cummings 823, ABR-20100350.R1, Chatham Township, Tioga County, Pa.; Consumptive Use of Up to 4.000 mgd; Approval Date: April 8, 2015.

32. SWEPI, LP, Pad ID: Bartlett 531, ABR-20100351.R1, Richmond Township, Tioga County, Pa.; Consumptive Use of Up to 4.000 mgd; Approval Date: April 8, 2015.

33. Cabot Oil & Gas Corporation, Pad ID: ChambersO P1, ABR-201504004, Harford Township, Susquehanna County, Pa.; Consumptive Use of Up to 4.250 mgd; Approval Date: April 13, 2015.

34. Cabot Oil & Gas Corporation, Pad ID: DeckerT P1, ABR-201504005, Harford Township, Susquehanna County, Pa.; Consumptive Use of Up to 4.250 mgd; Approval Date: April 13, 2015.

35. Chesapeake Appalachia, LLC, Pad ID: Lattimer, ABR-201008038.R1, Litchfield Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 13, 2015.

36. Chesapeake Appalachia, LLC, Pad ID: Moore Farm, ABR-201008050.R1, Canton Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 13, 2015.

37. Chesapeake Appalachia, LLC, Pad ID: Thall, ABR-201008140.R1, Albany Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 13, 2015.

38. EQT Production Company, Pad ID: Phoenix C, ABR-201006114.R1, Duncan Township, Tioga County, Pa.; Consumptive Use of Up to 3.000 mgd; Approval Date: April 14, 2015.

39. EQT Production Company, Pad ID: Phoenix E, ABR-201008130.R1, Duncan Township, Tioga County, Pa.; Consumptive Use of Up to 3.000 mgd; Approval Date: April 14, 2015.

40. EQT Production Company, Pad ID: Phoenix H, ABR-201010058.R1, Morris Township, Tioga County, Pa.; Consumptive Use of Up to 3.000 mgd; Approval Date: April 14, 2015.

41. EQT Production Company, Pad ID: Phoenix R, ABR-201011057.R1, Duncan Township, Tioga County, Pa.; Consumptive Use of Up to 3.000 mgd; Approval Date: April 14, 2015.

42. EQT Production Company, Pad ID: Longhorn C-1 (WDV1), ABR-201011061.R1, Jay Township, Elk

County, Pa.; Consumptive Use of Up to 3.000 mgd; Approval Date: April 14, 2015.

43. EQT Production Company, Pad ID: Phoenix S, ABR-201012009.R1, Duncan Township, Tioga County, Pa.; Consumptive Use of Up to 3.000 mgd; Approval Date: April 14, 2015.

44. SWEPI, LP, Pad ID: Kjelgaard, ABR-20090902.R1, Gaines Township, Tioga County, Pa.; Consumptive Use of Up to 4.990 mgd; Approval Date: April 16, 2015.

45. Seneca Resources Corporation, Pad ID: Wilcox Pad F, ABR-20090505.R1, Covington Township, Tioga County, Pa.; Consumptive Use of Up to 4.000 mgd; Approval Date: April 17, 2015.

46. Seneca Resources Corporation, Pad ID: J. Pino Pad G, ABR-20090717.R1, Covington Township, Tioga County, Pa.; Consumptive Use of Up to 4.000 mgd; Approval Date: April 17, 2015.

47. Seneca Resources Corporation, Pad ID: D.M. Pino Pad H, ABR-20090933.R1, Covington Township, Tioga County, Pa.; Consumptive Use of Up to 4.000 mgd; Approval Date: April 17, 2015.

48. Seneca Resources Corporation, Pad ID: Marvin 1V Pad, ABR-20090934.R1, Covington Township, Tioga County, Pa.; Consumptive Use of Up to 5.000 mgd; Approval Date: April 17, 2015.

49. Seneca Resources Corporation, Pad ID: Rich Valley 1V Pad, ABR-20091227.R1, Shippen Township, Cameron County, Pa.; Consumptive Use of Up to 5.000 mgd; Approval Date: April 17, 2015.

50. Cabot Oil & Gas Corporation, Pad ID: WarrinerR P4, ABR-201008123.R1, Dimock Township, Susquehanna County, Pa.; Consumptive Use of Up to 3.575 mgd; Approval Date: April 20, 2015.

51. Chesapeake Appalachia, LLC, Pad ID: Aikens, ABR-201008068.R1, Litchfield Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 20, 2015.

52. Chesapeake Appalachia, LLC, Pad ID: Donna, ABR-201008096.R1, Terry Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 20, 2015.

53. Chesapeake Appalachia, LLC, Pad ID: Clarke, ABR-201008145.R1, Overton Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 20, 2015.

54. Chesapeake Appalachia, LLC, Pad ID: Balent NEW, ABR-201008149.R1, Wysox Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 20, 2015.

55. Chesapeake Appalachia, LLC, Pad ID: McCabe, ABR-201008157.R1, Towanda Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 20, 2015.

56. Chesapeake Appalachia, LLC, Pad ID: Wolf, ABR-201008158.R1, Athens Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 20, 2015.

57. EOG Resources, Inc., Pad ID: GUINAN 2H, ABR-20091117.R1, Springfield Township, Bradford County, Pa.; Consumptive Use of Up to 1.999 mgd; Approval Date: April 22, 2015.

58. EOG Resources, Inc., Pad ID: HOPPAUGH 3H, ABR-20091121.R1, Springfield Township, Bradford County, Pa.; Consumptive Use of Up to 1.999 mgd; Approval Date: April 22, 2015.

59. EOG Resources, Inc., Pad ID: HARKNESS 3H, ABR-20091221.R1, Springfield Township, Bradford County, Pa.; Consumptive Use of Up to 1.999 mgd; Approval Date: April 22, 2015.

60. EOG Resources, Inc., Pad ID: BEARDSLEE 2H Pad, ABR-201008085.R1, Springfield Township, Bradford County, Pa.; Consumptive Use of Up to 4.999 mgd; Approval Date: April 22, 2015.

61. EOG Resources, Inc., Pad ID: GROSS 1H Pad, ABR-201008098.R1, Springfield Township, Bradford County, Pa.; Consumptive Use of Up to 4.999 mgd; Approval Date: April 22, 2015.

62. Seneca Resources Corporation, Pad ID: Wolfinger, ABR-20091229.R1, Shippen Township, Cameron County, Pa.; Consumptive Use of Up to 5.000 mgd; Approval Date: April 27, 2015.

63. SWN Production Company LLC, Pad ID: NR-25 NOWICKI, ABR-201504006, Oakland Township, Susquehanna County, Pa.; Consumptive Use of Up to 4.999 mgd; Approval Date: April 27, 2015.

64. SWN Production Company LLC, Pad ID: NR-05 BAC Realty, ABR-201504007, New Milford Township, Susquehanna County, Pa.; Consumptive Use of Up to 4.999 mgd; Approval Date: April 27, 2015.

65. Chesapeake Appalachia, LLC, Pad ID: Strobe, ABR-201007035.R1, Ulster Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 27, 2015.

66. Chesapeake Appalachia, LLC, Pad ID: Burleigh, ABR-201009067.R1, Wyalusing Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 27, 2015.

67. Chesapeake Appalachia, LLC, Pad ID: Foster, ABR-201009093.R1, Wysox Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 27, 2015.

68. Chesapeake Appalachia, LLC, Pad ID: Curtis New, ABR-201009100.R1, Asylum Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 27, 2015.

69. Seneca Resources Corporation, Pad ID: DCNR 595 Pad E, ABR-20100307.R1, Blossburg Borough, Tioga County, Pa.; Consumptive Use of Up to 4.000 mgd; Approval Date: April 29, 2015.

70. Seneca Resources Corporation, Pad ID: Wivell Pad 1, ABR-20100607.R1, Covington Township, Tioga County, Pa.; Consumptive Use of Up to 4.000 mgd; Approval Date: April 29, 2015.

71. Seneca Resources Corporation, Pad ID: Valldes Pad C, ABR-20100620.R1, Covington Township, Tioga County, Pa.; Consumptive Use of Up to 4.000 mgd; Approval Date: April 29, 2015.

72. Seneca Resources Corporation, Pad ID: Warren Pad B, ABR-20100621.R1, Richmond Township, Tioga County, Pa.; Consumptive Use of Up to 4.000 mgd; Approval Date: April 29, 2015.

73. Seneca Resources Corporation, Pad ID: Lehmann Pad K, ABR-201007115.R1, Covington Township, Tioga County, Pa.; Consumptive Use of Up to 4.000 mgd; Approval Date: April 29, 2015.

74. Seneca Resources Corporation, Pad ID: DCNR Tract 595 Pad I, ABR-201008043.R1, Bloss Township, Tioga County, Pa.; Consumptive Use of Up to 4.000 mgd; Approval Date: April 29, 2015.

75. Seneca Resources Corporation, Pad ID: DCNR Tract 595 Pad F, ABR-201008044.R1, Bloss Township, Tioga County, Pa.; Consumptive Use of Up to 4.000 mgd; Approval Date: April 29, 2015.

76. Seneca Resources Corporation, Pad ID: Covington Pad L, ABR-201008065.R1, Covington Township, Tioga County, Pa.; Consumptive Use of Up to 4.000 mgd; Approval Date: April 29, 2015.

77. Chesapeake Appalachia, LLC, Pad ID: Wygrala, ABR-201009072.R1, Wysox Township, Bradford County, Pa.; Consumptive Use of Up to 7.500 mgd; Approval Date: April 29, 2015.

Authority: Public Law 91-575, 84 Stat. 1509 *et seq.*, 18 CFR parts 806, 807, and 808.

Dated: May 15, 2015.

Andrew D. Dehoff,
Executive Director.

[FR Doc. 2015-12203 Filed 5-19-15; 8:45 am]

BILLING CODE 7040-01-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2015-27]

Petition for Exemption; Summary of Petition Received; The Boeing Company

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 June 9, 2015.

ADDRESSES: Send comments identified by docket number FAA-2015-0615 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: Sandra K. Long, 202-267-4714, 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 May 14, 2015.

Lirio Liu,

Director, Office of Rulemaking.

Petition for Exemption

Docket No.: FAA-2015-0615.

Petitioner: The Boeing Company.

Section(s) of 14 CFR Affected:

§§ 21.35(a), (b)(2) and (f)(2).

Description of Relief Sought: The petitioner seeks relief to accumulate additional flight test hours that represents the intended in-service aircraft configuration, capabilities, and operations after the approval of the 767-2C Amended Type Certificate. These additional flight test hours will add assurances that the 767-2C aircraft, its components and its equipment are reliable and function properly in accordance with § 21.35(b)(2). The exemption will allow relief from completing the required tests prior to issuance of the Type Certificate. This relief to defer testing will not exceed the aircraft initial entry into operational service.

[FR Doc. 2015-12114 Filed 5-19-15; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Notice of Intent To Release Airport Property From Quitclaim Deed; Fort Lauderdale Executive Airport, Fort Lauderdale, FL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Request for public comment.

SUMMARY: The FAA hereby provides notice of intent to release approximately 64.32 acres of airport property at Fort Lauderdale Executive Airport, Fort Lauderdale, FL, from the conditions, reservations, and restrictions as contained in a Quitclaim Deed agreement between the FAA and the City of Fort Lauderdale, FL, dated March 11, 1947. The release of property will allow the City of Fort Lauderdale to dispose of the property for other than aeronautical purposes. The property is

located within Tract 1 of F-X-E Plat (Parcels 19B, 25, 26 and 27) at the northwest corner of W. Commercial Boulevard (S.R. 870) and NW. 12th Avenue. The parcels are currently designated as non-aeronautical land use. The property will be released of its federal obligations for commercial land use. The fair market value of these parcels have been determined to be \$12,085,000.

DATES: Comments are due on or before June 19, 2015.

ADDRESSES: Documents are available for review at Fort Lauderdale Executive Airport, 6000 NW 21st Avenue, Fort Lauderdale, FL 33309; and the FAA Airports District Office, 5950 Hazeltine 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 Hazeltine National Drive, Suite 400, Orlando, FL 32822-5024. Documents reflecting the Sponsor's request are available for inspection by appointment only at Fort Lauderdale Executive Airport and by contacting the FAA at the address listed above.

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 May 14, 2015.

Bart Vernace,

Manager, Orlando Airports District Office, Southern Region.

[FR Doc. 2015-12260 Filed 5-19-15; 8:45 a.m.]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2013-0025]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew the exemptions from the vision requirement in the Federal Motor Carrier Safety Regulations for 19 individuals. FMCSA has statutory authority to exempt individuals from the vision requirement if the exemptions granted will not compromise safety. The Agency has concluded that granting these exemption renewals will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these commercial motor vehicle (CMV) drivers.

DATES: This decision is effective June 6, 2015. Comments must be received on or before June 19, 2015.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) numbers: Docket No. [Docket No. FMCSA-2013-0025], using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the on-line 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., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

- *Fax:* 1-202-493-2251.

Instructions: Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received without change to <http://www.regulations.gov>, including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or comments, go to <http://www.regulations.gov> at any time or Room W12-140 on the ground level of the West Building, 1200 New Jersey Avenue, SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at www.dot.gov/privacy.

FOR FURTHER INFORMATION CONTACT: Charles A. Horan, III, Director, Carrier, Driver and Vehicle Safety Standards, 202-366-4001, fmcsamedical@dot.gov, FMCSA, Department of Transportation, 1200 New Jersey Avenue, SE., Room W64-224, Washington, DC 20590-0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

I. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may renew an exemption from the vision requirements in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce, for a two-year period if it finds “such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption.” The procedures for requesting an exemption (including renewals) are set out in 49 CFR part 381.

II. Exemption Decision

This notice addresses 19 individuals who have requested renewal of their exemptions in accordance with FMCSA procedures. FMCSA has evaluated these 19 applications for renewal on their merits and decided to extend each exemption for a renewable two-year period. They are:

Glenn Blanton (OH), Matthew J. Buersken (MN), Mark E. Haukom (MN), Wesley D. Hogue (AR), Anthony Lang (NH), Jason C. Laub (NH), Edward J. Lavin (CT), Wayne D. Litwiller, Sr. (IL), James McClure (NC), Luther A. McKinney (VA), Steven J. McLain (TN), Enes Milanovic (MI), Donie L. Rhoads (MT), Leo D. Roy (NH), Steven Schaumberg (NJ), Merreo A. Stewart (MN), James B. Taflinger, Sr. (VA), Ronald W. Thompson (WI), Roy J. Ware (GA)

The exemptions are extended subject to the following conditions: (1) that each individual has a physical examination every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirements in 49 CFR 391.41(b)(10), and (b) by a medical examiner who attests that the individual is otherwise

physically qualified under 49 CFR 391.41; (2) that each individual provides a copy of the ophthalmologist’s or optometrist’s report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver’s qualification file and retains a copy of the certification on his/her person while driving for presentation to a duly authorized Federal, State, or local enforcement official. Each exemption will be valid for two years unless rescinded earlier by FMCSA. The exemption will be rescinded if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

III. Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than two years from its approval date and may be renewed upon application for additional two year periods. In accordance with 49 U.S.C. 31136(e) and 31315, each of the 19 applicants has satisfied the entry conditions for obtaining an exemption from the vision requirements (78 FR 20376; 78 FR 34141). Each of these 19 applicants has requested renewal of the exemption and has submitted evidence showing that the vision in the better eye continues to meet the requirement specified at 49 CFR 391.41(b)(10) and that the vision impairment is stable. In addition, a review of each record of safety while driving with the respective vision deficiencies over the past two years indicates each applicant continues to meet the vision exemption requirements.

These factors provide an adequate basis for predicting each driver’s ability to continue to drive safely in interstate commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of two years is likely to achieve a level of safety equal to that existing without the exemption.

IV. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this

notice (FMCSA-2013-0025), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov> and put the docket number, “FMCSA-2013-0025” in the “Keyword” box, and click “Search.” When the new screen appears, click on “Comment Now!” button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope. FMCSA will consider all comments and material received during the comment period and may change this notice based on your comments.

Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov> and in the search box insert the docket number, “FMCSA-2013-0025” in the “Keyword” box and click “Search.” Next, click “Open Docket Folder” button choose the document listed to review. If you do not have access to the Internet, you may view the docket online by visiting the Docket Management Facility in Room W12-140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE, Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

Issued on: May 11, 2015.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2015-12193 Filed 5-19-15; 8:45 am]

BILLING CODE 4910-EXP

DEPARTMENT OF TRANSPORTATION**Federal Motor Carrier Safety Administration**

[Docket No. FMCSA–2015–0024]

Parts and Accessories Necessary for Safe Operation; Virginia Tech Transportation Institute Exemption Application**AGENCY:** Federal Motor Carrier Safety Administration (FMCSA), DOT.**ACTION:** Notice of final disposition.

SUMMARY: The Federal Motor Carrier Safety Administration (FMCSA) announces its decision to grant Virginia Tech Transportation Institute's (VTTI) exemption application to allow the placement of camera-based data acquisition systems (DAS) at the bottom of windshields on commercial motor vehicles (CMVs). The Federal Motor Carrier Safety Regulations (FMCSRs) require antennas, transponders, and similar devices to be located not more than 6 inches below the upper edge of the windshield, outside the area swept by the windshield wipers, and outside the driver's sight lines to the road and highway signs and signals. As part of a National Highway Traffic Safety Administration (NHTSA) research program, VTTI is coordinating development and installation of the DASs in up to 150 CMVs. The exemption will enable VTTI and NHTSA to conduct research on the reliability of collision avoidance systems for CMVs. FMCSA believes that mounting the DASs at the bottom of the windshield would maintain a level of safety that is equivalent to, or greater than, the level of safety achieved without the exemption.

DATES: This exemption is effective May 20, 2015 and ends *May 20, 2017*.

FOR FURTHER INFORMATION CONTACT: Mr. Mike Huntley, Vehicle and Roadside Operations Division, Office of Carrier, Driver, and Vehicle Safety, MC–PSV, (202) 366–5370, Federal Motor Carrier Safety Administration, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.

ADDRESSES: For access to the docket to read background documents, including those referenced in this document, or to read comments received, go to:

- Regulations.gov, <http://www.regulations.gov>, at any time and insert FMCSA–2015–0024 in the “Keyword” box, and then click “Search.”
- Docket Management Facility, Room W12–140, DOT Building, 1200 New Jersey Ave. SE., Washington, DC 20590.

You may view the docket online by visiting the facility between 9 a.m. and 5 p.m., Monday through Friday except Federal holidays.

Viewing Comments and Documents

To view comments filed in this docket, go to <http://www.regulations.gov> and click on the “Read Comments” box in the upper right hand side of the screen. Then, in the “Keyword” box, insert “FMCSA–2015–0024” and click “Search.” Next, click “Open Docket Folder” in the “Actions” column. Finally, in the “Title” column, click on the document you would like to review. If you do not have access to the Internet, you may view the docket by visiting the Docket Management Facility at the address above.

Privacy Act

In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at www.dot.gov/privacy.

SUPPLEMENTARY INFORMATION:**Background**

FMCSA has authority under 49 U.S.C. 31136(e) and 31315 to grant exemptions from certain parts of the Federal Motor Carrier Safety Regulations. FMCSA must publish a notice of each exemption request in the **Federal Register** (49 CFR 381.315(a)). The Agency must provide the public an opportunity to inspect the information relevant to the application, including any safety analyses that have been conducted. The Agency must also provide an opportunity for public comment on the request.

The Agency reviews safety analyses and public comments submitted, and determines whether granting the exemption would likely achieve a level of safety equivalent to, or greater than, the level that would be achieved by compliance with the current regulation (49 CFR 381.305). The decision of the Agency must be published in the **Federal Register** (49 CFR 381.315(b)) with the reasons for denying or granting the application and, if granted, the name of the person or class of persons receiving the exemption, and the regulatory provision from which the exemption is granted. The notice must also specify the effective period and explain the terms and conditions of the exemption. The exemption may be renewed (49 CFR 381.300(b)).

VTTI's Application for Exemption

VTTI applied for an exemption from 49 CFR 393.60(e)(1) to allow the installation of DASs at the bottom of the windshield on CMVs (80 FR 8750, Feb. 18, 2015). A copy of the application is included in the docket referenced at the beginning of this notice.

Section 393.60(e)(1) of the FMCSRs prohibits the obstruction of the driver's field of view by devices mounted at the top of the windshield. Antennas, transponders and similar devices (devices) must not be mounted more than 152 mm (6 inches) below the upper edge of the windshield. These devices must be located outside the area swept by the windshield wipers and outside the driver's sight lines to the road and highway signs and signals.

VTTI applied for the exemption because it wants to install DASs in up to 150 CMVs operating throughout the United States in support of research being conducted on behalf of NHTSA. VTTI contends that it must be able to mount the DASs lower than allowed under 49 CFR 393.60(e)(1) “because the safety equipment must have a clear forward facing view of the road, and low enough to accurately scan facial features for detection of impaired driving.” VTTI wants to mount the DASs and necessary brackets at the bottom of the windshield, preferably 3 inches or less above of the bottom of the wiper sweep and out of the driver's sightlines to the road and highway signs and signals, to the extent practicable.

FMCSA Grant of Waiver to VTTI

Pursuant to 49 U.S.C. 31315(a) and 49 CFR part 381, subpart B, the FMCSA granted VTTI a 90-day waiver on January 26, 2015 to allow the placement of the DASs at the bottom of windshields on CMVs, outside of the area permitted by section 393.60 of the FMCSRs. This waiver is effective from January 26, 2015, through April 25, 2015. Up to 150 DASs have been installed in CMVs operated by 7 carriers.

During the waiver period, motor carriers participating in the NHTSA research program must ensure that the DASs are mounted within three inches of the bottom of the driver side windshield wiper sweep, and out of the driver's sightlines to the road and highway signs and signals as much as practicable. Vehicles participating in the study must carry a copy of the waiver in the vehicle. A copy of the FMCSA waiver letter to VTTI is included in the docket referenced at the beginning of this notice.

Comments

FMCSA published a notice of the exemption application in the **Federal Register** on February 18, 2015, and asked for public comment (80 FR 8750). No comments were received.

FMCSA Decision

The FMCSA has evaluated the VTTI exemption application. The Agency believes that granting the temporary exemption to allow the placement of the DASs and necessary mounting brackets at the bottom of the windshield, within and/or below 3 inches of the bottom of the windshield wiper sweep, will provide a level of safety that is equivalent to, or greater than the level of safety achieved without the exemption. FMCSA does not believe there will be any degradation in the safety performance of motor carriers utilizing the exemption during the 2-year exemption period because (1) there is nothing in available technical information to indicate that the DASs would obstruct drivers' views of the roadway, highway signs and surrounding traffic; (2) generally, trucks and buses have an elevated seating position which greatly improves the forward visual field of the driver, making any impairment of available sight lines minimal; and (3) the location three inches or less above the bottom of the driver's-side windshield wiper sweep, and out of the driver's sightline, is reasonable and enforceable at roadside. Without the exemption, NHTSA would be unable to test this innovative onboard safety monitoring system.

Terms and Conditions for the Exemption

The Agency hereby grants the exemption for a two-year period, beginning May 20, 2015 and ending *May 20, 2017*. During the temporary exemption period, up to 150 DASs may be installed in CMVs operated by the motor carriers listed below. These are the same carriers that have operated under the waiver:

1. USDOT #32052 Crosby Trucking Service Inc. in Mount Sydney, VA.
2. USDOT #369138 Rush Trucking Corporation in Wayne, MI.
3. USDOT #1977980 Kuperus Trucking Inc. in Jenison, MI.
4. USDOT #282628 Stagecoach Cartage and Distribution, LP in El Paso, TX.
5. USDOT #184405 J & M Tank Lines Inc. in Birmingham, AL.
6. USDOT #1243338 P&S Transportation LLC in Ensley, AL.
7. USDOT #75827 Modular Transport Company in Wyoming, MI.

These motor carriers must ensure that the DASs are mounted within and/or below 3 inches of the bottom of the driver side windshield wiper sweep, and out of the driver's sightlines to the road and highway signs and signals as much as practicable.

The exemption is valid for two years unless rescinded earlier by FMCSA. The exemption will be rescinded if (1) motor carriers and/or commercial motor vehicles fail to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315(b).

Interested parties possessing information that would demonstrate that motor carriers using the DASs are not achieving the requisite statutory level of safety should immediately notify FMCSA. The Agency will evaluate any such information and, if safety is being compromised or if the continuation of the exemption is not consistent with 49 U.S.C. 31136(e) and 31315(b), will take immediate steps to revoke the exemption.

Preemption

During the period the exemption is in effect, no State shall enforce any law or regulation that conflicts with or is inconsistent with this exemption with respect to a person operating under the exemption.

Issued on: May 5, 2015.

T.F. Scott Darling, III,
Chief Counsel.

[FR Doc. 2015-12199 Filed 5-19-15; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2014-0302]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of final disposition.

SUMMARY: FMCSA announces its decision to exempt 27 individuals from the vision requirement in the Federal Motor Carrier Safety Regulations (FMCSRs). They are unable to meet the vision requirement in one eye for various reasons. The exemptions will enable these individuals to operate commercial motor vehicles (CMVs) in interstate commerce without meeting

the prescribed vision requirement in one eye. The Agency has concluded that granting these exemptions will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these CMV drivers.

DATES: The exemptions were granted April 7, 2015. The exemptions expire on April 7, 2017.

FOR FURTHER INFORMATION CONTACT: Charles A. Horan, III, Director, Carrier, Driver and Vehicle Safety Standards, (202) 366-4001, fmcamedical@dot.gov, FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64-224, Washington, DC 20590-0001. Office hours are from 8:30 a.m. to 5 p.m., Monday through Friday, except Federal holidays. If you have questions on viewing or submitting material to the docket, contact Docket Services, telephone (202) 366-9826.

SUPPLEMENTARY INFORMATION:

I. Electronic Access

You may see all the comments online through the Federal Document Management System (FDMS) at <http://www.regulations.gov>.

Docket: For access to the docket to read background documents or comments, go to <http://www.regulations.gov> and/or Room W12-140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at www.dot.gov/privacy.

II. Background

On March 6, 2015, FMCSA published a notice of receipt of exemption applications from certain individuals, and requested comments from the public (80 FR 12248). That notice listed 27 applicants' case histories. The 27 individuals applied for exemptions from the vision requirement in 49 CFR 391.41(b)(10), for drivers who operate CMVs in interstate commerce.

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption for a 2-year period if it finds "such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption." The statute also

allows the Agency to renew exemptions at the end of the 2-year period. Accordingly, FMCSA has evaluated the 27 applications on their merits and made a determination to grant exemptions to each of them.

III. Vision and Driving Experience of the Applicants

The vision requirement in the FMCSRs provides:

A person is physically qualified to drive a commercial motor vehicle if that person has distant visual acuity of at least 20/40 (Snellen) in each eye without corrective lenses or visual acuity separately corrected to 20/40 (Snellen) or better with corrective lenses, distant binocular acuity of a least 20/40 (Snellen) in both eyes with or without corrective lenses, field of vision of at least 70° in the horizontal meridian in each eye, and the ability to recognize the colors of traffic signals and devices showing red, green, and amber (49 CFR 391.41(b)(10)).

FMCSA recognizes that some drivers do not meet the vision requirement but have adapted their driving to accommodate their vision limitation and demonstrated their ability to drive safely. The 27 exemption applicants listed in this notice are in this category. They are unable to meet the vision requirement in one eye for various reasons, including macular scar, globe laceration, retinal detachment, amblyopia, enucleation, cancerous choroid, Coats' Disease, macular degeneration, alternating esotropia, optic nerve atrophy, esotropia, degenerated optic nerve, refractive amblyopia, retinal scarring, full-thickness macular hole, Behcet's panuveities, primary open angle glaucoma, keratopathy, keratectomy, optic nerve compression, complete loss of vision, and retinal vascular occlusion. In most cases, their eye conditions were not recently developed. Fifteen of the applicants were either born with their vision impairments or have had them since childhood.

The twelve individuals that sustained their vision conditions as adults have had it for a range of five to 19 years.

Although each applicant has one eye which does not meet the vision requirement in 49 CFR 391.41(b)(10), each has at least 20/40 corrected vision in the other eye, and in a doctor's opinion, has sufficient vision to perform all the tasks necessary to operate a CMV. Doctors' opinions are supported by the applicants' possession of valid commercial driver's licenses (CDLs) or non-CDLs to operate CMVs. Before issuing CDLs, States subject drivers to knowledge and skills tests designed to

evaluate their qualifications to operate a CMV.

All of these applicants satisfied the testing requirements for their State of residence. By meeting State licensing requirements, the applicants demonstrated their ability to operate a CMV, with their limited vision, to the satisfaction of the State.

While possessing a valid CDL or non-CDL, these 27 drivers have been authorized to drive a CMV in intrastate commerce, even though their vision disqualified them from driving in interstate commerce. They have driven CMVs with their limited vision in careers ranging from four to 50 years. In the past three years, one of drivers was involved in a crash and one was convicted of a moving violation in a CMV.

The qualifications, experience, and medical condition of each applicant were stated and discussed in detail in the March 6, 2015 notice (80 FR 12248).

IV. Basis for Exemption Determination

Under 49 U.S.C. 31136(e) and 31315, FMCSA may grant an exemption from the vision requirement in 49 CFR 391.41(b)(10) if the exemption is likely to achieve an equivalent or greater level of safety than would be achieved without the exemption. Without the exemption, applicants will continue to be restricted to intrastate driving. With the exemption, applicants can drive in interstate commerce. Thus, our analysis focuses on whether an equal or greater level of safety is likely to be achieved by permitting each of these drivers to drive in interstate commerce as opposed to restricting him or her to driving in intrastate commerce.

To evaluate the effect of these exemptions on safety, FMCSA considered the medical reports about the applicants' vision as well as their driving records and experience with the vision deficiency.

To qualify for an exemption from the vision requirement, FMCSA requires a person to present verifiable evidence that he/she has driven a commercial vehicle safely with the vision deficiency for the past 3 years. Recent driving performance is especially important in evaluating future safety, according to several research studies designed to correlate past and future driving performance. Results of these studies support the principle that the best predictor of future performance by a driver is his/her past record of crashes and traffic violations. Copies of the studies may be found at Docket Number FMCSA-1998-3637.

FMCSA believes it can properly apply the principle to monocular drivers,

because data from the Federal Highway Administration's (FHWA) former waiver study program clearly demonstrate the driving performance of experienced monocular drivers in the program is better than that of all CMV drivers collectively (See 61 FR 13338, 13345, March 26, 1996). The fact that experienced monocular drivers demonstrated safe driving records in the waiver program supports a conclusion that other monocular drivers, meeting the same qualifying conditions as those required by the waiver program, are also likely to have adapted to their vision deficiency and will continue to operate safely.

The first major research correlating past and future performance was done in England by Greenwood and Yule in 1920. Subsequent studies, building on that model, concluded that crash rates for the same individual exposed to certain risks for two different time periods vary only slightly (See Bates and Neyman, University of California Publications in Statistics, April 1952). Other studies demonstrated theories of predicting crash proneness from crash history coupled with other factors. These factors—such as age, sex, geographic location, mileage driven and conviction history—are used every day by insurance companies and motor vehicle bureaus to predict the probability of an individual experiencing future crashes (See Weber, Donald C., "Accident Rate Potential: An Application of Multiple Regression Analysis of a Poisson Process," Journal of American Statistical Association, June 1971). A 1964 California Driver Record Study prepared by the California Department of Motor Vehicles concluded that the best overall crash predictor for both concurrent and nonconcurrent events is the number of single convictions. This study used 3 consecutive years of data, comparing the experiences of drivers in the first 2 years with their experiences in the final year.

Applying principles from these studies to the past 3-year record of the 27 applicants, one driver was involved in a crash, and one was convicted of a moving violation in a CMV. All the applicants achieved a record of safety while driving with their vision impairment, demonstrating the likelihood that they have adapted their driving skills to accommodate their condition. As the applicants' ample driving histories with their vision deficiencies are good predictors of future performance, FMCSA concludes their ability to drive safely can be projected into the future.

We believe that the applicants' intrastate driving experience and history

provide an adequate basis for predicting their ability to drive safely in interstate commerce. Intrastate driving, like interstate operations, involves substantial driving on highways on the interstate system and on other roads built to interstate standards. Moreover, driving in congested urban areas exposes the driver to more pedestrian and vehicular traffic than exists on interstate highways. Faster reaction to traffic and traffic signals is generally required because distances between them are more compact. These conditions tax visual capacity and driver response just as intensely as interstate driving conditions. The veteran drivers in this proceeding have operated CMVs safely under those conditions for at least 3 years, most for much longer. Their experience and driving records lead us to believe that each applicant is capable of operating in interstate commerce as safely as he/she has been performing in intrastate commerce. Consequently, FMCSA finds that exempting these applicants from the vision requirement in 49 CFR 391.41(b)(10) is likely to achieve a level of safety equal to that existing without the exemption. For this reason, the Agency is granting the exemptions for the 2-year period allowed by 49 U.S.C. 31136(e) and 31315 to the 27 applicants listed in the notice of March 6, 2015 (80 FR 12248).

We recognize that the vision of an applicant may change and affect his/her ability to operate a CMV as safely as in the past. As a condition of the exemption, therefore, FMCSA will impose requirements on the 27 individuals consistent with the grandfathering provisions applied to drivers who participated in the Agency's vision waiver program.

Those requirements are found at 49 CFR 391.64(b) and include the following: (1) That each individual be physically examined every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirement in 49 CFR 391.41(b)(10) and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provide a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file, or keep a copy in his/her driver's qualification file if he/she is self-employed. The driver must have a copy of the certification when driving, for presentation to a duly authorized

Federal, State, or local enforcement official.

V. Discussion of Comments

FMCSA received no comments in this proceeding.

IV. Conclusion

Based upon its evaluation of the 27 exemption applications, FMCSA exempts the following drivers from the vision requirement in 49 CFR 391.41(b)(10), subject to the requirements cited above (49 CFR 391.64(b)):

Joel C. Bailey (FL)
 Mackfie Bradley, Jr. (NC)
 Justin C. Bruchman (WI)
 Bradley J. Compton (ID)
 Anthony C. Curtis (WA)
 Douglas S. Dalling (PA)
 Lloyd A. Dornbusch (PA)
 Randall R. Drake (CA)
 Paul E. Emmons (RI)
 Thomas P. Fitzsimmons Jr. (NC)
 Steve L. Frisby (CA)
 Daryl G. Gibson (FL)
 Mark J. Goodrich (PA)
 Ramon L. Green (LA)
 Carl E. Hess (PA)
 Mark E. Jeans (OK)
 Chad Kauffman (PA)
 Scottie W. Lewis (GA)
 David S. Mayo (VA)
 Ross E. McCleary (NE)
 Alex D. McCrady (NH)
 Stacy L. Michael (OH)
 Charles A. Morgan (NC)
 Paul C. Swanson (IL)
 Terrance W. Temple (OH)
 Rick A. Tucker (MO)
 Jason R. White (OH)

In accordance with 49 U.S.C. 31136(e) and 31315, each exemption will be valid for 2 years unless revoked earlier by FMCSA. The exemption will be revoked if: (1) The person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136 and 31315.

If the exemption is still effective at the end of the 2-year period, the person may apply to FMCSA for a renewal under procedures in effect at that time.

Issued on: May 11, 2015.

Larry W. Minor,

Associate Administrator for Policy.

[FR Doc. 2015-12198 Filed 5-19-15; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Federal Motor Carrier Safety Administration

[Docket No. FMCSA-2003-14504; FMCSA-2005-20560; FMCSA-2007-27515]

Qualification of Drivers; Exemption Applications; Vision

AGENCY: Federal Motor Carrier Safety Administration (FMCSA), DOT.

ACTION: Notice of renewal of exemptions; request for comments.

SUMMARY: FMCSA announces its decision to renew the exemptions from the vision requirement in the Federal Motor Carrier Safety Regulations for 15 individuals. FMCSA has statutory authority to exempt individuals from the vision requirement if the exemptions granted will not compromise safety. The Agency has concluded that granting these exemption renewals will provide a level of safety that is equivalent to or greater than the level of safety maintained without the exemptions for these commercial motor vehicle (CMV) drivers.

DATES: This decision is effective June 13, 2015. Comments must be received on or before June 19, 2015.

ADDRESSES: You may submit comments bearing the Federal Docket Management System (FDMS) numbers: Docket No. [Docket No. FMCSA-2003-14504; FMCSA-2005-20560; FMCSA-2007-27515], using any of the following methods:

- *Federal eRulemaking Portal:* Go to <http://www.regulations.gov>. Follow the on-line 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., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal Holidays.

- *Fax:* 1-202-493-2251.

Instructions: Each submission must include the Agency name and the docket number for this notice. Note that DOT posts all comments received without change to <http://www.regulations.gov>, including any personal information included in a comment. Please see the Privacy Act heading below.

Docket: For access to the docket to read background documents or

comments, go to <http://www.regulations.gov> at any time or Room W12-140 on the ground level of the West Building, 1200 New Jersey Avenue SE., Washington, DC, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The Federal Docket Management System (FDMS) is available 24 hours each day, 365 days each year. If you want acknowledgment that we received your comments, please include a self-addressed, stamped envelope or postcard or print the acknowledgement page that appears after submitting comments on-line.

Privacy Act: In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its rulemaking process. DOT posts these comments, without edit, including any personal information the commenter provides, to www.regulations.gov, as described in the system of records notice (DOT/ALL-14 FDMS), which can be reviewed at

FOR FURTHER INFORMATION CONTACT:

Charles A. Horan, III, Director, Carrier, Driver and Vehicle Safety Standards, 202-366-4001, fmcsamedical@dot.gov, FMCSA, Department of Transportation, 1200 New Jersey Avenue SE., Room W64-224, Washington, DC 20590-0001. Office hours are from 8:30 a.m. to 5 p.m. Monday through Friday, except Federal holidays.

SUPPLEMENTARY INFORMATION:

I. Background

Under 49 U.S.C. 31136(e) and 31315, FMCSA may renew an exemption from the vision requirements in 49 CFR 391.41(b)(10), which applies to drivers of CMVs in interstate commerce, for a two-year period if it finds "such exemption would likely achieve a level of safety that is equivalent to or greater than the level that would be achieved absent such exemption." The procedures for requesting an exemption (including renewals) are set out in 49 CFR part 381.

II. Exemption Decision

This notice addresses 15 individuals who have requested renewal of their exemptions in accordance with FMCSA procedures. FMCSA has evaluated these 15 applications for renewal on their merits and decided to extend each exemption for a renewable two-year period. They are:

Roosevelt Bell, Jr. (NC), David K. Boswell (TN), Melvin M. Carter (WA), Bernabe V. Cerda (TX), Michael S. Crawford (IL), Rex A. Dyer (VT), Patrick J. Goebel (IA), Thomas A. Gotto (IA), Wilbur J. Johnson (VA), Kenneth C.

Reeves (OR), Charles J. Rowsey (NC), Thomas E. Summers, Sr. (OH), Jon C. Thompson (TX), Daniel E. Watkins (FL), Tommy N. Whitworth (TX).

The exemptions are extended subject to the following conditions: (1) that each individual has a physical examination every year (a) by an ophthalmologist or optometrist who attests that the vision in the better eye continues to meet the requirements in 49 CFR 391.41(b)(10), and (b) by a medical examiner who attests that the individual is otherwise physically qualified under 49 CFR 391.41; (2) that each individual provides a copy of the ophthalmologist's or optometrist's report to the medical examiner at the time of the annual medical examination; and (3) that each individual provide a copy of the annual medical certification to the employer for retention in the driver's qualification file and retains a copy of the certification on his/her person while driving for presentation to a duly authorized Federal, State, or local enforcement official. Each exemption will be valid for two years unless rescinded earlier by FMCSA. The exemption will be rescinded if: (1) the person fails to comply with the terms and conditions of the exemption; (2) the exemption has resulted in a lower level of safety than was maintained before it was granted; or (3) continuation of the exemption would not be consistent with the goals and objectives of 49 U.S.C. 31136(e) and 31315.

III. Basis for Renewing Exemptions

Under 49 U.S.C. 31315(b)(1), an exemption may be granted for no longer than two years from its approval date and may be renewed upon application for additional two year periods. In accordance with 49 U.S.C. 31136(e) and 31315, each of the 15 applicants has satisfied the entry conditions for obtaining an exemption from the vision requirements (68 FR 19598; 68 FR 33570; 70 FR 17504; 70 FR 25878; 70 FR 30997; 72 FR 21313; 72 FR 27624; 72 FR 28093; 72 FR 32703; 74 FR 23472; 76 FR 32017; 78 FR 32708). Each of these 15 applicants has requested renewal of the exemption and has submitted evidence showing that the vision in the better eye continues to meet the requirement specified at 49 CFR 391.41(b)(10) and that the vision impairment is stable. In addition, a review of each record of safety while driving with the respective vision deficiencies over the past two years indicates each applicant continues to meet the vision exemption requirements.

These factors provide an adequate basis for predicting each driver's ability to continue to drive safely in interstate

commerce. Therefore, FMCSA concludes that extending the exemption for each renewal applicant for a period of two years is likely to achieve a level of safety equal to that existing without the exemption.

IV. Public Participation and Request for Comments

FMCSA encourages you to participate by submitting comments and related materials.

Submitting Comments

If you submit a comment, please include the docket number for this notice (FMCSA-2003-14504; FMCSA-2005-20560; FMCSA-2007-27515), indicate the specific section of this document to which each comment applies, and provide a reason for each suggestion or recommendation. You may submit your comments and material online or by fax, mail, or hand delivery, but please use only one of these means. FMCSA recommends that you include your name and a mailing address, an email address, or a phone number in the body of your document so the Agency can contact you if it has questions regarding your submission.

To submit your comment online, go to <http://www.regulations.gov> and put the docket number, "FMCSA-2003-14504; FMCSA-2005-20560; FMCSA-2007-27515" in the "Keyword" box, and click "Search." When the new screen appears, click on "Comment Now!" button and type your comment into the text box in the following screen. Choose whether you are submitting your comment as an individual or on behalf of a third party and then submit. If you submit your comments by mail or hand delivery, submit them in an unbound format, no larger than 8½ by 11 inches, suitable for copying and electronic filing. If you submit comments by mail and would like to know that they reached the facility, please enclose a stamped, self-addressed postcard or envelope. FMCSA will consider all comments and material received during the comment period and may change this notice based on your comments.

Viewing Comments and Documents

To view comments, as well as any documents mentioned in this preamble as being available in the docket, go to <http://www.regulations.gov> and in the search box insert the docket number, "FMCSA-2003-14504; FMCSA-2005-20560; FMCSA-2007-27515" in the "Keyword" box and click "Search." Next, click "Open Docket Folder" button choose the document listed to review. If you do not have access to the Internet, you may view the docket

online by visiting the Docket Management Facility in Room W12-140 on the ground floor of the DOT West Building, 1200 New Jersey Avenue SE., Washington, DC 20590, between 9 a.m. and 5 p.m., e.t., Monday through Friday, except Federal holidays.

Issued on: May 11, 2015.

Larry W. Minor,

Associate Administration for Policy.

[FR Doc. 2015-12196 Filed 5-19-15; 8:45 am]

BILLING CODE 4910-EX-P

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Application for Special Permits

AGENCY: Office of Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration, (PHMSA), DOT.

ACTION: List of Applications for Special Permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations (49 CFR part 107, subpart B), notice is hereby given that the Office of Hazardous Materials Safety has received the application described herein. Each mode of transportation for which a particular special permit is requested is indicated by a number in the "Nature of Application" portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft.

DATES: Comments must be received on or before June 19, 2015.

Address Comments To: Record Center, Pipeline and Hazardous Materials Safety Administration, U.S.

Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION: Copies of the applications are available for inspection in the Records Center, East Building, PHH-30, 1200 New Jersey Avenue Southeast, Washington, DC or at <http://regulations.gov>.

This notice of receipt of applications for special permit is published in accordance with Part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on May 8, 2015.

Donald Burger,

Chief, General Approvals and Permits.

Application No.	Docket No.	Applicant	Regulation(s) affected	Nature of special permits thereof
16450-N	U.S. Department of Energy, Washington, DC.	49 CFR 173.242	To authorize the transportation in commerce of lithium hydride in alternative bulk packagings. (mode 1)
16452-N	The Procter & Gamble Company, Cincinnati, OH.	49 CFR parts 171-180	To authorize the transportation in commerce of small quantities of a Division 2.2 liquefied gas in small, non-refillable, plastic receptacles as not subject to the Hazardous Materials Regulations. (modes 1, 2, 3, 4, 5)
16460-N	Florida Power and Light Company, West Palm Beach, FL.	49 CFR 172.201(e)	To authorize the transportation in commerce of lithium ion batteries that are permanently mounted in small trailers without having to retain a record of each shipment made when using a "permanent shipping paper." (mode 1)
16461-N	Coastal Hydrotesting LLC, Baltimore, MD.	49 CFR 172.203(a), 172.301(c), 173.302a(b), 180.205.	To authorize the transportation in commerce of certain cylinders that have been tested using ultrasonic examination with visual external examination in lieu of hydrostatic testing and internal visual inspection. (modes 1, 2, 3, 4, 5)
16462-N	Helimax Aviation, Inc., McClellan, CA.	49 CFR 172.101 Hazardous Materials Table Column (9B), 172.200, 172.204(c)(3), 172.300, 172.400, 172.500, 175.30, part 17B.	To authorize the transportation in commerce of certain hazardous materials by 14 CFR part 133 Rotorcraft External Load Operations transporting hazardous materials attached to or suspended from an aircraft without being subject to certain hazard communication requirements, quantity limitations and certain loading and stowage requirements. (mode 4)
16469-N	ACS UE Testing LLC, Denver, CO.	49 CFR 172.203(a), 172.301(c), 180.205.	To authorize the transportation in commerce of certain cylinders that have been tested using ultrasonic examination with visual external examination in lieu of hydrostatic testing and internal visual inspection. (modes 1,2)

[FR Doc. 2015-11817 Filed 5-19-15; 8:45 am]

BILLING CODE 4909-60-M

DEPARTMENT OF TRANSPORTATION

Pipeline and Hazardous Materials Safety Administration

Hazardous Materials: Notice of Application for Modification of Special Permit

AGENCY: Office of Hazardous Materials Safety, Pipeline and Hazardous Materials Safety Administration (PHMSA), DOT.

ACTION: List of Application for Modification of Special Permits.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, special permits from the Department of Transportation's Hazardous Material Regulations (49 CFR part 107, subpart

B), notice is hereby given that the Office of Hazardous Materials Safety has received the applications described herein. This notice is abbreviated to expedite docketing and public notice. Because the sections affected, modes of transportation, and the nature of application have been shown in earlier **Federal Register** publications, they are not repeated here. Requests for modification of special permits (e.g. to provide for additional hazardous materials, packaging design changes, additional mode of transportation, etc.) are described in footnotes to the application number. Application numbers with the suffix "M" denote a modification request. These applications have been separated from the new application for special permits to facilitate processing.

DATES: Comments must be received on or before June 4, 2015.

Address Comments To: Record Center, Pipeline and Hazardous

Materials Safety Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the special permit number.

FOR FURTHER INFORMATION CONTACT:

Copies of the applications are available for inspection in the Records Center, East Building, PHH-30, 1200 New Jersey Avenue Southeast, Washington, DC or at <http://regulations.gov>.

This notice of receipt of applications for modification of special permit is published in accordance with Part 107 of the Federal hazardous materials transportation law (49 U.S.C. 5117(b); 49 CFR 1.53(b)).

Issued in Washington, DC, on May 7, 2015.

Daniel Burger,

Chief, General Approvals and Permits.

MODIFICATION SPECIAL PERMITS

Application No.	Docket No.	Applicant	Regulation(s) affected	Nature of special permits thereof
8757-M	Milton Roy Company, Ivyland, PA.	49 CFR 173.302(a)(1); 173.304(a)(1); 175.3; 173.304(b)(1); 178.42.	To modify the special permit to authorize additional hazardous materials.
10232-M	ITW Sexton, Decatur, AL ..	49 CFR 173.304(d) and 173.306(a)(3).	To modify the special permit to authorize an additional hazardous material and limited quantity authorized.
11666-M	SGL Carbon, LLC (SGL), Charlotte, NC.	49 CFR 173.240(b)	To modify the special permit to authorize green graphite products being shipped on open flat-bed trailers to be secured with plastic bandings.
12092-M	KMR Industries, LLC, Columbia, MD.	49 CFR 173.34(e)	To modify the special permit to authorize DOT specification 48W240 or 4BW260 cylinder closed by plugs or flanges to authorize up to 1,000 pounds water capacity.
12929-M	Matheson Tri-Gas, Inc., Basking Ridge, NJ.	49 CFR 173.301(j)(1)	To modify the special permit to replace the work instructions for DOT specification cylinders manufactured with foreign specification charged for export only.
14848-M	Corning Incorporated, Corning, NY.	49 CFR 172.202, 172.301, 172.400, 172.504 and 177.834(h).	To modify the special permit to consolidate DOT-SP 14848 and DOT-SP 1427 to a single special permit.

MODIFICATION SPECIAL PERMITS

Application No.	Docket No.	Applicant	Regulation(s) affected	Nature of special permits thereof
14849-M	Call2Recycle, Inc. Atlanta, GA.	49 CFR 172.200, 172.300, 172.400.	To modify the special permit to authorize dry cell alkaline batteries up to 12 volts in combination with any other used or spent batteries rated greater than 9-volts in the same package.
16333-M	Liberty Industrial Gases & Welding Supply Inc. Brooklyn, NY.	49 CFR 171.2(3) and 177.801.	To modify the special permit originally issued on an emergency basis to authorize an additional two years.

[FR Doc. 2015-11825 Filed 5-19-15; 8:45 am]

BILLING CODE 4909-60-M

DEPARTMENT OF THE TREASURY

Submission for OMB Review; Comment Request

AGENCY: Department of the Treasury.

ACTION: Notice.

SUMMARY: 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 June 19, 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 and (2) Treasury PRA Clearance Officer, 1750 Pennsylvania Ave. NW., Suite 8140, Washington, DC 20220, or email at PRA@treasury.gov.

FOR FURTHER INFORMATION CONTACT: Copies of the submission may be obtained by emailing PRA@treasury.gov, calling (202) 927-5331, or viewing the entire information collection request at www.reginfo.gov.

SUPPLEMENTARY INFORMATION:

Bureau of the Fiscal Service (FS)

OMB Number: 1530-0031.

Type of Review: Revision of a currently approved collection.

Title: Application by Voluntary Guardian of Incapacitated Owner of United States Savings Bonds/Notes.

Form: FS Form 2513.

Abstract: Used by voluntary guardian of incapacitated bond owner(s) to establish right to act of behalf of owner.

Affected Public: Individuals or Households.

Estimated Annual Burden Hours: 333.

Dated: May 14, 2015.

Dawn D. Wolfgang,

Treasury PRA Clearance Officer.

[FR Doc. 2015-12151 Filed 5-19-15; 8:45 am]

BILLING CODE 4810-AS-P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900-0018]

Proposed Information Collection (Application for Accreditation as Service Organization Representative) Activity: Comment Request

AGENCY: Office of General Counsel, Department of Veterans Affairs.

ACTION: Notice.

SUMMARY: The Office of General Counsel (OGC), 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. This notice solicits comments on information needed to determine accredited service organization representatives' qualifications to represent claimants before VA.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before July 20, 2015.

ADDRESSES: Submit written comments on the collection of information through www.Regulations.gov or to Dana Raffaelli, Office of the General Counsel (0220), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420 or email to dana.raffaelli2@va.gov. Please refer to "OMB Control No. 2900-0018" in any correspondence. During the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at www.Regulations.gov.

FOR FURTHER INFORMATION CONTACT: Dana Raffaelli at (202) 461-7699 or FAX (202) 273-6404.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104-13; 44 U.S.C. 3501-3521), 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, OGC invites comments on: (1) Whether the proposed collection of information is necessary for the proper performance of OGC's functions, including whether the information will have practical utility;

(2) the accuracy of OGC'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: Application for Accreditation as Service Organization Representative, VA Form 21; Accreditation Cancellation Information.

OMB Control Number: 2900-0018.

Type of Review: Revision of a currently approved collection and modification to the collection.

Abstract: Service organizations are required to file an application with VA to establish eligibility for accreditation for representatives of that organization to represent benefit claimants before VA. VA Form 21 is completed by service organizations to establish accreditation for representatives, recertify the qualifications of accredited representatives.

Organizations requesting cancellation of a representative's accreditation based on misconduct or incompetence or resignation to avoid cancellation of accreditation based upon misconduct or incompetence, are required to inform VA of the specific reason for the cancellation request. VA will use the information collected to determine whether service organizations representatives continue to meet regulatory eligibility requirements to ensure claimants have qualified representatives to assist in the preparation, presentation and prosecution of their claims for benefits. VA is modifying the collection to include an optional request to permit the organization to provide an email address and phone number in which the representative may be reached. VA believes that the additional contact information pertaining to the organization will be helpful in that it provides an additional means of communication between VA and the organization as well as provides an additional way that Veterans and their family may contact the representative. The organization may choose to provide a general phone number and email address for the organization, e.g., tampa@vso.com, or the representative's individual email address through the organization and direct phone number, e.g., johnsmith@vso.com. VA does not anticipate the modification request will result in an additional burden. VA believes that the organizations already have the information available to them,

and adding that information to the form should not take additional time. This is supported by the fact that many organizations are already providing the additional contact information. Finally, this request will be optional.

Affected Public: Not-for profit institutions.

Estimated Annual Burden: 782 hours.

Estimated Average Burden Per Respondent: 15 minutes for new applicants, 10 minutes for recertification, and 30 minutes for accreditation cancellation information responses.

Frequency of Response: On occasion.

Estimated Number of Respondents: 3,157 (2962 new applicants, 170 recertification, and 25 accreditation cancellation information responses).

By direction of the Secretary.

Crystal Rennie,

Department Clearance Officer, Department of Veterans Affairs.

[FR Doc. 2015-12212 Filed 5-19-15; 8:45 am]

BILLING CODE 8320-01-P

DEPARTMENT OF VETERANS AFFAIRS

[OMB Control No. 2900—NEW]

Proposed Information Collection (Awards & ROI) Activity: Comment Request

AGENCY: Office of Small and Disadvantaged Business Utilization (OSDBU), The Department of Veterans Affairs (VA).

ACTION: Notice.

SUMMARY: VA OSDBU 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 new collection of information and allow 60 days for public comment in response to the notice. This notice solicits comments on information needed to (1) determine the return on investment (ROI) provided by the National Veterans Small Business Engagement (NVSBE) to the Department of Veterans Affairs (VA), other Federal agencies, and small and large business attendees, (2) have a mechanism that allows to share ROI and satisfaction levels with potential attendees in order to make informed decisions regarding their participation in future NVSBEs.

DATES: Written comments and recommendations on the proposed collection of information should be received on or before July 20, 2015.

ADDRESSES: Submit written comments on the collection of information through Federal Docket Management System (FDMS) at www.Regulations.gov or to Milagros Ortiz, OSDBU, (OOSB) or email to: milagros.ortiz@va.gov. Please refer to “OMB Control No. 2900—NEW (Awards & ROI)” in any correspondence. During the comment period, comments may be viewed online through FDMS.

FOR FURTHER INFORMATION CONTACT: Milagros Ortiz (202) 461-4279 or Fax (202) 461-4301.

SUPPLEMENTARY INFORMATION: Under the PRA of 1995 (Pub. L. 104-13; 44 U.S.C. 3501-3521), 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, OMB invites comments on: (1) Whether the proposed

collection of information is necessary for the proper performance of OMB's functions, including whether the information will have practical utility; (2) the accuracy of OMB'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: Awards & ROI.

OMB Control Number: 2900—NEW.

Type of Review: New collection.

Abstract: The Office of Small and Disadvantaged Business Utilization (OSDBU) needs to measure the return on investment received by attendees of the 2014 National Veteran Small Business Engagement. This will be determined by the incidence of federal and commercial contracts and sub-contracts received by large and small business as result of their participation at this event, and the benefits received by connecting with decision makers during the engagement.

Affected Public: Small and large business representatives that attended the NVSBE.

Estimated Annual Burden: 40 hours.

Estimated Average Burden per Respondent: 3 minutes.

Frequency of Response: Once a year, 6 months after the NVSBE.

Estimated Number of Respondents: 800 per year.

By direction of the Secretary.

Crystal Rennie,

Department Clearance Officer, Department of Veterans Affairs.

[FR Doc. 2015-12201 Filed 5-19-15; 8:45 am]

BILLING CODE 8320-01-P



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Part II

Department of Commerce

National Oceanic and Atmospheric Administration

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Seismic Surveys in Cook Inlet, Alaska; Notices

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration**

RIN 0648–XD830

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Seismic Surveys in Cook Inlet, Alaska

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

ACTION: Notice; issuance of an incidental harassment authorization.

SUMMARY: NMFS is issuing an Incidental Harassment Authorization in response to a request from SAExploration Inc. (SAE) for authorization to take marine mammals incidental to an oil and gas exploration seismic survey program in Cook Inlet, Alaska between May 13, 2015 and May 12, 2016.

DATES: *Effective:* May 13, 2015 through May 12, 2016.

ADDRESSES: Electronic copies of the IHA, application, and associated Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) may be obtained by writing to Jolie Harrison, Division Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East West Highway, Silver Spring, MD 20910, telephoning the contact listed below (see **FOR FURTHER INFORMATION CONTACT**), or visiting the internet at: <http://www.nmfs.noaa.gov/pr/permits/incidental.htm>. Documents cited in this notice may also be viewed, by appointment, during regular business hours, at the aforementioned address.

FOR FURTHER INFORMATION CONTACT: Sara Young, Office of Protected Resources, NMFS, (301) 427–8401.

SUPPLEMENTARY INFORMATION:**Background**

Sections 101(a)(5)(A) and (D) of the MMPA (16 U.S.C. 1361 *et seq.*) direct the Secretary of Commerce to allow, upon request, the incidental, but not intentional, taking of small numbers of marine mammals by U.S. citizens who engage in a specified activity (other than commercial fishing) within a specified geographical region if certain findings are made and either regulations are issued or, if the taking is limited to harassment, a notice of a proposed authorization is provided to the public for review.

An authorization for incidental takings shall be granted if NMFS finds

that the taking will have a negligible impact on the species or stock(s), will not have an unmitigable adverse impact on the availability of the species or stock(s) for subsistence uses (where relevant), and if the permissible methods of taking and requirements pertaining to the mitigation, monitoring and reporting of such takings are set forth. NMFS has defined “negligible impact” in 50 CFR 216.103 as “an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival.”

Except with respect to certain activities not pertinent here, the MMPA defines “harassment” as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild [Level A harassment]; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment].

Summary of Request

On October 28, 2014, we received a request from SAE for authorization to take marine mammals incidental to seismic surveys in Cook Inlet, Alaska. After further correspondence and revisions by the applicant, we determined that the application was adequate and complete on January 12, 2015. On March 20, 2015, NMFS published a notice in the **Federal Register** of our proposal to issue an IHA with preliminary determinations (80 FR 14913). The filing of the notice initiated a 30-day public comment period. The comments and our responses are discussed later in this document.

SAE proposes to conduct oil and gas exploration seismic surveys. The activity will occur between May 13, 2015 and May 12, 2016, for a period of 160 days. The following specific aspects of the activity are likely to result in the take of marine mammals: Operation of seismic airguns in arrays of 440 in³ and 1,760 in³. Take, by Level B Harassment only, of individuals of beluga whale, humpback whale, minke whale, gray whale, harbor porpoise, Dall’s porpoise, killer whale, harbor seal, and Steller sea lion is anticipated to result from the specified activity.

Description of the Specified Activity*Overview*

SAE plans to conduct 3D seismic surveys over multiple years in the marine waters of both upper and lower Cook Inlet. This authorization will cover activities occurring between May 13, 2015 and May 12, 2016. The ultimate survey area is divided into two units (upper and lower Cook Inlet). The total potential survey area is 3,934 square kilometers (1,519 square miles); however, only a portion (currently unspecified) of this area will ultimately be surveyed, and no more than 777 square kilometers (300 square miles) in a given year. The exact location of where the 2015 survey will be conducted is not known at this time, and probably will not be known until late spring 2015 when SAE’s clients have finalized their data acquisition needs.

The components of the project include laying recording sensors (nodes) on the ocean floor, operating seismic source vessels towing active air gun arrays, and retrieval of nodes. There will also be additional boat activity associated with crew transfer, recording support, and additional monitoring for marine mammals. The primary seismic source for offshore recording consists of a 2 × 880-cubic-inch tri-cluster array for a total of 1,760-cubic-inches (although a 440-cubic-inch array may be used in very shallow water locations as necessary). Each of the arrays will be deployed in a configuration outlined in Appendix A of the application. The arrays will be centered approximately 15 meters (50 feet) behind the source vessel stern, at a depth of 4 meters (12 feet), and towed along predetermined source lines at speeds between 7.4 and 9.3 kilometers per hour (4 and 5 knots). Two vessels with full arrays will be operating simultaneously in an alternating shot mode; one vessel shooting while the other is recharging. Shot intervals are expected to be about 16 seconds for each array resulting in an overall shot interval of 8 seconds considering the two alternating arrays. Operations are expected to occur 24 hours a day, with actual daily shooting to total about 12 hours. An acoustical positioning (or pinger) system will be used to position and interpolate the location of the nodes. A vessel-mounted transceiver calculates the position of the nodes by measuring the range and bearing from the transceiver to a small acoustic transponder fitted to every third node. The transceiver uses sonar to interrogate the transponders, which respond with short pulses that are used in measuring the range and bearing.

Several offshore vessels will be required to support recording, shooting, and housing in the marine and transition zone environments. Exact vessels to be used have not been determined.

Dates and Duration

The request for incidental harassment authorization is primarily for the 2015 Cook Inlet open water season. The plan is to conduct seismic surveys in the Upper Cook unit sometime between May 13, 2015 through May 12, 2016. The northern border of the seismic survey area depicted in Figure 1 takes into account the restriction that no activity occur between April 15 to October 15 in waters within 16 kilometers (10 miles) of the Susitna Delta (defined as the nearshore area between the mouths of the Beluga and the Little Susitna rivers). A small wedge of the upper Cook unit falls within 16 kilometers of the Beluga River mouth, but survey here will occur after October 15, taking into account any timing restrictions with nearshore beluga habitat. The seismic acquisition in lower Cook unit will initially begin in late August or mid-September, and run until December 15 taking into account any self-imposed location/timing restrictions to avoid encounters with sea otters or Steller's eiders. The exact survey dates in a given unit will depend on ice conditions, timing restrictions, and other factors. If the upper Cook Inlet seismic surveys are delayed by spring ice conditions, some survey may occur in lower Cook Inlet from March to May to maximize use of the seismic fleet. Actual data acquisition is expected to occur for only 2 to 3 hours at a time during each of the 3 to 4 daily slack tides. Thus, it is expected that the air guns will operate an average of about 8 to 10 total hours per day. It is estimated that it will take 160 days to complete both the upper and lower Cook units, and that no more than 777 square kilometers (300 square miles) of survey area will be shot in 2015.

Specified Geographic Region

The area of Cook Inlet that SAE plans to operate in has been divided into two subsections: Upper and Lower Cook Inlet. Upper Cook (2,126 square kilometers; 821 square miles) begins at the line delineating Cook Inlet beluga whale (*Delphinapterus leucas*) Critical Habitat Area 1 and 2, south to a line approximately 10 kilometers (6 miles) south of both the Lower Cook (1,808 square kilometer; 698 square mile) begins east of Kalgin Island and running along the east side of lower Cook Inlet to Anchor Point (Figure 2 in SAE application).

Detailed Description of Activities

The Notice of Proposed IHA (80 FR 14913, March 20, 2015) contains a full detailed description of the 3D seismic survey, including the recording system, sensor positioning, and seismic source. That information has not changed and is therefore not repeated here.

Comments and Responses

A Notice of Proposed IHA was published in the **Federal Register** on March 20, 2015 (80 FR 14913) for public comment. During the 30-day public comment period, NMFS received four comment letters from the following: The Natural Resource Defense Council (NRDC); the Marine Mammal Commission (MMC); Furie Operating Alaska LLC (Furie); and one private citizen.

All of the public comment letters received on the Notice of Proposed IHA (80 FR 14913, March 20, 2015) are available on the internet at: <http://www.nmfs.noaa.gov/pr/permits/incidental.htm>. Following is a summary of the public comments and NMFS' responses.

Comment 1: One private citizen requested that we deny issuance of the IHA because marine mammals would be killed as a result of the survey.

Response: Extensive analysis of the proposed 3D seismic survey was conducted in accordance with the MMPA, Endangered Species Act (ESA), and National Environmental Policy Act (NEPA). Pursuant to those statutes, we analyzed the impacts to marine mammals (including those listed as threatened or endangered under the ESA), their habitat (including critical habitat designated under the ESA), and to the availability of marine mammals for taking for subsistence uses. The MMPA analyses revealed that the activities would have a negligible impact on affected marine mammal species or stocks and would not have an unmitigable adverse impact on the availability of marine mammals for taking for subsistence uses. The ESA analysis concluded that the activities likely would not jeopardize the continued existence of ESA-listed species or destroy or adversely modify designated critical habitat. The NEPA analysis concluded that there would not be a significant impact on the human environment. Moreover, this activity is not expected to result in the death of any marine mammal species, and no such take is authorized.

Comment 2: Furie supports issuance of this IHA in a timely manner and urges NMFS to recognize the benefits of seismic surveys and subsequent development of energy resources.

Response: After careful evaluation of all comments and the data and information available regarding potential impacts to marine mammals and their habitat and to the availability of marine mammals for subsistence uses, NMFS has issued the final authorization to SAE to take marine mammals incidental to conducting a 3D seismic survey program in Cook Inlet for the period May 13, 2015 through May 12, 2016.

Comment 3: The MMC recommends that NMFS defer issuance of the IHA until such time as NMFS can, with reasonable confidence, support a conclusion that the activities would affect no more than a small number of Cook Inlet beluga whales and have no more than a negligible impact on the population. The MMC recommends that NMFS defer issuance until we have better information on the cause or causes of ongoing decline of the population and a reasonable basis for determining that authorizing additional takes would not contribute to or exacerbate that decline. The MMC continues to believe that any activity that may contribute to or that may worsen the observed decline should not be viewed as having a negligible impact on the population. The NRDC states that NMFS failed to meet both the "small numbers" and "negligible impact" standards.

Response: In accordance with our implementing regulations at 50 CFR 216.104(c), we use the best available scientific evidence to determine whether the taking by the specified activity within the specified geographic region will have a negligible impact on the species or stock and will not have an unmitigable adverse impact on the availability of such species or stock for subsistence uses. Based on the scientific evidence available, NMFS determined that the impacts of the 3D seismic survey program, which are primarily acoustic in nature, would meet these standards. Moreover, SAE proposed and NMFS has required in the IHA a rigorous mitigation plan to reduce impacts to Cook Inlet beluga whales and other marine mammals to the lowest level practicable, including measures to power down or shutdown airguns if any beluga whale is observed approaching or within the Level B harassment zone and restricting activities within a 10 mi (16 km) radius of the Susitna Delta from April 15 through October 15, which is an important area for beluga feeding and calving in the spring and summer months. This shutdown measure is more restrictive than the standard shutdown measures typically applied, and combined with the Susitna Delta

exclusion (minimizing adverse effects to foraging), is expected to reduce both the scope and severity of potential harassment takes, ensuring that there are no energetic impacts from the harassment that would adversely affect reproductive rates or survivorship.

Our analysis indicates that issuance of this IHA will not contribute to or worsen the observed decline of the Cook Inlet beluga whale population. Additionally, the ESA Biological Opinion determined that the issuance of an IHA is not likely to jeopardize the continued existence of the Cook Inlet beluga whales or the western distinct population segment of Steller sea lions or destroy or adversely modify Cook Inlet beluga whale critical habitat. The Biological Opinion also outlined Terms and Conditions and Reasonable and Prudent Measures to reduce impacts, which have been incorporated into the IHA. Therefore, based on the analysis of potential effects, the parameters of the seismic survey, and the rigorous mitigation and monitoring program, NMFS determined that the activity would have a negligible impact on the population.

Moreover, the seismic survey would take only small numbers of marine mammals relative to their population sizes. The number of belugas likely to be taken represent less than 9.6% of the population. As described in the proposed IHA **Federal Register** notice, NMFS used a method that incorporates density of marine mammals overlaid with the anticipated ensonified area to calculate an estimated number of takes for belugas, which was estimated to be less than 10% of the stock abundance, which NMFS considers small. In addition to this quantitative evaluation, NMFS has also considered qualitative factors that further support the "small numbers" determination, including: (1) The seasonal distribution and habitat use patterns of Cook Inlet beluga whales, which suggest that for much of the time only a small portion of the population would be accessible to impacts from SAE's activity, as most animals are concentrated in upper Cook Inlet; and (2) the mitigation requirements, which provide spatio-temporal limitations that avoid impacts to large numbers of animals feeding and calving in the Susitna Delta and limit exposures to sound levels associated with Level B harassment. Based on all of this information, NMFS determined that the number of beluga whales likely to be taken is small. See response to Comment 5 and our small numbers analysis later in this document for more information about the small numbers

determination for beluga whales and the other marine mammal species.

Comment 4: The MMC recommends that NMFS develop a policy that sets forth clear criteria and/or thresholds for determining what constitutes "small numbers" and "negligible impact" for the purpose of authorizing incidental takes of marine mammals. The MMC understands that NMFS has been working on developing a policy and would welcome an opportunity to discuss this policy further before it is finalized.

Response: NMFS is in the process of developing both a clearer policy to outline the criteria for determining what constitutes "small numbers" and an improved analytical framework for determining whether an activity will have a "negligible impact" for the purpose of authorizing takes of marine mammals. We fully intend to engage the MMC in these processes at the appropriate time.

Comment 5: The NRDC pointed by reference to the other proposed activities in Cook Inlet during the 2015 open water season. The NRDC and the MMC both note that NMFS must address the cumulative effects of activities in Cook Inlet on Cook Inlet beluga whales and whether the cumulative impacts of all the activities are having "either individually or in combination" a greater than negligible impact on marine mammals.

Response: Neither the MMPA nor NMFS' implementing regulations specify how to consider other activities and their impacts on the same populations when conducting a negligible impact analysis. However, consistent with the 1989 preamble for NMFS' implementing regulations (54 FR 40338, September 29, 1989), the impacts from other past and ongoing anthropogenic activities are incorporated into the negligible impact analysis via their impacts on the environmental baseline (*e.g.*, as reflected in the density/distribution and status of the species, population size and growth rate, and ambient noise).

In addition, cumulative effects were addressed in the EA and Biological Opinion prepared for this action. The cumulative effects section of the EA has been expanded from the draft EA to discuss potential effects in greater detail. These documents, as well as the Alaska Marine Stock Assessments and the most recent abundance estimate for Cook Inlet beluga whales (Shelden *et al.*, 2015, are part of NMFS' Administrative Record for this action, and provided the decision maker with information regarding other activities in the action area that affect marine

mammals, an analysis of cumulative impacts, and other information relevant to the determination made under the MMPA.

Comment 6: The NRDC states that NMFS failed to account for survey duration in the estimation of beluga whale takes and that NMFS based beluga takes using a predictive habitat density model (Goetz *et al.*, 2012) that is based on data from summer months and confined to summer distribution when belugas are generally concentrated in the Upper Inlet, even though activity could occur year round.

Response: The numerical estimation of take for beluga whales does consider survey duration in the calculation. The Goetz *et al.* 2012 model is the best available data for beluga density in Cook Inlet. The method used by NMFS to estimate take uses the best available data to most accurately estimate the number of belugas taken. This is done by multiplying the density of the area surveyed on a given day by the area ensonified on that day of surveying to yield the number of belugas that were likely exposed during that day of surveying. This is then added to the next day of surveying and so forth in an additive model until the number of 30 belugas is reached. If the number of 30 belugas is reached using this calculation before SAE has completed their 160 days of proposed surveying, survey activity must cease. Additionally, if they finish their 160 days without reaching the limit of 30 belugas their activity must still cease. The model, by being additive in nature for each day of surveying, accounts for the duration of the survey, as well as capturing a more specific density value than using an Inlet-wide density estimate.

Moreover, the model (or other numerical methods for estimating take) does not take into consideration the rigorous mitigation protocols that will be implemented by SAE to reduce the number of actual Level B harassment takes of Cook Inlet beluga whales. As mentioned previously, the IHA contains a condition restricting SAE's airgun operations within 10 mi (16 km) of the mean higher high water line of the Susitna Delta from April 15 through October 15. During this time, a significant portion of the Cook Inlet beluga whale population occurs in this area for feeding and calving. This setback distance includes the entire 160 dB radius of 5.9 mi (9.5 km) predicted for the full airgun array plus an additional 4.1 mi (6.5 km) of buffer, thus reducing the number of animals that may be exposed to Level B harassment thresholds. SAE is also required to shut down the airguns if any beluga whale is

sighted approaching or entering the Level B harassment zone to avoid take. NMFS combined use of the National Marine Mammal Laboratory (NMML) model, which we determined to be the best available data upon which to base density estimates, with consideration of all of the mitigation measures required to be implemented to authorize 30 beluga whale takes. This approach is reasonable and does not contradict available science and data of beluga whale distribution and local abundance during the period of operations.

Comment 7: The NRDC states that in the case of marine mammals other than beluga whales, NMFS repeated past errors associated with its use of raw NMML survey data. Errors in the density calculations include the failure to incorporate correction factors for missed marine mammals in the analysis and the failure to fully account for survey duration by multiplying densities (which are calculated on an hourly basis) by the number of survey days but not the number of hours in a day.

Response: Correction factors for marine mammal surveys, with the exception of beluga whales, are not available for Cook Inlet. The primary purpose and focus of the NMFS aerial surveys in Cook Inlet for the past decade has been to monitor the beluga whale population. Although incidental observations of other marine mammals are noted during these surveys, they are focused on beluga whales. With the exception of the beluga whale, no detailed statistical analysis of Cook Inlet marine mammal survey results has been conducted, and no correction factors have been developed for Cook Inlet marine mammals. The only published Cook Inlet correction factor is for beluga whales. Developing correction factors for other marine mammals would have required different survey data collection and consideration of unavailable data such as Cook Inlet sight ability, movement patterns, tidal correlations and detailed statistical analyses. For example, other marine mammal numbers are often rounded to the nearest 10 or 100 during the NMFS aerial survey; resulting in unknown observation bias. Therefore, the data from the NMFS surveys are the best available and number of animals taken are still likely overestimated because of the assumption that there is a 100% turnover rate of marine mammals each day.

Survey duration was appropriately considered in the estimations by multiplying density by area of ensonification by number of survey days. NMFS does not calculate takes on

an hourly basis, and, additionally, the multiple hours surveyed within a day are reflected in the area of ensonification, which considers the distance they can move within a day and is therefore larger than what would be covered in one hour. Additionally, as NMFS has used the density estimate from NMFS aerial surveys, multiplied by the area ensonified per day, multiplied by the number of days, this calculation produces the number instances of exposure during the survey. This is likely an overestimate of individuals taken by Level B harassment, as a single individual can be exposed on multiple days over the course of the survey, especially when a small patch of area is shot over a duration of five days. While protected species observers (PSOs) cannot detect every single animal within the Level B harassment zone, monitoring reports from similar activities indicate that sightings did not exceed anticipated estimates.

Comment 8: The NRDC commented that NMFS underestimated the size of SAE's impact area by: (1) Using an outdated and incorrect threshold for behavioral take; and (2) disregarding the best available evidence on the potential for temporary and permanent threshold shift on mid- and high-frequency cetaceans and on pinnipeds.

Response: The comment that NMFS uses an outdated and incorrect threshold for behavioral takes does not include any specific recommendations. NMFS uses 160 dB (rms) as the exposure level for estimating Level B harassment takes for most species in most cases. This threshold was established for underwater impulse sound sources based on measured avoidance responses observed in whales in the wild. Specifically, the 160 dB threshold was derived from data for mother-calf pairs of migrating gray whales (Malme *et al.*, 1983, 1984) and bowhead whales (Richardson *et al.*, 1985, 1986) responding to seismic airguns (*e.g.*, impulsive sound source). We acknowledge there is more recent information bearing on behavioral reactions to seismic airguns, but those data only illustrate how complex and context-dependent the relationship is between the two. See 75 FR 49710, 49716 (August 13, 2010) (IHA for Shell seismic survey in Alaska). Accordingly, it is not a matter of merely replacing the existing threshold with a new one. NOAA is working to develop more sophisticated draft guidance for determining impacts from acoustic sources, including information for determining Level B harassment thresholds. Due to the complexity of the

task, any guidance will require a rigorous review that includes internal agency review, public notice and comment, and additional external peer review before any final product is published. In the meantime, and taking into consideration the facts and available science, NMFS determined it is reasonable to use the 160 dB threshold for estimating takes of marine mammals in Cook Inlet by Level B harassment. However, we discuss the science on this issue qualitatively in our analysis of potential effects to marine mammals.

The comment that NMFS disregarded the best available evidence on the potential for temporary and permanent threshold shift on mid- and high-frequency cetaceans and on pinnipeds does not contain any specific recommendations. We acknowledge there is more recent information available bearing on the relevant exposure levels for assessing temporary and permanent hearing impacts. (See NMFS' **Federal Register** notice (78 FR 78822, December 27, 2013) for NMFS' draft guidance for assessing the onset of permanent and temporary threshold shift.) Again, NMFS will be issuing guidance, but that process is not complete, so we did not use it to assign new thresholds for calculating take estimates for hearing impacts. However, we did consider the information, and it suggests the current 180 and 190 dB thresholds are appropriate and that they likely overestimate potential for hearing impacts. See 75 FR 49710, 49715, 49724 (August 13, 2010) (IHA for Shell seismic survey in Alaska; responses to comment 8 and comment 27). Moreover, the required mitigation is designed to ensure there are no exposures at levels thought to cause hearing impairment, and, for several of the marine mammal species in the project area, mitigation measures are designed to reduce or eliminate exposure to Level B harassment thresholds.

Comment 9: The NRDC comments that the proposed mitigation measures fail to meet the MMPA's "least practicable adverse impact" standard. The NRDC provides a list of approximately eight measures that NMFS "failed to consider or adequately consider."

Response: NMFS provided a detailed discussion of proposed mitigation measures and the MMPA's "least practicable impact" standard in the notice of the proposed IHA (80 FR 14913, March 20, 2015), which are repeated in the "Mitigation" section of this notice. The measures that NMFS allegedly failed to consider or

adequately consider are identified and discussed below:

(1) Field testing and use of alternative technologies, such as vibroseis and gravity gradiometry, to reduce or eliminate the need for airguns and delaying seismic acquisition in higher density areas until the alternative technology of marine vibroseis becomes available: SAE requested takes of marine mammals incidental to the seismic survey operations described in the IHA application, which identified airgun arrays as the technique SAE would employ to acquire seismic data. It would be inappropriate for NMFS to change the specified activity and it is beyond the scope of the request for takes incidental to SAE's operation of airguns and other active acoustic sources.

SAE knows of no current technology scaled for industrial use that is reliable enough to meet the environmental challenges of operating in Cook Inlet. SAE is aware that many prototypes are currently in development, and may ultimately incorporate these new technologies into their evaluation process as they enter commercial viability. However, none of these technologies are currently ready for use on a large scale in Cook Inlet. As this technology is developed, SAE will evaluate its utility for operations in the Cook Inlet environment.

(2) Required use of the lowest practicable source level in conducting airgun activity: SAE determined that the 1760 in³ array provides the data required for SAE's operations.

(3) Seasonal exclusions around river mouths, including early spring (pre-April 14) exclusions around the Beluga River and Susitna Delta, and avoidance of other areas that have a higher probability of beluga occurrence: NMFS has required a 10 mile (16 km) exclusion zone around the Susitna Delta (which includes the Beluga River) in this IHA. This mitigation mirrors a measure in the Incidental Take Statement for the 2012 and 2013 Biological Opinions. Seismic survey operations involving the use of airguns will be prohibited in this area between April 15 and October 15. In both the MMPA and ESA analysis, NMFS determined that this date range is sufficient to protect Cook Inlet beluga whales and the critical habitat in the Susitna Delta. While data indicate that belugas may use this part of the inlet year round, peak use occurs from early May to late September. NMFS added a 2-week buffer on both ends of this peak usage period to add extra protection to feeding and calving belugas. (In addition, the Alaska Department of Fish and Game (ADF&G) prohibits the use of

airguns within 1 mi (1.6 km) of the mouth of any stream listed by the ADF&G on the Catalogue of Waters Important for the Spawning, Rearing, or Migration of Anadromous Fishes. See additional explanation in "Mitigation Measures Considered but not Required" section, later in this document.)

(4) Limitation of the mitigation airgun to the longest shot interval necessary to carry out its intended purpose: This general comment contained no specific recommendations. SAE requires shot intervals of 50m at a speed of 4–5 knots to obtain the information from their survey. However NMFS has added a mitigation measure that SAE reduce the shot interval for the mitigation gun to one shot per minute.

(5) Immediate suspension of airgun activity, pending investigation, if any beluga strandings occur within or within an appropriate distance of the survey area. The IHA requires SAE to immediately cease activities and report unauthorized takes of marine mammals, such as live stranding, injury, serious injury, or mortality. NMFS will review the circumstances of SAE's unauthorized take and determine if additional mitigation measures are needed before activities can resume to minimize the likelihood of further unauthorized take and to ensure MMPA compliance. SAE may not resume activities until notified by NMFS. Separately the IHA includes measures if injured or dead marine mammals are sighted and the cause cannot be easily determined. In those cases, NMFS will review the circumstances of the stranding event while SAE continues with operations.

(6) Establishment of a larger exclusion zone for beluga whales that is not predicated on the detection of whale aggregations or cow-calf pairs: Both the proposed IHA notice and the issued IHA contain a requirement for SAE to delay the start of airgun use or shutdown the airguns if a beluga whale is visually sighted or detected by passive acoustic monitoring approaching or within the 160-dB disturbance zone until the animal(s) are no longer present within the 160-dB zone. The measure applies to the sighting of any beluga whale, not just sightings of groups or cow-calf pairs.

Comment 10: The MMC suggests additional mitigation measures are used including: (1) Aerial surveys, (2) passive acoustic monitoring, as well as (3) a 30 minute post-activity monitoring period.

Response: NMFS provided a detailed discussion of proposed mitigation measures and the MMPA's "least practicable impact" standard in the notice of the proposed IHA (80 FR

14913, March 20, 2015), which are repeated in the "Mitigation" section of this notice. The measures that NMFS allegedly failed to consider or adequately consider are identified and discussed below:

(1) Use of advance aerial surveys to redirect activity is not required for this action. Aerial surveys for this project could be used for monitoring the disturbance zone to the 160dB level (6.83 km). However, exposures that occur in this zone, or Level B takes, are already accounted for in the take estimation section below. Visual observers, which are already known to be effective in this environment, will adhere to strict standards for preventing animals from entering the 180dB/190dB injury exclusion zone, as well as monitoring for animals that may be traveling in the direction of or approaching the injury exclusion zone. The prohibitive cost of daily aerial surveys for a survey area of only 777km², combined with the limited added value given the general effectiveness of vessel and land-based observers, and considering the fact that we believe that the activity will have a negligible impact even in the absence of mitigation make the suite of mitigation measures we have included adequate to achieve the least practicable adverse impact.

(2) The passive acoustic monitoring plan for Apache Alaska Corporation's 2012 survey anticipated the use of a bottom-mounted telemetry buoy to broadcast acoustic measurements using a radio-system link back to a monitoring vessel. Although a buoy was deployed during the first week of surveying under the 2012 IHA, it was not successful. Upon deployment, the buoy immediately turned upside down due to the strong current in Cook Inlet. After retrieval, the buoy was not redeployed and the survey used a single omnidirectional hydrophone lowered from the side of the mitigation vessel. During the entire 2012 survey season, Apache's PAM equipment yielded only six confirmed marine mammal detections, one of which was a Cook Inlet beluga whale. The single Cook Inlet beluga whale detection did not, however, result in a shutdown procedure.

Additionally, Joint Base Elmendorf-Fort Richardson, the National Marine Mammal Laboratory, and Alaska Department of Fish & Game conducted a 2012 study (Gillespie *et al.*, 2013) to determine if beluga whale observations at the mouth of Eagle River corresponded with acoustic detections received by a PAMBuoy data collection system. The PAMBuoy data collection system was deployed in the mouth of

Eagle River from 12–31 August 2012. This study was a trial period conducted with one hydrophone at the mouth of the river. Overall, it was successful in detecting beluga whale echolocation clicks and whistles, but came with several limitations:

- The PAM system was able to reliably detect all whales approaching or entering the river but still performs less well than a human observer;
- Sounds from vessels in Cook Inlet (e.g. vessel noise) have a large chance of interfering with detections from PAM. The mouth of Eagle River has very little vessel traffic, which is likely why the study was successful there and not likely to be successful in Cook Inlet;
- PAMBouys could be a navigational hazard in Cook Inlet for commercial, subsistence, and sport fishing, as well as the commercial vessel traffic traveling through Cook Inlet;
- The limited testing in a very small area should not become the new standard of monitoring in the entire Cook Inlet. The tide, vessel traffic, bathymetry, and substrate of Cook Inlet are far more complex than the study area;
- It appears the hydrophone must be hardwired to the shore which is not practical for mobile marine seismic operations;
- Currently, deployment of the system is done by walking tripods onto the mudflats. This is not feasible for the vast majority of the SAE project area. Walking onto the mudflats in parts of Cook Inlet also poses a safety risk;
- The study found considerable investment would be necessary to develop an ice and debris proof mounting system. Other issues with hydrophone configuration include: At extreme low tides, the hydrophone was uncovered and therefore not usable; the hydrophone had to be located in such a position so that it could be occasionally visually inspected; hydrophone battery supply has to constantly be checked; the costs and practicalities of long-term hydrophone mounting and data transmission have not been determined.; and only one hydrophone was tested, and SAE would need several hydrophones;
- Observer sightings and acoustic detections of belugas generally corresponded with one another. Thus PAMBouys would be simply duplicating PSO and aerial efforts;
- The wireless modem that transmits the acoustic data to the “base station” was only tested to 3.2 km; and
- The study did not conclude anything about the detection range of the system, except that it was greater than 400 m.

NMFS has been made aware of an over-the-side hydrophone that has successfully detected belugas in Eagle River, Alaska. Upon beginning operations, SAE has 30 days to acquire a hydrophone that covers a frequency range of 0.1–160 kHz to allow detecting both social and echolocation signals, with a system sensitivity in the range – 165 to – 185 dB re 1 V/μPa, and floor noise spectra similar to Beaufort Sea State 0. SAE will use this hydrophone during nighttime ramp-ups from the mitigation airgun to detect beluga whales, humpbacks, and Steller sea lions that may be within the 160dB disturbance zone.

(3) A post-activity monitoring period of 30 minutes has been added as a requirement for this activity. This monitoring period after the cessation of airgun operations can provide useful observations to compare the behavior and abundance of animals during different scenarios of various noise levels. This change has been noted in the Authorization text.

Comment 11: The MMC notes that NMFS is reviewing two other IHA applications for proposed seismic surveys in Cook Inlet in 2015 and that it is not clear whether these applications are seeking separate authorizations for some or all of the same activities. NMFS needs to adopt policies and institute procedures to ensure that separate applications to conduct essentially the same activities in the same areas are considered more holistically. If indeed the applicants are proposing to conduct multiple seismic surveys within the same area, it would increase the numbers of marine mammals taken and expose beluga whales and other marine mammals to unnecessary, avoidable risks. Section 101(a)(5)(D)(ii)(I) of the MMPA directs NMFS to structure IHAs so that they prescribe “other means of effecting the least practicable impact on such species or stock and its habitat.” Allowing multiple operators to obtain separate IHAs to conduct duplicative surveys is inconsistent with that mandate. Data sharing and collaboration is critical in habitat areas used by endangered populations, such as Cook Inlet beluga whales. The MMC recommends that NMFS encourage SAE and other applicants proposing to conduct seismic surveys in Cook Inlet in 2015 to collaborate on those surveys and, to the extent possible, submit a single application seeking authorization for incidental harassment of marine mammals.

In a similar comment, the NRDC expressed concern over the number of activities proposed in the same area for the same season referencing

applications for: Furie, Bluecrest, Buccaneer, and Apache.

Response: We agree and have encouraged SAE to cooperate with other interested parties to minimize the impacts of new seismic surveys in the region. Apache has told NMFS that their proposed activities are a separate project to that of SAE. Currently, SAE works with other oil and gas operators in the area to enter into cooperative agreements. Sometimes these negotiations are successful, but at other times the companies cannot reach an agreement acceptable to both parties. SAE will continue its discussions with other operators in Cook Inlet to find opportunities to joint venture in oil and gas operations, including seismic data acquisition.

The portion of the statute cited by the MMC refers to the need to require mitigation measures to ensure that the specified activity for which take is authorized in that particular authorization “effects the least practicable impact.” SAE proposed and NMFS has required a rigorous mitigation and monitoring plan to ensure that SAE’s program meets that standard. Moreover, NMFS will not issue IHAs to other applicants if the negligible impact standard cannot be met.

Lastly, there are no applications being processed for Furie or Buccaneer. Apache does not anticipate conducting seismic activity in the 2015 season. Additionally, the activities proposed by Bluecrest are not seismic surveys and in a far southerly portion of the Inlet, with no overlap with SAE’s activities.

Comment 12: Both the NRDC and the MMC comment that authorization should not be issued until the Cook Inlet Beluga Whale Take Recovery Plan is finalized and published.

Response: The Cook Inlet Beluga Whale Recovery Plan is still under development and will not be available in time to authorize activities for the 2015 open water season. It is possible the Recovery Plan will be available for next season. It is not necessary to have the Recovery Plan finalized to authorize SAE’s activity, as NMFS is still able to make a negligible impact determination for beluga whales.

Comment 13: The MMC comments that various applicants in the Cook Inlet region have used differing density estimates for calculating take of marine mammal species in the Inlet and that all applicants should use the same densities.

Response: The density estimates used by SAE specifically for harbor porpoises, harbor seals, and killer whales are the best available science at

this time. The data are from NMFS aerial surveys over a ten year period (2000–2012). NMFS is working with applicants to incorporate these density estimates into future applications and take authorizations. However, where applicable, density estimates and derived take estimation may vary based on site-specific knowledge of abundance, density, seasonality, or other qualities that could allow for a more nuanced assessment of the presence of a particular stock in a given location.

Comment 14: The MMC also comments that in the application, SAE states it will only survey in an area of 777km² but that the proposed action area is much larger. The MMC requests that SAE specify the area in which they expect to operate so that take estimations more accurately reflect the scope of the project.

Response: Due to the nature of SAE's work, contracts are awarded throughout the season and the exact locations of operation are not known to SAE at the time of the application. However, SAE has provided how much area they plan to survey and NMFS has calculated take estimation using the number of survey days requested and daily ensonified area to calculate take instead of the 777km² unique area specified in the application to ensure a robust calculation of exposures to the 160dB level.

Comment 15: The MMC comments that SAE should be required to investigate and report on detection probabilities from various observation platforms for differing sea states and light conditions.

Response: NMFS acknowledges that collecting detection probabilities from various platforms under different conditions would be very useful information and could better inform monitoring reports by discerning how many animals were likely taken. However, constructing a study to investigate detection probabilities requires a great deal of planning and many more observers than are involved in this survey. NMFS would like to work with the MMC in the future to discuss how best to conduct this work and refine detection probabilities for seismic surveys.

Comment 16: The NRDC comments on several issues under NEPA, related to cumulative effects and the suite of alternatives. These comments are: (1) NEPA mandates that NMFS may not authorize activities while a programmatic EIS is underway; (2) The No Action alternative must assume SAE will not conduct the proposed activity; and (3) The third alternative with

additional mitigation measures is not sufficiently analyzed and defined.

Response: The NEPA analysis is an important component of our process. Our responses to the issues raised by the NRDC are as follows:

(1) The regulatory text referenced by NRDC in their comments, 40 CFR 1506.1, states that "While work on a required program environmental impact statement is in progress and the action is not covered by an existing program statement, agencies shall not undertake in the interim any major Federal action covered by the program which may significantly affect the quality of the human environment." NRDC is likely referencing NMFS' **Federal Register** Notice of Intent to Prepare an EIS for Cook Inlet (79 FR 61616; October 14, 2014). That provision is not applicable here as NMFS' decision to prepare an EIS is not required, but rather voluntary. The programmatic EIS is meant to address hypothetical increasing future levels of activity in Cook Inlet, not a specific proposed project. Lastly, the regulatory text references activities that are expected to have a significant impact on the human environment, and NMFS has determined that this activity will not have such an impact, as specified in the Finding of No Significant Impact (FONSI). At this time, NMFS is evaluating each activity individually, taking into consideration cumulative impacts, with an EA, to determine if the action under consideration can support a FONSI.

(2) The No Action alternative in NMFS' draft EA for this activity was written to reflect a situation in which NMFS did not authorize the activity and the survey went forward without mitigation and monitoring. However, after further consideration, NMFS has decided to modify the No Action alternative to represent a situation in which NMFS did not issue an authorization and the applicant did not conduct their proposed activity. These changes are reflected in the Final EA.

(3) The third alternative in the EA is a scenario that includes all of the mitigation measures of the preferred alternative, as well as additional cutting edge technologies that have been suggested by commenters in previous authorizations, including NRDC. However, this alternative does not contain the more detailed analysis requested by NRDC because many of the included technologies are not viable at this time. Many are still in the developmental or preliminary testing phase, or do not currently have guidelines pertaining to appropriate operating conditions around marine mammals, such as unmanned aerial

vehicles. The No Action alternative and the Preferred alternative both contain more in-depth analyses as appropriate.

Comment 17: The NRDC comments that the dates in the proposed IHA suggest a curtailing of public review in violation of the Administrative Procedure Act.

Response: The date provided in the proposed IHA was the date proposed by the applicant originally for this work. Due to the time required to analyze and respond to comments sufficiently, this date was postponed and the authorization will be effective on: May 13, 2015.

Comment 18: The MMC comments that the use of a 2.5 turnover factor in take estimation of harbor seals is inappropriate. The MMC requests that NMFS use the same density \times daily ensonified area \times number of days formula used for the other species. The MMC also notes that if NMFS uses a turnover factor that it should consult the literature to create a more biologically relevant turnover factor than Wood *et al.* 2012.

Response: After reviewing the Commission's comment, NMFS decided to adjust the method used to estimate take for harbor seals in Cook Inlet. The daily ensonified area \times number of survey days \times density method yields an estimate of instances of take that is 19,315. Not only is this likely an overestimate of instances, but it is also significantly higher than the number of individual harbor seals expected to be exposed, as described in more details in the Estimated Take section. NMFS applied the survey method used by SAE, patch shooting, and applied the number of days required to shoot a patch to estimate the number of days an animal at a given haulout could be exposed. This is an average of 3 days, but no more than 5. When this factor is applied to the overestimate of exposures by using the ensonified daily area method, the number of exposed seals is much lower, at 6,438. This number may be reduced even further as individuals could be exposed at multiple patches. Separately, NMFS then considered the harbor seal densities alongside monitoring reports from Apache's work in 2012. NMFS looked at the monitoring reports from Apache's aerial surveys in June and used correction factors from the literature to determine the number of seals in the water. This number was also multiplied to match the number of SAE's proposed survey days (160) to yield a number of 8,250 instances of take, notably lower than 19,315. Additionally, in their 147 days of surveying, Apache reported sightings of 285 seals. While it is understood that

this is lower than the actual number of exposures, as all seals in the 160dB range are not visible, this number is 131 times smaller than the calculated number of exposures using the daily ensonified area method. These methods are discussed in greater detail in the Takes Estimation section of this document, but in summary we concluded that not more than 25% of the population of harbor seals would be taken.

Description of Marine Mammals in the Area of the Specified Activity

Marine mammals most likely to be found in the upper Cook activity area are the beluga whale (*Delphinapterus leucas*), harbor porpoise (*Phocoena*

phocoena), and harbor seal (*Phoca vitulina*). However, these species are found there in low numbers, and generally only during the summer fish runs (Nemeth *et al.* 2007, Boveng *et al.* 2012). These species are also found in the Lower Cook Inlet survey area along with humpback whales (*Megaptera novaeangliae*), minke whales (*Balaenoptera acutorostra*), gray whales (*Eschrichtius robustus*), killer whales (*Orcinus orca*), Dall’s porpoise (*Phocoenoides dalli*), and Steller sea lions (*Eumetopia jubatus*). Minke whales have been considered migratory in Alaska (Allen and Angliss, 2014) but have recently been observed off Cape Starichkof and Anchor Point year-round

(Owl Ridge, 2014). Humpback and gray whales are seasonal in Lower Cook, while the remaining species could be encountered at any time of the year. During marine mammal monitoring conducted off Cape Starichkof between May and August 2013, observers recorded small numbers of humpback whales, minke whales, gray whales, killer whales, and Steller sea lions, and moderate numbers of harbor porpoises and harbor seals (Owl Ridge, 2014). This survey also recorded a single beluga observed 6 kilometers north of Cape Starichkof in August 2013. The stock sizes for marine mammals found in the project area in Cook Inlet are shown in Table 1.

TABLE 1—MARINE MAMMALS INHABITING THE COOK INLET ACTION AREA

Species	Stock	ESA/MMPA status ¹ ; Strategic (Y/N)	Stock abundance (CV, N _{min} , most recent abundance survey) ²	Relative occurrence in Cook Inlet; season of occurrence
Humpback whale	Central North Pacific.	E/D;Y	7,469 (0.095; 5,833; 2000)	Occasionally seen in Lower Inlet, summer.
Minke whale	Alaska	;;N	1,233 (0.034; N/A; 2003)	Infrequently occur but reported year-round.
Gray whale	Eastern North Pacific.	;;N	19,126 (0.071; 18,017; 2007)	Rare migratory visitor; late winter.
Killer whale	Alaska Resident	;;N	2,347 (N/A; 2,084; 2009)	Occasionally sighted in Lower Cook Inlet.
Beluga whale	Alaska Transient	;;N	345 (N/A; 303; 2003).	Use upper Inlet in summer and lower in winter: annual.
	Cook Inlet	E/D;Y	312 (0.10; 280; 2012)	
Harbor porpoise	Gulf of Alaska	;;Y	31,046 (0.214; 25,987; 1998)	Widespread in the Inlet: annual (less in winter).
Dall’s porpoise	Alaska	Infrequently found in Lower Inlet.
Steller sea lion	Western DPS	E/D;Y	79,300 (N/A; 45,659; 2012)	Primarily found in lower Inlet.
Harbor seal	Cook Inlet/Shelikof	;;N	22,900 (0.053; 21,896; 2006)	Frequently found in upper and lower inlet; annual (more in northern Inlet in summer).

Source: Allen and Angliss (2014, 2013), Carretta *et al.* (2013), Zerbini *et al.* (2006)

Humpback Whale (Megaptera novaeangliae)

Although there is considerable distributional overlap in the humpback whale stocks that use Alaska, the whales seasonally found in lower Cook Inlet are probably of the Central North Pacific stock. Listed as endangered under the Endangered Species Act (ESA), this stock has recently been estimated at 7,469, with the portion of the stock that feeds in the Gulf of Alaska estimated at 2,845 animals (Allen and Angliss 2014). The Central North Pacific stock winters in Hawaii and summers from British Columbia to the Aleutian Islands (Calambokidis *et al.* 1997), including Cook Inlet.

Humpback use of Cook Inlet is largely confined to lower Cook Inlet. They have been regularly seen near Kachemak Bay during the summer months (Rugh *et al.* 2005a), and there is a whale-watching

venture in Homer capitalizing on this seasonal event. There are anecdotal observations of humpback whales as far north as Anchor Point, with recent summer observations extending to Cape Starichkof (Owl Ridge 2014). Humpbacks might be encountered in the vicinity of Anchor Point if seismic operations were to occur off the point during the summer. However, SAE plans, for the most part, to limit seismic activity along the Kenai Peninsula to during the spring and fall.

Minke Whale (Balaenoptera acutorostra)

Minke whales are the smallest of the rorqual group of baleen whales reaching lengths of up to 35 feet. They are also the most common of the baleen whales, although there are no population estimates for the North Pacific, although estimates have been made for some portions of Alaska. Zerbini *et al.* (2006)

estimated the coastal population between Kenai Fjords and the Aleutian Islands at 1,233 animals.

During Cook Inlet-wide aerial surveys conducted from 1993 to 2004, minke whales were encountered only twice (1998, 1999), both times off Anchor Point 16 miles northwest of Homer. A minke whale was also reported off Cape Starichkof in 2011 (A. Holmes, pers. comm.) and 2013 (E. Fernandez and C. Hesselbach, pers. comm.), suggesting this location is regularly used by minke whales, including during the winter. Recently, several minke whales were recorded off Cape Starichkof in early summer 2013 during exploratory drilling conducted there (Owl Ridge 2014). There are no records north of Cape Starichkof, and this species is unlikely to be seen in upper Cook Inlet. There is a chance of encountering this

whale during seismic operations along the Kenai Peninsula in lower Cook Inlet.

Gray Whale (Eschrichtius robustus)

Each spring, the Eastern North Pacific stock of gray whale migrates 8,000 kilometers (5,000 miles) northward from breeding lagoons in Baja California to feeding grounds in the Bering and Chukchi seas, reversing their travel again in the fall (Rice and Wolman 1971). Their migration route is for the most part coastal until they reach the feeding grounds. A small portion of whales do not annually complete the full circuit, as small numbers can be found in the summer feeding along the Oregon, Washington, British Columbia, and Alaskan coasts (Rice *et al.* 1984, Moore *et al.* 2007).

Human exploitation reduced this stock to an estimated “few thousand” animals (Jones and Schwartz 2002). However, by the late 1980s, the stock was appearing to reach carrying capacity and estimated to be at 26,600 animals (Jones and Schwartz 2002). By 2002, that stock had been reduced to about 16,000 animals, especially following unusually high mortality events in 1999 and 2000 (Allen and Angliss 2014). The stock has continued to grow since then and is currently estimated at 19,126 animals with a minimum estimate of 18,017 (Carretta *et al.* 2013). Most gray whales migrate past the mouth of Cook Inlet to and from northern feeding grounds. However, small numbers of summering gray whales have been noted by fisherman near Kachemak Bay and north of Anchor Point. Further, summering gray whales were seen offshore of Cape Starichkof by marine mammal observers monitoring Buccaneer’s Cosmopolitan drilling program in 2013 (Owl Ridge 2014). Regardless, gray whales are not expected to be encountered in upper Cook Inlet, where there are no records, but might be encountered during seismic operations along the Kenai Peninsula south of Ninilchik. However, seismic surveys are not planned in this region during the summer months when gray whales are most expected.

Beluga Whale (Delphinapterus leucas)

The Cook Inlet beluga whale Distinct Population Segment (DPS) is a small geographically isolated population that is separated from other beluga populations by the Alaska Peninsula. The population is genetically (mtDNA) distinct from other Alaska populations suggesting the Peninsula is an effective barrier to genetic exchange (O’Corry-Crowe *et al.* 1997) and that these whales may have been separated from other stocks at least since the last ice age.

Laidre *et al.* (2000) examined data from more than 20 marine mammal surveys conducted in the northern Gulf of Alaska and found that sightings of belugas outside Cook Inlet were exceedingly rare, and these were composed of a few stragglers from the Cook Inlet DPS observed at Kodiak Island, Prince William Sound, and Yakutat Bay. Several marine mammal surveys specific to Cook Inlet (Laidre *et al.* 2000, Speckman and Piatt 2000), including those that concentrated on beluga whales (Rugh *et al.* 2000, 2005a), clearly indicate that this stock largely confines itself to Cook Inlet. There is no indication that these whales make forays into the Bering Sea where they might intermix with other Alaskan stocks.

The Cook Inlet beluga DPS was originally estimated at 1,300 whales in 1979 (Calkins 1989) and has been the focus of management concerns since experiencing a dramatic decline in the 1990s. Between 1994 and 1998 the stock declined 47 percent which was attributed to overharvesting by subsistence hunting. Subsistence hunting was estimated to annually remove 10 to 15 percent of the population during this period. Only five belugas have been harvested since 1999, yet the population has continued to decline, with the most recent estimate at only 312 animals (Allen and Angliss 2014). NMFS listed the population as “depleted” in 2000 as a consequence of the decline, and as “endangered” under the Endangered Species Act (ESA) in 2008 when the population failed to recover following a moratorium on subsistence harvest. In April 2011, NMFS designated critical habitat for the beluga under the ESA (Figure 3). The most recent aerial survey, conducted in 2014, suggests that the Cook Inlet population of belugas is comprised of 340 individuals (Shelden *et al.* 2015).

Prior to the decline, this DPS was believed to range throughout Cook Inlet and occasionally into Prince William Sound and Yakutat (Nemeth *et al.* 2007). However the range has contracted coincident with the population reduction (Speckman and Piatt 2000). During the summer and fall beluga whales are concentrated near the Susitna River mouth, Knik Arm, Turnagain Arm, and Chickaloon Bay (Nemeth *et al.* 2007) where they feed on migrating eulachon (*Thaleichthys pacificus*) and salmon (*Onchorhynchus spp.*) (Moore *et al.* 2000). Critical Habitat Area 1 reflects this summer distribution (Figure 5 in SAE Application). During the winter, beluga whales concentrate in deeper waters in the mid-inlet to Kalgin Island, and in the shallow waters along

the west shore of Cook Inlet to Kamishak Bay (Critical Habitat Area 2; Figure 5 in SAE Application). Some whales may also winter in and near Kachemak Bay.

Harbor Porpoise (Phocoena phocoena)

Harbor porpoise are small (1.5 meters length), relatively inconspicuous toothed whales. The Gulf of Alaska Stock is distributed from Cape Suckling to Unimak Pass and was most recently estimated at 31,046 animals (Allen and Angliss 2014). They are found primarily in coastal waters less than 100 meters (100 meters) deep (Hobbs and Waite 2010) where they feed on Pacific herring (*Clupea pallasii*), other schooling fishes, and cephalopods.

Although they have been frequently observed during aerial surveys in Cook Inlet, most sightings are of single animals, and are concentrated at Chinitna and Tuxedni bays on the west side of lower Cook Inlet (Rugh *et al.* 2005a). Dahlheim *et al.* (2000) estimated the 1991 Cook Inlet-wide population at only 136 animals. However, they are one of the three marine mammals (besides belugas and harbor seals) regularly seen in upper Cook Inlet (Nemeth *et al.* 2007), especially during spring eulachon and summer salmon runs. Because harbor porpoise have been observed throughout Cook Inlet during the summer months, including mid-inlet waters, they could be encountered during seismic operations in upper Cook Inlet.

Dall’s Porpoise (Phocoenoides dalli)

Dall’s porpoise are widely distributed throughout the North Pacific Ocean including Alaska, although they are not found in upper Cook Inlet and the shallower waters of the Bering, Chukchi, and Beaufort Seas (Allen and Angliss 2014). Compared to harbor porpoise, Dall’s porpoise prefer the deep offshore and shelf slope waters. The Alaskan population has been estimated at 83,400 animals (Allen and Angliss 2014), making it one of the more common cetaceans in the state. Dall’s porpoise have been observed in lower Cook Inlet, including Kachemak Bay and near Anchor Point (Owl Ridge 2014), but sightings there are rare. There is a remote chance that Dall’s porpoise might be encountered during seismic operations along the Kenai Peninsula.

Killer Whale (Orcinus orca)

Two different stocks of killer whales inhabit the Cook Inlet region of Alaska: The Alaska Resident Stock and the Gulf of Alaska, Aleutian Islands, Bering Sea Transient Stock (Allen and Angliss 2014). The resident stock is estimated at

2,347 animals and occurs from Southeast Alaska to the Bering Sea (Allen and Angliss 2014). Resident whales feed exclusively on fish and are genetically distinct from transient whales (Saulitis *et al.* 2000). The transient whales feed primarily on marine mammals (Saulitis *et al.* 2000). The transient population inhabiting the Gulf of Alaska shares mitochondrial DNA haplotypes with whales found along the Aleutian Islands and the Bering Sea suggesting a common stock, although there appears to be some subpopulation genetic structuring occurring to suggest the gene flow between groups is limited (see Allen and Angliss 2014). For the three regions combined, the transient population has been estimated at 587 animals (Allen and Angliss 2014).

Killer whales are occasionally observed in lower Cook Inlet, especially near Homer and Port Graham (Shelden *et al.* 2003, Rugh *et al.* 2005a). A concentration of sightings near Homer and inside Kachemak Bay may represent high use or may reflect high observer-effort, given most records are from a whale-watching venture based in Homer. The few whales that have been photographically identified in lower Cook Inlet belong to resident groups more commonly found in nearby Kenai Fjords and Prince William Sound (Shelden *et al.* 2003). Prior to the 1980s, killer whale sightings in upper Cook Inlet were very rare. During aerial surveys conducted between 1993 and 2004, killer whales were observed on only three flights, all in the Kachemak and English Bay area (Rugh *et al.* 2005a). However, anecdotal reports of killer whales feeding on belugas in upper Cook Inlet began increasing in the 1990s, possibly in response to declines in sea lion and harbor seal prey elsewhere (Shelden *et al.* 2003). These sporadic ventures of transient whales into beluga summering grounds have been implicated as a possible contributor to decline of Cook Inlet belugas in the 1990s, although the number of confirmed mortalities from killer whales is small (Shelden *et al.* 2003). If killer whales were to venture into upper Cook Inlet in 2015, they might be encountered during both seismic operations in both upper and lower Cook Inlet.

Steller Sea Lion (Eumetopia jubatus)

The Western Stock of the Steller sea lion is defined as all populations west of longitude 144 °W. to the western end of the Aleutian Islands. The most recent estimate for this stock is 45,649 animals (Allen and Angliss 2014), considerably less than that estimated 140,000 animals

in the 1950s (Merrick *et al.* 1987). Because of this dramatic decline, the stock was listed under the ESA as a threatened DPS in 1990, and relisted as endangered in 1997. Critical habitat was designated in 1993, and is defined as a 20-nautical-mile radius around all major rookeries and haulout sites. The 20-nautical-mile buffer was established based on telemetry data that indicated these sea lions concentrated their summer foraging effort within this distance of rookeries and haul outs.

Steller sea lions inhabit lower Cook Inlet, especially in the vicinity of Shaw Island and Elizabeth Island (Nagahut Rocks) haulout sites (Rugh *et al.* 2005a), but are rarely seen in upper Cook Inlet (Nemeth *et al.* 2007). Of the 42 Steller sea lion groups recorded during Cook Inlet aerial surveys between 1993 and 2004, none were recorded north of Anchor Point and only one in the vicinity of Kachemak Bay (Rugh *et al.* 2005a). Marine mammal observers associated with Buccaneer's drilling project off Cape Starichkof did observe seven Steller sea lions during the summer of 2013 (Owl Ridge 2014).

The upper reaches of Cook Inlet may not provide adequate foraging conditions for sea lions for establishing a major haul out presence. Steller sea lions feed largely on walleye pollock (*Theragra chalcogramma*), salmon (*Oncorhynchus spp.*), and arrowtooth flounder (*Atheresthes stomias*) during the summer, and walleye pollock and Pacific cod (*Gadus macrocephalus*) during the winter (Sinclair and Zeppelin 2002), none of which, except for salmon, are found in abundance in upper Cook Inlet (Nemeth *et al.* 2007). Steller sea lions are unlikely to be encountered during seismic operations in upper Cook Inlet, but they could possibly be encountered along the Kenai Peninsula, especially closer to Anchor Point.

Harbor Seal (Phoca vitulina)

With more than 150,000 animals state-wide (Allen and Angliss 2014), harbor seals are one of the more common marine mammal species in Alaskan waters. They are most commonly seen hauled out at tidal flats and rocky areas. Harbor seals feed largely on schooling fish such as walleye pollock, Pacific cod, salmon, Pacific herring, eulachon, and squid. Although harbor seals may make seasonal movements in response to prey, they are resident to Alaska and do not migrate.

The Cook Inlet/Shelikof Stock, ranging from approximately Anchorage down along the south side of the Alaska Peninsula to Unimak Pass, has been recently estimated at a stable 22,900

(Allen and Angliss 2014). Large numbers concentrate at the river mouths and embayments of lower Cook Inlet, including the Fox River mouth in Kachemak Bay (Rugh *et al.* 2005a). Montgomery *et al.* (2007) recorded over 200 haulout sites in lower Cook Inlet alone. However, only a few dozens to a couple hundred seals seasonally occur in upper Cook Inlet (Rugh *et al.* 2005a), mostly at the mouth of the Susitna River where their numbers vary in concert with the spring eulachon and summer salmon runs (Nemeth *et al.* 2007, Boveng *et al.* 2012). In 2012, up to 100 harbor seals were observed hauled out at the mouths of the Theodore and Lewis rivers during monitoring activity associated with SAE's (with Apache) 2012 Cook Inlet seismic program. Montgomery *et al.* (2007) also found seals elsewhere in Cook Inlet to move in response to local steelhead (*Oncorhynchus mykiss*) and salmon runs. Harbor seals may be encountered during seismic operations in both upper and lower Cook Inlet.

Potential Effects of the Specified Activity on Marine Mammals

This section includes a summary and discussion of the ways that components (*e.g.*, seismic airgun operations, vessel movement) of the specified activity, including mitigation, may impact marine mammals. The "Estimated Take by Incidental Harassment" section later in this document will include a quantitative analysis of the number of individuals that are expected to be taken by this activity. The "Negligible Impact Analysis" section will include the analysis of how this specific activity will impact marine mammals and will consider the content of this section, the "Estimated Take by Incidental Harassment" section, the "Mitigation" section, and the "Anticipated Effects on Marine Mammal Habitat" section to draw conclusions regarding the likely impacts of this activity on the reproductive success or survivorship of individuals and from that on the affected marine mammal populations or stocks.

Operating active acoustic sources, such as airgun arrays, has the potential for adverse effects on marine mammals. The majority of anticipated impacts will be from the use of acoustic sources.

Acoustic Impacts

When considering the influence of various kinds of sound on the marine environment, it is necessary to understand that different kinds of marine life are sensitive to different frequencies of sound. Based on available behavioral data, audiograms have been

derived using auditory evoked potentials, anatomical modeling, and other data. Southall *et al.* (2007) designated “functional hearing groups” for marine mammals and estimate the lower and upper frequencies of functional hearing of the groups. The functional groups and the associated frequencies are indicated below (note that animals are less sensitive to sounds at the outer edge of their functional range and most sensitive to sounds of frequencies within a smaller range somewhere in the middle of their functional hearing range) and have been modified slightly from Southall *et al.* 2007 to incorporate some newer information:

- Low frequency cetaceans (13 species of mysticetes): functional hearing is estimated to occur between approximately 7 Hz and 30 kHz; (Ketten and Mountain 2009; Tubelli *et al.* 2012)
- Mid-frequency cetaceans (32 species of dolphins, six species of larger toothed whales, and 19 species of beaked and bottlenose whales): Functional hearing is estimated to occur between approximately 150 Hz and 160 kHz; (Southall *et al.* 2007)
- High frequency cetaceans (eight species of true porpoises, six species of river dolphins, Kogia, the franciscana, and four species of cephalorhynchids): Functional hearing is estimated to occur between approximately 200 Hz and 180 kHz; (Southall *et al.* 2007)
- Phocid pinnipeds in Water: Functional hearing is estimated to occur between approximately 75 Hz and 100 kHz; (Hemilä *et al.* 2006; Mulow *et al.* 2011; Reichmuth *et al.* 2013) and
- Otariid pinnipeds in Water: Functional hearing is estimated to occur between approximately 100 Hz and 40 kHz. (Reichmuth *et al.* 2013)

As mentioned previously in this document, nine marine mammal species (seven cetacean and two pinniped species) are likely to occur in the seismic survey area. Of the seven cetacean species likely to occur in SAE’s project area, three classified as a low-frequency cetaceans (humpback, minke, gray whale), two are classified as mid-frequency cetaceans (beluga and killer whales), and two are classified as a high-frequency cetaceans (Dall’s and harbor porpoise) (Southall *et al.*, 2007). Of the two pinniped species likely to occur in SAE’s project area, one is classified as a phocid (harbor seal), and one is classified as an otariid (Steller sea lion). A species’ functional hearing group is a consideration when we analyze the effects of exposure to sound on marine mammals.

1. Potential Effects of Airgun Sounds on Marine Mammals

The effects of sounds from airgun pulses might include one or more of the following: Tolerance, masking of natural sounds, behavioral disturbance, and temporary or permanent hearing impairment or non-auditory effects (Richardson *et al.*, 1995). As outlined in previous NMFS documents, the effects of noise on marine mammals are highly variable, often depending on species and contextual factors (based on Richardson *et al.*, 1995).

Tolerance: Numerous studies have shown that pulsed sounds from air guns are often readily detectable in the water at distances of many kilometers. Numerous studies have also shown that marine mammals at distances more than a few kilometers from operating survey vessels often show no apparent response. That is often true even in cases when the pulsed sounds must be readily audible to the animals based on measured received levels and the hearing sensitivity of that mammal group. In general, pinnipeds and small odontocetes (toothed whales) seem to be more tolerant of exposure to air gun pulses than baleen whales. Although various toothed whales, and (less frequently) pinnipeds have been shown to react behaviorally to airgun pulses under some conditions, at other times, mammals of both types have shown no overt reactions. Weir (2008) observed marine mammal responses to seismic pulses from a 24 airgun array firing a total volume of either 5,085 in³ or 3,147 in³ in Angolan waters between August 2004 and May 2005. Weir recorded a total of 207 sightings of humpback whales (n = 66), sperm whales (n = 124), and Atlantic spotted dolphins (n = 17) and reported that there were no significant differences in encounter rates (sightings/hr) for humpback and sperm whales according to the airgun array’s operational status (*i.e.*, active versus silent).

Behavioral Disturbance: Marine mammals may behaviorally respond when exposed to anthropogenic noise. These behavioral reactions are often shown as: Changing durations of surfacing and dives, number of blows per surfacing, or moving direction and/or speed; reduced/increased vocal activities; changing/cessation of certain behavioral activities (such as socializing or feeding); visible startle response or aggressive behavior (such as tail/fluke slapping or jaw clapping); avoidance of areas where noise sources are located; and/or flight responses (*e.g.*, pinnipeds flushing into water from haulouts or rookeries).

The biological significance of many of these behavioral disturbances is difficult to predict. The consequences of behavioral modification to individual fitness can range from none up to potential changes to growth, survival, or reproduction, depending on the context, duration, and degree of behavioral modification. Examples of behavioral modifications that could impact growth, survival or reproduction include: Drastic changes in diving/surfacing/swimming patterns that lead to stranding (such as those associated with beaked whale strandings related to exposure to military mid-frequency tactical sonar); longer-term abandonment of habitat that is specifically important for feeding, reproduction, or other critical needs, or significant disruption of feeding or social interaction resulting in substantive energetic costs, inhibited breeding, or prolonged or permanent cow-calf separation.

The onset of behavioral disturbance from anthropogenic noise depends on both external factors (characteristics of noise sources and their paths) and the receiving animals (hearing, motivation, experience, demography) and is also difficult to predict (Southall *et al.*, 2007).

Toothed whales. Few systematic data are available describing reactions of toothed whales to noise pulses. However, systematic work on sperm whales (Tyack *et al.*, 2003) has yielded an increasing amount of information about responses of various odontocetes to seismic surveys based on monitoring studies (*e.g.*, Stone, 2003; Smultea *et al.*, 2004; Moulton and Miller, 2005). Stone *et al.*, 2003 reported reduced sighting rates of small odontoceter during periods of shooting during seismic surveys with large airgun arrays. Moulton and Miller (2004) also found that the range of audibility of seismic pules for mid-sized odontocetes was largely underestimated by models.

Seismic operators and marine mammal observers sometimes see dolphins and other small toothed whales near operating airgun arrays, but, in general, there seems to be a tendency for most delphinids to show some limited avoidance of seismic vessels operating large airgun systems. However, some dolphins seem to be attracted to the seismic vessel and floats, and some ride the bow wave of the seismic vessel even when large arrays of airguns are firing. Nonetheless, there have been indications that small toothed whales sometimes move away or maintain a somewhat greater distance from the vessel when a large array of airguns is operating than when it is

silent (e.g., Goold, 1996a,b,c; Calambokidis and Osmeck, 1998; Stone, 2003). The beluga may be a species that (at least in certain geographic areas) shows long-distance avoidance of seismic vessels. Aerial surveys during seismic operations in the southeastern Beaufort Sea recorded much lower sighting rates of beluga whales within 10–20 km (6.2–12.4 mi) of an active seismic vessel. These results were consistent with the low number of beluga sightings reported by observers aboard the seismic vessel, suggesting that some belugas might have been avoiding the seismic operations at distances of 10–20 km (6.2–12.4 mi) (Miller *et al.*, 2005).

Captive bottlenose dolphins and (of more relevance in this project) beluga whales exhibit changes in behavior when exposed to strong pulsed sounds similar in duration to those typically used in seismic surveys (Finneran *et al.*, 2002, 2005). However, the animals tolerated high received levels of sound (pk–pk level >200 dB re 1 μ Pa) before exhibiting aversive behaviors.

Observers stationed on seismic vessels operating off the United Kingdom from 1997–2000 have provided data on the occurrence and behavior of various toothed whales exposed to seismic pulses (Stone, 2003; Gordon *et al.*, 2004). Killer whales were found to be significantly farther from large airgun arrays during periods of shooting compared with periods of no shooting. The displacement of the median distance from the array was approximately 0.5 km (0.3 mi) or more. Killer whales also appear to be more tolerant of seismic shooting in deeper water.

Reactions of toothed whales to large arrays of airguns are variable and, at least for delphinids, seem to be confined to a smaller radius than has been observed for mysticetes. However, based on the limited existing evidence, belugas should not necessarily generally be grouped with delphinids in the “less responsive” category.

Pinnipeds. Pinnipeds are not likely to show a strong avoidance reaction to the airgun sources used. Visual monitoring from seismic vessels has shown only slight (if any) avoidance of airguns by pinnipeds and only slight (if any) changes in behavior. Monitoring work in the Alaskan Beaufort Sea during 1996–2001 provided considerable information regarding the behavior of Arctic ice seals exposed to seismic pulses (Harris *et al.*, 2001; Moulton and Lawson, 2002). These seismic projects usually involved arrays of 6 to 16 airguns with total volumes of 560 to 1,500 in³. The combined results suggest

that some seals avoid the immediate area around seismic vessels. In most survey years, ringed seal sightings tended to be farther away from the seismic vessel when the airguns were operating than when they were not (Moulton and Lawson, 2002). However, these avoidance movements were relatively small, on the order of 100 m (328 ft) to a few hundreds of meters, and many seals remained within 100–200 m (328–656 ft) of the trackline as the operating airgun array passed by. Seal sighting rates at the water surface were lower during airgun array operations than during no-airgun periods in each survey year except 1997. Similarly, seals are often very tolerant of pulsed sounds from seal-scaring devices (Mate and Harvey, 1987; Jefferson and Curry, 1994; Richardson *et al.*, 1995a). However, initial telemetry work suggests that avoidance and other behavioral reactions by two other species of seals, grey and harbor seals, to small airgun sources may at times be stronger than evident to date from visual studies of pinniped reactions to airguns (Thompson *et al.*, 1998). Even if reactions of the species occurring in the activity area are as strong as those evident in the telemetry study, reactions are expected to be confined to relatively small distances and durations, with no long-term effects on pinniped individuals or populations.

Masking: Masking is the obscuring of sounds of interest by other sounds, often at similar frequencies. Marine mammals use acoustic signals for a variety of purposes, which differ among species, but include communication between individuals, navigation, foraging, reproduction, avoiding predators, and learning about their environment (Erbe and Farmer, 2000; Tyack, 2000). Masking, or auditory interference, generally occurs when sounds in the environment are louder than, and of a similar frequency to, auditory signals an animal is trying to receive. Masking is a phenomenon that affects animals trying to receive acoustic information about their environment, including sounds from other members of their species, predators, prey, and sounds that allow them to orient in their environment. Masking these acoustic signals can disturb the behavior of individual animals, groups of animals, or entire populations.

Masking occurs when anthropogenic sounds and signals (that the animal utilizes) overlap at both spectral and temporal scales. For the airgun sound generated from the seismic surveys, sound will consist of low frequency (under 500 Hz) pulses with extremely short durations (less than one second).

Lower frequency man-made sounds are more likely to affect detection of potentially important natural sounds such as surf and prey noise, or communication calls for low frequency specialists. There is little concern regarding masking near the sound source due to the brief duration of these pulses and relatively longer silence between air gun shots (approximately 12 seconds). However, at long distances (over tens of kilometers away), due to multipath propagation and reverberation, the durations of airgun pulses can be “stretched” to seconds with long decays (Madsen *et al.*, 2006), although the intensity of the sound is greatly reduced.

This could affect communication signals used by low frequency mysticetes when they occur near the noise band and thus reduce the communication space of animals (e.g., Clark *et al.*, 2009) and cause increased stress levels (e.g., Foote *et al.*, 2004; Holt *et al.*, 2009); however, no baleen whales are expected to occur within the action area. Marine mammals are thought to be able to compensate for masking by adjusting their acoustic behavior by shifting call frequencies, and/or increasing call volume and vocalization rates. For example, blue whales were found to increase call rates when exposed to seismic survey noise in the St. Lawrence Estuary (Di Iorio and Clark, 2010). The North Atlantic right whales (*Eubalaena glacialis*) exposed to high shipping noise increase call frequency (Parks *et al.*, 2007), while some humpback whales respond to low-frequency active sonar playbacks by increasing song length (Miller *et al.*, 2000). Additionally, beluga whales have been known to change their vocalizations in the presence of high background noise possibly to avoid masking calls (Au *et al.*, 1985; Lesage *et al.*, 1999; Scheifele *et al.*, 2005). Although some degree of masking is inevitable when high levels of manmade broadband sounds are introduced into the sea, marine mammals have evolved systems and behavior that function to reduce the impacts of masking. Structured signals, such as the echolocation click sequences of small toothed whales, may be readily detected even in the presence of strong background noise because their frequency content and temporal features usually differ strongly from those of the background noise (Au and Moore, 1988, 1990). The components of background noise that are similar in frequency to the sound signal in question primarily determine the degree of masking of that signal.

Redundancy and context can also facilitate detection of weak signals. These phenomena may help marine mammals detect weak sounds in the presence of natural or manmade noise. Most masking studies in marine mammals present the test signal and the masking noise from the same direction. The sound localization abilities of marine mammals suggest that, if signal and noise come from different directions, masking would not be as severe as the usual types of masking studies might suggest (Richardson *et al.*, 1995). The dominant background noise may be highly directional if it comes from a particular anthropogenic source such as a ship or industrial site. Directional hearing may significantly reduce the masking effects of these sounds by improving the effective signal-to-noise ratio. In the cases of higher frequency hearing by the bottlenose dolphin, beluga whale, and killer whale, empirical evidence confirms that masking depends strongly on the relative directions of arrival of sound signals and the masking noise (Penner *et al.*, 1986; Dubrovskiy, 1990; Bain *et al.*, 1993; Bain and Dahlheim, 1994). Toothed whales and probably other marine mammals as well, have additional capabilities besides directional hearing that can facilitate detection of sounds in the presence of background noise. There is evidence that some toothed whales can shift the dominant frequencies of their echolocation signals from a frequency range with a lot of ambient noise toward frequencies with less noise (Au *et al.*, 1974, 1985; Moore and Pawloski, 1990; Thomas and Turl, 1990; Romanenko and Kitain, 1992; Lesage *et al.*, 1999). A few marine mammal species are known to increase the source levels or alter the frequency of their calls in the presence of elevated sound levels (Dahlheim, 1987; Au, 1993; Lesage *et al.*, 1993, 1999; Terhune, 1999; Foote *et al.*, 2004; Parks *et al.*, 2007, 2009; Di Iorio and Clark, 2009; Holt *et al.*, 2009).

These data demonstrating adaptations for reduced masking pertain mainly to the very high frequency echolocation signals of toothed whales. There is less information about the existence of corresponding mechanisms at moderate or low frequencies or in other types of marine mammals. For example, Zaitseva *et al.* (1980) found that, for the bottlenose dolphin, the angular separation between a sound source and a masking noise source had little effect on the degree of masking when the sound frequency was 18 kHz, in contrast to the pronounced effect at higher frequencies. Directional hearing has

been demonstrated at frequencies as low as 0.5–2 kHz in several marine mammals, including killer whales (Richardson *et al.*, 1995a). This ability may be useful in reducing masking at these frequencies. In summary, high levels of sound generated by anthropogenic activities may act to mask the detection of weaker biologically important sounds by some marine mammals. This masking may be more prominent for lower frequencies. For higher frequencies, such as that used in echolocation by toothed whales, several mechanisms are available that may allow them to reduce the effects of such masking.

Threshold Shift (noise-induced loss of hearing)—When animals exhibit reduced hearing sensitivity (*i.e.*, sounds must be louder for an animal to detect them) following exposure to an intense sound or sound for long duration, it is referred to as a noise-induced threshold shift (TS). An animal can experience temporary threshold shift (TTS) or permanent threshold shift (PTS). TTS can last from minutes or hours to days (*i.e.*, there is complete recovery), can occur in specific frequency ranges (*i.e.*, an animal might only have a temporary loss of hearing sensitivity between the frequencies of 1 and 10 kHz), and can be of varying amounts (for example, an animal's hearing sensitivity might be reduced initially by only 6 dB or reduced by 30 dB). PTS is permanent, but some recovery is possible. PTS can also occur in a specific frequency range and amount as mentioned above for TTS.

The following physiological mechanisms are thought to play a role in inducing auditory TS: Effects to sensory hair cells in the inner ear that reduce their sensitivity, modification of the chemical environment within the sensory cells, residual muscular activity in the middle ear, displacement of certain inner ear membranes, increased blood flow, and post-stimulatory reduction in both efferent and sensory neural output (Southall *et al.*, 2007). The amplitude, duration, frequency, temporal pattern, and energy distribution of sound exposure all can affect the amount of associated TS and the frequency range in which it occurs. As amplitude and duration of sound exposure increase, so, generally, does the amount of TS, along with the recovery time. For intermittent sounds, less TS could occur than compared to a continuous exposure with the same energy (some recovery could occur between intermittent exposures depending on the duty cycle between sounds) (Kryter *et al.*, 1966; Ward, 1997). For example, one short but loud

(higher SPL) sound exposure may induce the same impairment as one longer but softer sound, which in turn may cause more impairment than a series of several intermittent softer sounds with the same total energy (Ward, 1997). Additionally, though TTS is temporary, prolonged exposure to sounds strong enough to elicit TTS, or shorter-term exposure to sound levels well above the TTS threshold, can cause PTS, at least in terrestrial mammals (Kryter, 1985). In the case of the seismic survey, animals are not expected to be exposed to levels high enough or durations long enough to result in PTS.

PTS is considered auditory injury (Southall *et al.*, 2007). Irreparable damage to the inner or outer cochlear hair cells may cause PTS; however, other mechanisms are also involved, such as exceeding the elastic limits of certain tissues and membranes in the middle and inner ears and resultant changes in the chemical composition of the inner ear fluids (Southall *et al.*, 2007).

Although the published body of scientific literature contains numerous theoretical studies and discussion papers on hearing impairments that can occur with exposure to a loud sound, only a few studies provide empirical information on the levels at which noise-induced loss in hearing sensitivity occurs in nonhuman animals. For marine mammals, published data are limited to the captive bottlenose dolphin, beluga, harbor porpoise, and Yangtze finless porpoise (Finneran *et al.*, 2000, 2002, 2003, 2005, 2007, 2010a, 2010b; Finneran and Schlundt, 2010; Lucke *et al.*, 2009; Mooney *et al.*, 2009a, 2009b; Popov *et al.*, 2011a, 2011b; Kastelein *et al.*, 2012a; Schlundt *et al.*, 2000; Nachtigall *et al.*, 2003, 2004). For pinnipeds in water, data are limited to measurements of TTS in harbor seals, an elephant seal, and California sea lions (Kastak *et al.*, 1999, 2005; Kastelein *et al.*, 2012b).

Marine mammal hearing plays a critical role in communication with conspecifics, and interpretation of environmental cues for purposes such as predator avoidance and prey capture. Depending on the degree (elevation of threshold in dB), duration (*i.e.*, recovery time), and frequency range of TTS, and the context in which it is experienced, TTS can have effects on marine mammals ranging from discountable to serious (similar to those discussed in auditory masking, below). For example, a marine mammal may be able to readily compensate for a brief, relatively small amount of TTS in a non-critical frequency range that occurs during a time where ambient noise is lower and

there are not as many competing sounds present. Alternatively, a larger amount and longer duration of TTS sustained during time when communication is critical for successful mother/calf interactions could have more serious impacts. Similarly, depending on the degree and frequency range, the effects of PTS on an animal could range in severity, although it is considered generally more serious because it is a permanent condition. Of note, reduced hearing sensitivity as a simple function of aging has been observed in marine mammals, as well as humans and other taxa (Southall *et al.*, 2007), so we can infer that strategies exist for coping with this condition to some degree, though likely not without cost.

Given the higher level of sound necessary to cause PTS as compared with TTS, it is considerably less likely that PTS would occur during the seismic surveys in Cook Inlet. Cetaceans generally avoid the immediate area around operating seismic vessels, as do some other marine mammals. Some pinnipeds show avoidance reactions to airguns, but their avoidance reactions are generally not as strong or consistent as those of cetaceans, and occasionally they seem to be attracted to operating seismic vessels (NMFS, 2010).

Non-auditory Physical Effects: Non-auditory physical effects might occur in marine mammals exposed to strong underwater pulsed sound. Possible types of non-auditory physiological effects or injuries that theoretically might occur in mammals close to a strong sound source include stress, neurological effects, bubble formation, and other types of organ or tissue damage. Some marine mammal species (*i.e.*, beaked whales) may be especially susceptible to injury and/or stranding when exposed to strong pulsed sounds.

Classic stress responses begin when an animal's central nervous system perceives a potential threat to its homeostasis. That perception triggers stress responses regardless of whether a stimulus actually threatens the animal; the mere perception of a threat is sufficient to trigger a stress response (Moberg, 2000; Sapolsky *et al.*, 2005; Seyle, 1950). Once an animal's central nervous system perceives a threat, it mounts a biological response or defense that consists of a combination of the four general biological defense responses: Behavioral responses; autonomic nervous system responses; neuroendocrine responses; or immune responses.

In the case of many stressors, an animal's first and most economical (in terms of biotic costs) response is behavioral avoidance of the potential

stressor or avoidance of continued exposure to a stressor. An animal's second line of defense to stressors involves the sympathetic part of the autonomic nervous system and the classical "fight or flight" response, which includes the cardiovascular system, the gastrointestinal system, the exocrine glands, and the adrenal medulla to produce changes in heart rate, blood pressure, and gastrointestinal activity that humans commonly associate with "stress." These responses have a relatively short duration and may or may not have significant long-term effects on an animal's welfare.

An animal's third line of defense to stressors involves its neuroendocrine or sympathetic nervous systems; the system that has received the most study has been the hypothalamus-pituitary-adrenal system (also known as the HPA axis in mammals or the hypothalamus-pituitary-interrenal axis in fish and some reptiles). Unlike stress responses associated with the autonomic nervous system, virtually all neuroendocrine functions that are affected by stress—including immune competence, reproduction, metabolism, and behavior—are regulated by pituitary hormones. Stress-induced changes in the secretion of pituitary hormones have been implicated in failed reproduction (Moberg, 1987; Rivier, 1995), altered metabolism (Elasser *et al.*, 2000), reduced immune competence (Blecha, 2000), and behavioral disturbance. Increases in the circulation of glucocorticosteroids (cortisol, corticosterone, and aldosterone in marine mammals; see Romano *et al.*, 2004) have been equated with stress for many years.

The primary distinction between stress (which is adaptive and does not normally place an animal at risk) and distress is the biotic cost of the response. During a stress response, an animal uses glycogen stores that can be quickly replenished once the stress is alleviated. In such circumstances, the cost of the stress response would not pose a risk to the animal's welfare. However, when an animal does not have sufficient energy reserves to satisfy the energetic costs of a stress response, energy resources must be diverted from other biotic functions, which impair those functions that experience the diversion. For example, when mounting a stress response diverts energy away from growth in young animals, those animals may experience stunted growth. When mounting a stress response diverts energy from a fetus, an animal's reproductive success and fitness will suffer. In these cases, the animals will have entered a pre-pathological or

pathological state which is called "distress" (*sensu* Seyle, 1950) or "allostatic loading" (*sensu* McEwen and Wingfield, 2003). This pathological state will last until the animal replenishes its biotic reserves sufficient to restore normal function. Note that these examples involved a long-term (days or weeks) stress response due to exposure to stimuli.

Relationships between these physiological mechanisms, animal behavior, and the costs of stress responses have also been documented fairly well through controlled experiment; because this physiology exists in every vertebrate that has been studied, it is not surprising that stress responses and their costs have been documented in both laboratory and free-living animals (for examples see, Holberton *et al.*, 1996; Hood *et al.*, 1998; Jessop *et al.*, 2003; Krausman *et al.*, 2004; Lankford *et al.*, 2005; Reneerkens *et al.*, 2002; Thompson and Hamer, 2000). Although no information has been collected on the physiological responses of marine mammals to anthropogenic sound exposure, studies of other marine animals and terrestrial animals would lead us to expect some marine mammals to experience physiological stress responses and, perhaps, physiological responses that would be classified as "distress" upon exposure to anthropogenic sounds.

For example, Jansen (1998) reported on the relationship between acoustic exposures and physiological responses that are indicative of stress responses in humans (*e.g.*, elevated respiration and increased heart rates). Jones (1998) reported on reductions in human performance when faced with acute, repetitive exposures to acoustic disturbance. Trimper *et al.* (1998) reported on the physiological stress responses of osprey to low-level aircraft noise while Krausman *et al.* (2004) reported on the auditory and physiology stress responses of endangered Sonoran pronghorn to military overflights. Smith *et al.* (2004a, 2004b) identified noise-induced physiological transient stress responses in hearing-specialist fish (*i.e.*, goldfish) that accompanied short- and long-term hearing losses. Welch and Welch (1970) reported physiological and behavioral stress responses that accompanied damage to the inner ears of fish and several mammals.

Hearing is one of the primary senses marine mammals use to gather information about their environment and communicate with conspecifics. Although empirical information on the effects of sensory impairment (TTS, PTS, and acoustic masking) on marine mammals remains limited, we assume

that reducing a marine mammal's ability to gather information about its environment and communicate with other members of its species would induce stress, based on data that terrestrial animals exhibit those responses under similar conditions (NRC, 2003) and because marine mammals use hearing as their primary sensory mechanism. Therefore, we assume that acoustic exposures sufficient to trigger onset PTS or TTS would be accompanied by physiological stress responses. However, marine mammals also might experience stress responses at received levels lower than those necessary to trigger onset TTS. Based on empirical studies of the time required to recover from stress responses (Moberg, 2000), NMFS also assumes that stress responses could persist beyond the time interval required for animals to recover from TTS and might result in pathological and pre-pathological states that would be as significant as behavioral responses to TTS. Resonance effects (Gentry, 2002) and direct noise-induced bubble formations (Crum *et al.*, 2005) are implausible in the case of exposure to an impulsive broadband source like an airgun array. If seismic surveys disrupt diving patterns of deep-diving species, this might result in bubble formation and a form of the bends, as speculated to occur in beaked whales exposed to sonar. However, there is no specific evidence of this upon exposure to airgun pulses. Additionally, no beaked whale species occur in the seismic survey area.

In general, very little is known about the potential for strong, anthropogenic underwater sounds to cause non-auditory physical effects in marine mammals. Such effects, if they occur at all, would presumably be limited to short distances and to activities that extend over a prolonged period. The available data do not allow identification of a specific exposure level above which non-auditory effects can be expected (Southall *et al.*, 2007) or any meaningful quantitative predictions of the numbers (if any) of marine mammals that might be affected in those ways. There is no definitive evidence that any of these effects occur even for marine mammals in close proximity to large arrays of airguns. In addition, marine mammals that show behavioral avoidance of seismic vessels, including belugas and some pinnipeds, are especially unlikely to incur non-auditory impairment or other physical effects. Therefore, it is unlikely that such effects would occur during SAE's surveys given the brief duration of

exposure and the planned monitoring and mitigation measures described later in this document.

Stranding and Mortality: Marine mammals close to underwater detonations of high explosive can be killed or severely injured, and the auditory organs are especially susceptible to injury (Ketten *et al.* 1993; Ketten 1995). Airgun pulses are less energetic and their peak amplitudes have slower rise times. To date, there is no evidence that serious injury, death, or stranding by marine mammals can occur from exposure to air gun pulses, even in the case of large air gun arrays.

However, in past IHA notices for seismic surveys, commenters have referenced two stranding events allegedly associated with seismic activities, one off Baja California and a second off Brazil. NMFS has addressed this concern several times, including in the **Federal Register** notice announcing the IHA for Apache Alaska's first seismic survey in 2012. Readers are encouraged to review NMFS's response to comments on this matter found in 69 FR 74905 (December 14, 2004), 71 FR 43112 (July 31, 2006), 71 FR 50027 (August 24, 2006), 71 FR 49418 (August 23, 2006), and 77 FR 27720 (May 11, 2012).

Beluga whale strandings in Cook Inlet are not uncommon; however, these events often coincide with extreme tidal fluctuations ("spring tides") or killer whale sightings (Shelden *et al.*, 2003). For example, in August 2012, a group of Cook Inlet beluga whales stranded in the mud flats of Turnagain Arm during low tide and were able to swim free with the flood tide. No strandings or marine mammals in distress were observed during the 2D test survey conducted by Apache in March 2011, and none were reported by Cook Inlet inhabitants. As a result, NMFS does not expect any marine mammals will incur serious injury or mortality in Cook Inlet or strand as a result of the seismic survey.

2. Potential Effects From Pingers on Marine Mammals

Active acoustic sources other than the airguns will be used for SAE's oil and gas exploration seismic survey program in Cook Inlet. The specifications for the pingers (source levels and frequency ranges) were provided earlier in this document. In general, pingers are known to cause behavioral disturbance and are commonly used to deter marine mammals from commercial fishing gear or fish farms. Due to the potential to change marine mammal behavior, shut downs described for airguns will also be applied to pinger use.

Vessel Impacts

Vessel activity and noise associated with vessel activity will temporarily increase in the action area during SAE's seismic survey as a result of the operation of nine vessels. To minimize the effects of vessels and noise associated with vessel activity, SAE will follow NMFS's Marine Mammal Viewing Guidelines and Regulations and will alter heading or speed if a marine mammal gets too close to a vessel. In addition, vessels will be operating at slow speed (4–5 knots) when conducting surveys and in a purposeful manner to and from work sites in as direct a route as possible. Marine mammal monitoring observers and passive acoustic devices will alert vessel captains as animals are detected to ensure safe and effective measures are applied to avoid coming into direct contact with marine mammals. Therefore, NMFS neither anticipates nor authorizes takes of marine mammals from ship strikes.

Odontocetes, such as beluga whales, killer whales, and harbor porpoises, often show tolerance to vessel activity; however, they may react at long distances if they are confined by ice, shallow water, or were previously harassed by vessels (Richardson *et al.*, 1995). Beluga whale response to vessel noise varies greatly from tolerance to extreme sensitivity depending on the activity of the whale and previous experience with vessels (Richardson *et al.*, 1995). Reactions to vessels depend on whale activities and experience, habitat, boat type, and boat behavior (Richardson *et al.*, 1995) and may include behavioral responses, such as altered headings or avoidance (Blane and Jackson, 1994; Erbe and Farmer, 2000); fast swimming; changes in vocalizations (Lesage *et al.*, 1999; Scheifele *et al.*, 2005); and changes in dive, surfacing, and respiration patterns.

There are few data published on pinniped responses to vessel activity, and most of the information is anecdotal (Richardson *et al.*, 1995). Generally, sea lions in water show tolerance to close and frequently approaching vessels and sometimes show interest in fishing vessels. They are less tolerant when hauled out on land; however, they rarely react unless the vessel approaches within 100–200 m (330–660 ft; reviewed in Richardson *et al.*, 1995).

Entanglement

Although some of SAE's equipment contains cables or lines, the risk of entanglement is extremely remote. Additionally, mortality from entanglement is not anticipated. The

material used by SAE and the amount of slack is not anticipated to allow for marine mammal entanglements.

Anticipated Effects on Marine Mammal Habitat

The primary potential impacts to marine mammal habitat and other marine species are associated with elevated sound levels produced by airguns and other active acoustic sources. However, other potential impacts to the surrounding habitat from physical disturbance are also possible. This section describes the potential impacts to marine mammal habitat from the specified activity. Because the marine mammals in the area feed on fish and/or invertebrates there is also information on the species typically preyed upon by the marine mammals in the area. As noted earlier, upper Cook Inlet is an important feeding and calving area for the Cook Inlet beluga whale and critical habitat has been designated for this species in the seismic survey area.

Common Marine Mammal Prey in the Project Area

Fish are the primary prey species for marine mammals in upper Cook Inlet. Beluga whales feed on a variety of fish, shrimp, squid, and octopus (Burns and Seaman, 1986). Common prey species in Knik Arm include salmon, eulachon and cod. Harbor seals feed on fish such as pollock, cod, capelin, eulachon, Pacific herring, and salmon, as well as a variety of benthic species, including crabs, shrimp, and cephalopods. Harbor seals are also opportunistic feeders with their diet varying with season and location. The preferred diet of the harbor seal in the Gulf of Alaska consists of pollock, octopus, capelin, eulachon, and Pacific herring (Calkins, 1989). Other prey species include cod, flat fishes, shrimp, salmon, and squid (Hoover, 1988). Harbor porpoises feed primarily on Pacific herring, cod, whiting (hake), pollock, squid, and octopus (Leatherwood *et al.*, 1982). In the upper Cook Inlet area, harbor porpoise feed on squid and a variety of small schooling fish, which would likely include Pacific herring and eulachon (Bowen and Siniff, 1999; NMFS, unpublished data). Killer whales feed on either fish or other marine mammals depending on genetic type (resident versus transient respectively). Killer whales in Knik Arm are typically the transient type (Shelden *et al.*, 2003) and feed on beluga whales and other marine mammals, such as harbor seal and harbor porpoise. The Steller sea lion diet consists of a variety of fishes (capelin, cod, herring, mackerel, pollock, rockfish, salmon, sand lance,

etc.), bivalves, squid, octopus, and gastropods.

Potential Impacts on Prey Species

With regard to fish as a prey source for cetaceans and pinnipeds, fish are known to hear and react to sounds and to use sound to communicate (Tavolga *et al.*, 1981) and possibly avoid predators (Wilson and Dill, 2002). Experiments have shown that fish can sense both the strength and direction of sound (Hawkins, 1981). Primary factors determining whether a fish can sense a sound signal, and potentially react to it, are the frequency of the signal and the strength of the signal in relation to the natural background sound level.

Fishes produce sounds that are associated with behaviors that include territoriality, mate search, courtship, and aggression. It has also been speculated that sound production may provide the means for long distance communication and communication under poor underwater visibility conditions (Zelick *et al.*, 1999), although the fact that fish communicate at low-frequency sound levels where the masking effects of ambient noise are naturally highest suggests that very long distance communication would rarely be possible. Fishes have evolved a diversity of sound generating organs and acoustic signals of various temporal and spectral contents. Fish sounds vary in structure, depending on the mechanism used to produce them (Hawkins, 1993). Generally, fish sounds are predominantly composed of low frequencies (less than 3 kHz).

Since objects in the water scatter sound, fish are able to detect these objects through monitoring the ambient noise. Therefore, fish are probably able to detect prey, predators, conspecifics, and physical features by listening to environmental sounds (Hawkins, 1981). There are two sensory systems that enable fish to monitor the vibration-based information of their surroundings. The two sensory systems, the inner ear and the lateral line, constitute the acoustico-lateralis system.

Although the hearing sensitivities of very few fish species have been studied to date, it is becoming obvious that the intra- and inter-specific variability is considerable (Coombs, 1981). Nedwell *et al.* (2004) compiled and published available fish audiogram information. A noninvasive electrophysiological recording method known as auditory brainstem response is now commonly used in the production of fish audiograms (Yan, 2004). Popper and Carlson (1998) and the Navy (2001) found that fish generally perceive underwater sounds in the frequency

range of 50–2,000 Hz, with peak sensitivities below 800 Hz. Even though some fish are able to detect sounds in the ultrasonic frequency range, the thresholds at these higher frequencies tend to be considerably higher than those at the lower end of the auditory frequency range.

Fish are sensitive to underwater impulsive sounds due to swim bladder resonance. As the pressure wave passes through a fish, the swim bladder is rapidly squeezed as the high pressure wave, and then the under pressure component of the wave, passes through the fish. The swim bladder may repeatedly expand and contract at the high sound pressure levels, creating pressure on the internal organs surrounding the swim bladder.

Literature relating to the impacts of sound on marine fish species can be divided into the following categories: (1) Pathological effects; (2) physiological effects; and (3) behavioral effects. Pathological effects include lethal and sub-lethal physical damage to fish; physiological effects include primary and secondary stress responses; and behavioral effects include changes in exhibited behaviors of fish. Behavioral changes might be a direct reaction to a detected sound or a result of the anthropogenic sound masking natural sounds that the fish normally detect and to which they respond. The three types of effects are often interrelated in complex ways. For example, some physiological and behavioral effects could potentially lead to the ultimate pathological effect of mortality. Hastings and Popper (2005) reviewed what is known about the effects of sound on fishes and identified studies needed to address areas of uncertainty relative to measurement of sound and the responses of fishes. Popper *et al.* (2003/2004) also published a paper that reviews the effects of anthropogenic sound on the behavior and physiology of fishes.

The level of sound at which a fish will react or alter its behavior is usually well above the detection level. Fish have been found to react to sounds when the sound level increased to about 20 dB above the detection level of 120 dB (Ona, 1988); however, the response threshold can depend on the time of year and the fish's physiological condition (Engas *et al.*, 1993). In general, fish react more strongly to pulses of sound rather than a continuous signal (Blaxter *et al.*, 1981), and a quicker alarm response is elicited when the sound signal intensity rises rapidly compared to sound rising more slowly to the same level.

Investigations of fish behavior in relation to vessel noise (Olsen *et al.*, 1983; Ona, 1988; Ona and Godo, 1990) have shown that fish react when the sound from the engines and propeller exceeds a certain level. Avoidance reactions have been observed in fish such as cod and herring when vessels approached close enough that received sound levels are 110 dB to 130 dB (Nakken, 1992; Olsen, 1979; Ona and Godo, 1990; Ona and Toresen, 1988). However, other researchers have found that fish such as polar cod, herring, and capelin are often attracted to vessels (apparently by the noise) and swim toward the vessel (Rostad *et al.*, 2006). Typical sound source levels of vessel noise in the audible range for fish are 150 dB to 170 dB (Richardson *et al.*, 1995).

Carlson (1994), in a review of 40 years of studies concerning the use of underwater sound to deter salmonids from hazardous areas at hydroelectric dams and other facilities, concluded that salmonids were able to respond to low-frequency sound and to react to sound sources within a few feet of the source. He speculated that the reason that underwater sound had no effect on salmonids at distances greater than a few feet is because they react to water particle motion/acceleration, not sound pressures. Detectable particle motion is produced within very short distances of a sound source, although sound pressure waves travel farther.

Potential Impacts to the Benthic Environment

SAE's seismic survey requires the deployment of a submersible recording system in the inter-tidal and marine zones. An autonomous "nodal" (*i.e.*, no cables) system would be placed on the seafloor by specific vessels in lines parallel to each other with a node line spacing of 402 m (0.25 mi). Each nodal "patch" will have 32 node lines parallel to each other. The lines generally run perpendicular to the shoreline. An entire patch will be placed on the seafloor prior to airgun activity. As the patches are surveyed, the node lines will be moved either side to side or inline to the next location. Placement and retrieval of the nodes may cause temporary and localized increases in turbidity on the seafloor. The substrate of Cook Inlet consists of glacial silt, clay, cobbles, pebbles, and sand (Sharma and Burrell, 1970). Sediments like sand and cobble dissipate quickly when suspended, but finer materials like clay and silt can create thicker plumes that may harm fish; however, the turbidity created by placing and removing nodes on the seafloor will

settle to background levels within minutes after the cessation of activity.

In addition, seismic noise will radiate throughout the water column from airguns and pingers until it dissipates to background levels. No studies have demonstrated that seismic noise affects the life stages, condition, or amount of food resources (fish, invertebrates, eggs) used by marine mammals, except when exposed to sound levels within a few meters of the seismic source or in few very isolated cases. NMFS has also required a seasonal closure near the Susitna River Delta from April 15 to October 15, which is an essential foraging location for Cook Inlet belugas. Where fish or invertebrates did respond to seismic noise, the effects were temporary and of short duration. Consequently, disturbance to fish species due to the activities associated with the seismic survey (*i.e.*, placement and retrieval of nodes and noise from sound sources) will be short term and fish will be expected to return to their pre-disturbance behavior once seismic survey activities cease.

Based on the preceding discussion, the activity is not expected to have any habitat-related effects that could cause significant or long-term consequences for individual marine mammals or their populations.

Mitigation

In order to issue an incidental take authorization (ITA) under section 101(a)(5)(D) of the MMPA, NMFS must set forth the permissible methods of taking pursuant to such activity, and other means of effecting the least practicable impact on such species or stock and its habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance, and on the availability of such species or stock for taking for certain subsistence uses (where relevant).

Mitigation Measures in SAE's Application

For the mitigation measures, SAE listed the following protocols to be implemented during its seismic survey program in Cook Inlet.

1. Operation of Mitigation Airgun at Night

SAE will conduct both daytime and nighttime operations. Nighttime operations will be initiated only if a "mitigation airgun" (typically the 10 in³) has been continuously operational from the time that PSO monitoring has ceased for the day. Seismic activity will not ramp up from an extended shutdown (*i.e.*, when the airgun has been down with no activity for at least 10

minutes) during nighttime operations, and survey activities will be suspended until the following day. At night, the vessel captain and crew will maintain lookout for marine mammals and will order the airgun(s) to be shut down if marine mammals are observed in or about to enter the established exclusion zones.

2. Exclusion and Disturbance Zones

SAE will establish exclusion zones to avoid Level A harassment ("injury exclusion zone") of all marine mammals and to avoid Level B harassment ("disturbance exclusion zone") of any beluga whales or groups of five or more killer whales or harbor porpoises detected within the designated zones. The injury exclusion zone will correspond to the area around the source within which received levels equal or exceed 180 dB re 1 μ Pa [rms] for cetaceans and 190 dB re 1 μ Pa [rms] for pinnipeds, and SAE will shut down or power down operations if any marine mammals are seen approaching or entering this zone (more detail below). The disturbance exclusion zone will correspond to the area around the source within which received levels equal or exceed 160 dB re 1 μ Pa [rms] and SAE will implement power down and/or shutdown measures, as appropriate, if any beluga whales, humpback whales, Steller sea lions, or group of five or more killer whales or harbor porpoises are seen entering or approaching the disturbance exclusion zone.

3. Power Down and Shutdown Procedures

A power down is the immediate reduction in the number of operating energy sources from a full array firing to a mitigation airgun. A shutdown is the immediate cessation of firing of all energy sources. The arrays will be immediately powered down whenever a marine mammal is sighted approaching close to or within the applicable exclusion zone of the full arrays but is outside the applicable exclusion zone of the single source. If a marine mammal is sighted within the applicable exclusion zone of the single energy source, the entire array will be shutdown (*i.e.*, no sources firing). Following a power down or a shutdown, airgun activity will not resume until the marine mammal has clearly left the applicable injury or disturbance exclusion zone. The animal will be considered to have cleared the zone if it: (1) Is visually observed to have left the zone; (2) has not been seen within the zone for 15 minutes in the case of pinnipeds and small odontocetes; or (3)

has not been seen within the zone for 30 minutes in the case of large odontocetes, including killer whales and belugas.

Visual monitoring by qualified PSOs will continue for 30 minutes after a shutdown or at the end of a period of seismic surveying to monitor for animals returning to the previously ensonified area.

4. Ramp-Up Procedures

A ramp-up of an airgun array provides a gradual increase in sound levels, and involves a step-wise increase in the number and total volume of air guns firing until the full volume is achieved. The purpose of a ramp-up (or “soft start”) is to “warn” cetaceans and pinnipeds in the vicinity of the airguns and to provide the time for them to leave the area and thus avoid any potential injury or impairment of their hearing abilities.

During the seismic survey, the seismic operator will ramp up the airgun array slowly at a rate of no more than 6 dB per 5-minute period. Ramp-up is used at the start of airgun operations, after a power- or shut-down, and after any period of greater than 10 minutes in duration without airgun operations (“extended shutdown”).

A full ramp-up after a shutdown will not begin until there has been a minimum of 30 minutes of observation of the applicable exclusion zone by PSOs to assure that no marine mammals are present. The entire exclusion zone must be visible during the 30-minute lead-in to a full ramp up. If the entire exclusion zone is not visible, then ramp-up from a cold start cannot begin. If a marine mammal(s) is sighted within the injury exclusion zone during the 30-minute watch prior to ramp-up, ramp-up will be delayed until the marine mammal(s) is sighted outside of the zone or the animal(s) is not sighted for at least 15–30 minutes: 15 minutes for small odontocetes and pinnipeds (e.g. harbor porpoises, harbor seals, and Steller sea lions), or 30 minutes for large odontocetes (e.g., killer whales and beluga whales).

5. Speed or Course Alteration

If a marine mammal is detected outside the injury exclusion zone and, based on its position and the relative motion, is likely to enter that zone, the vessel’s speed and/or direct course may, when practical and safe, be changed to avoid the marine mammal and also minimize the effect on the seismic program. This can be used in coordination with a power down procedure. The marine mammal activities and movements relative to the

seismic and support vessels will be closely monitored to ensure that the marine mammal does not approach within the applicable exclusion radius. If the mammal appears likely to enter the exclusion radius, further mitigative actions will be taken, *i.e.*, either further course alterations, power down, or shut down of the airgun(s).

6. Measures for Beluga Whales and Groups of Killer Whales and Harbor Porpoises

The following are additional protective measures for beluga whales and groups of five or more killer whales and harbor porpoises. Specifically, a 160-dB vessel monitoring zone will be established and monitored in Cook Inlet during all seismic surveys. If a beluga whale or groups of five or more killer whales and/or harbor porpoises are visually sighted approaching or within the 160-dB disturbance zone, survey activity will not commence until the animals are no longer present within the 160-dB disturbance zone. Whenever any beluga whales or groups of five or more killer whales and/or harbor porpoises are detected approaching or within the 160-dB disturbance zone, the airguns may be powered down before the animal is within the 160-dB disturbance zone, as an alternative to a complete shutdown. If a power down is not sufficient, the sound source(s) will be shut-down until the animals are no longer present within the 160-dB zone.

Additional Mitigation Measures Required by NMFS

In addition to the mitigation measures above, NMFS requires implementation of the following mitigation measures.

SAE will not operate airguns within 10 miles (16 km) of the mean higher high water (MHHW) line of the Susitna Delta (Beluga River to the Little Susitna River) between April 15 and October 15. The purpose of this mitigation measure is to protect beluga whales in the designated critical habitat in this area that is important for beluga whale feeding and calving during the spring and fall months. The range of the setback required by NMFS was designated to protect this important habitat area and also to create an effective buffer where sound does not encroach on this habitat. This seasonal exclusion will be in effect from April 15–October 15. Activities may occur within this area from October 16–April 14.

A “mitigation airgun” (10in³) will be operated at approximately one shot per minute, only during daylight and when there is good visibility, and will not be operated for longer than 3 hours in

duration. In cases when the next start-up after the turn is expected to be during lowlight or low visibility, use of the mitigation airgun may be initiated 30 minutes before darkness or low visibility conditions occur and may be operated until the start of the next seismic acquisition line. The mitigation gun must still be operated at approximately one shot per minute.

When nighttime operations ramp up from the mitigation airgun, SAE will be required to use passive acoustic monitoring for at least 30 minutes prior to ramp-up to detect beluga whales, humpback whales, and Steller sea lions that may be within the 160dB disturbance zone. The support vessel must remain sufficiently distant from the seismic source vessel to ensure that beluga whales, if present and vocalizing, can be detected. Passive acoustic monitoring must continue throughout seismic operations occurring between local sunset and sunrise.

NMFS requires that SAE must suspend seismic operations if a live marine mammal stranding is reported in Cook Inlet coincident to, or within 72 hours of, seismic survey activities involving the use of airguns (regardless of any suspected cause of the stranding). The shutdown must occur if the animal is within a distance two times that of the 160 dB isopleth of the largest airgun array configuration in use. This distance was chosen to create an additional buffer beyond the distance at which animals would typically be considered harassed, as animals involved in a live stranding event are likely compromised, with potentially increased susceptibility to stressors, and the goal is to decrease the likelihood that they are further disturbed or impacted by the seismic survey, regardless of what the original cause of the stranding event was. Shutdown procedures will remain in effect until NMFS determines and advises SAE that all live animals involved in the stranding have left the area (either of their own volition or following herding by responders).

Finally, NMFS requires that if any marine mammal species are encountered during seismic activities for which take is not authorized, and are likely to be exposed to sound pressure levels (SPLs) greater than or equal to 160 dB re 1 μ Pa (rms), then SAE must alter speed or course, power down or shut down the sound source to avoid take of those species.

Mitigation Conclusions

NMFS has carefully evaluated SAE’s mitigation measures and considered a range of other measures in the context of ensuring that NMFS prescribes the

means of affecting the least practicable adverse impact on the affected marine mammal species and stocks and their habitat. Our evaluation of mitigation measures included consideration of the following factors in relation to one another:

- The manner in which, and the degree to which, the successful implementation of the measures are expected to minimize adverse impacts to marine mammals;
- The proven or likely efficacy of the specific measure to minimize adverse impacts as planned; and
- The practicability of the measure for applicant implementation.

Any mitigation measure(s) prescribed by NMFS should be able to accomplish, have a reasonable likelihood of accomplishing (based on current science), or contribute to the accomplishment of one or more of the general goals listed below:

1. Avoidance or minimization of injury or death of marine mammals wherever possible (goals 2, 3, and 4 may contribute to this goal).
2. A reduction in the numbers of marine mammals (total number or number at biologically important time or location) exposed to received levels of seismic airguns, or other activities expected to result in the take of marine mammals (this goal may contribute to 1, above, or to reducing harassment takes only).
3. A reduction in the number of times (total number or number at biologically important time or location) individuals would be exposed to received levels of seismic airguns or other activities expected to result in the take of marine mammals (this goal may contribute to 1, above, or to reducing harassment takes only).
4. A reduction in the intensity of exposures (either total number or number at biologically important time or location) to received levels of seismic airguns or other activities expected to result in the take of marine mammals (this goal may contribute to 1, above, or to reducing the severity of harassment takes only).
5. Avoidance or minimization of adverse effects to marine mammal habitat, paying special attention to the food base, activities that block or limit passage to or from biologically important areas, permanent destruction of habitat, or temporary destruction/disturbance of habitat during a biologically important time.
6. For monitoring directly related to mitigation—an increase in the probability of detecting marine mammals, thus allowing for more

effective implementation of the mitigation.

Based on our evaluation of the applicant's mitigation measures, as well as other measures considered by NMFS, NMFS has determined that the mitigation measures provide the means of effecting the least practicable adverse impact on marine mammals species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Monitoring and Reporting

Monitoring Measures

1. Visual Vessel-based Monitoring

Vessel-based monitoring for marine mammals will be done by experienced PSOs throughout the period of marine survey activities. PSOs will monitor the occurrence and behavior of marine mammals near the survey vessel during all daylight periods (nautical dawn to nautical dusk) during operation and during most daylight periods when airgun operations are not occurring. PSO duties will include watching for and identifying marine mammals, recording their numbers, distances, and reactions to the survey operations, and documenting observed "take by harassment" as defined by NMFS.

A minimum number of seven PSOs (two per source vessel and two per support vessel, with one additional PSO on the mitigation vessel to operate the hydrophone) will be required onboard the survey vessel to meet the following criteria: (1) 100 percent monitoring coverage during all periods of survey operations in daylight (nautical twilight-dawn to nautical twilight-dusk); (2) maximum of 4 consecutive hours on watch per PSO; and (3) maximum of 12 hours of watch time per day per PSO.

PSO teams will consist of NMFS-approved field biologists. An experienced field crew leader will supervise the PSO team onboard the survey vessel. SAE will have PSOs aboard three vessels: the two source vessels and one support vessel (*M/V Dreamcatcher*). Two PSOs will be on the source vessels, and three PSOs will be on the support vessel to observe and implement the exclusion, power down, and shut down areas. When marine mammals are about to enter or are sighted within designated harassment and exclusion zones, airgun or pinger operations will be powered down (when applicable) or shut down immediately. The vessel-based observers will watch for marine mammals during all periods when sound sources are in operation and for a minimum of 30 minutes prior to the start of airgun or pinger

operations after an extended shut down as well as 30 minutes after the end of airgun operation.

The observer(s) will watch for marine mammals from the best available vantage point on the source and support vessels, typically the flying bridge. The observer(s) will scan systematically with the unaided eye and 7x50 reticle binoculars, assisted by 40x80 long-range binoculars.

All observations will be recorded in a standardized format. When a mammal sighting is made, the following information about the sighting will be recorded:

- Species, group size, age/size/sex categories (if determinable), sighting cue, behavior when first sighted and after initial sighting, time of sighting, heading (if consistent), bearing and distance from the PSO, direction and speed relative to vessel, apparent reaction to activities (*e.g.*, none, avoidance, approach, paralleling, etc.), closest point of approach, and behavioral pace;
- Time, location, speed, activity of the vessel (*e.g.*, seismic airguns off, pingers on, etc.), sea state, ice cover, visibility, and sun glare; and
- The positions of other vessel(s) in the vicinity of the PSO location.

The ship's position, speed of support vessels, and water temperature, water depth, sea state, ice cover, visibility, and sun glare will also be recorded at the start and end of each observation watch, every 30 minutes during a watch, and whenever there is a change in any of those variables.

2. Visual Shore-Based Monitoring

In addition to the vessel-based PSOs, SAE will utilize shore-based monitoring daily in the event of summer seismic activity occurring nearshore to Cook Inlet beluga Critical Habitat Area 1, to visually monitor for marine mammals. The shore-based PSOs will scan the area prior to, during, and after the airgun operations and will be in contact with the vessel-based PSOs via radio to communicate sightings of marine mammals approaching or within the project area. This communication will allow the vessel-based observers to go on a "heightened" state of alert regarding occurrence of marine mammals in the area and aid in timely implementation of mitigation measures.

Reporting Measures

Immediate reports will be submitted to NMFS if 25 belugas are detected in the Level B disturbance exclusion zone to evaluate and make necessary adjustments to monitoring and mitigation. If the number of detected

takes for any marine mammal species is met or exceeded, SAE will immediately cease survey operations involving the use of active sound sources (*e.g.*, airguns and pingers) and notify NMFS.

1. Weekly Reports

SAE will submit a weekly field report to NMFS Headquarters as well as the Alaska Regional Office, no later than close of business each Thursday during the weeks when in-water seismic survey activities take place. The weekly field reports will summarize species detected (number, location, distance from seismic vessel, behavior), in-water activity occurring at the time of the sighting (discharge volume of array at time of sighting, seismic activity at time of sighting, visual plots of sightings, and number of power downs and shutdowns), behavioral reactions to in-water activities, and the number of marine mammals exposed.

2. Monthly Reports

Monthly reports will be submitted to NMFS for all months during which in-water seismic activities take place. The monthly report will contain and summarize the following information:

- Dates, times, locations, heading, speed, weather, sea conditions (including Beaufort sea state and wind force), and associated activities during all seismic operations and marine mammal sightings.

- Species, number, location, distance from the vessel, and behavior of any sighted marine mammals, as well as associated seismic activity (number of power-downs and shutdowns), observed throughout all monitoring activities.

- An estimate of the number (by species) of: (i) Pinnipeds that have been exposed to the seismic activity (based on visual observation) at received levels greater than or equal to 160 dB re 1 μ Pa (rms) and/or 190 dB re 1 μ Pa (rms) with a discussion of any specific behaviors those individuals exhibited; and (ii) cetaceans that have been exposed to the seismic activity (based on visual observation) at received levels greater than or equal to 160 dB re 1 μ Pa (rms) and/or 180 dB re 1 μ Pa (rms) with a discussion of any specific behaviors those individuals exhibited.

- A description of the implementation and effectiveness of the: (i) Terms and conditions of the Biological Opinion's Incidental Take Statement (ITS); and (ii) mitigation measures of the IHA. For the Biological Opinion, the report shall confirm the implementation of each Term and Condition, as well as any conservation recommendations, and describe their effectiveness for minimizing the adverse

effects of the action on ESA-listed marine mammals.

3. Annual Reports

SAE will submit an annual report to NMFS's Permits and Conservation Division within 90 days after the end of operations on the water or at least 90 days prior to requiring a subsequent authorization, whichever comes first. The annual report will include:

- Summaries of monitoring effort (*e.g.*, total hours, total distances, and marine mammal distribution through the study period, accounting for sea state and other factors affecting visibility and detectability of marine mammals).

- Analyses of the effects of various factors influencing detectability of marine mammals (*e.g.*, sea state, number of observers, and fog/glare).

- Species composition, occurrence, and distribution of marine mammal sightings, including date, water depth, numbers, age/size/gender categories (if determinable), group sizes, and ice cover.

- Analyses of the effects of survey operations.

- Sighting rates of marine mammals during periods with and without seismic survey activities (and other variables that could affect detectability), such as: (i) Initial sighting distances versus survey activity state; (ii) closest point of approach versus survey activity state; (iii) observed behaviors and types of movements versus survey activity state; (iv) numbers of sightings/individuals seen versus survey activity state; (v) distribution around the source vessels versus survey activity state; and (vi) numbers of animals detected in the 160 dB harassment (disturbance exclusion) zone.

NMFS will review the draft annual report. SAE must then submit a final annual report to the Chief, Permits and Conservation Division, Office of Protected Resources, NMFS, within 30 days after receiving comments from NMFS on the draft annual report. If NMFS has no comment on the draft annual report, the draft report shall be considered to be the final report.

4. Notification of Injured or Dead Marine Mammals

In the unanticipated event that the specified activity clearly causes the take of a marine mammal in a manner prohibited by this Authorization, such as an injury (Level A harassment), serious injury or mortality (*e.g.*, ship-strike, gear interaction, and/or entanglement), SAE shall immediately cease the specified activities and immediately report the incident to the

Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, her designees, and the Alaska Regional Stranding Coordinators. The report must include the following information:

- Time, date, and location (latitude/longitude) of the incident;
- Name and type of vessel involved;
- Vessel's speed during and leading up to the incident;
- Description of the incident;
- Status of all sound source use in the 24 hours preceding the incident;
- Water depth;
- Environmental conditions (*e.g.*, wind speed and direction, Beaufort sea state, cloud cover, and visibility);
- Description of all marine mammal observations in the 24 hours preceding the incident;
- Species identification or description of the animal(s) involved;
- Fate of the animal(s); and
- Photographs or video footage of the animal(s) (if equipment is available).

Activities shall not resume until NMFS is able to review the circumstances of the prohibited take. NMFS shall work with SAE to determine what is necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. SAE may not resume their activities until notified by NMFS via letter or email, or telephone.

In the event that SAE discovers an injured or dead marine mammal, and the lead PSO determines that the cause of the injury or death is unknown and the death is relatively recent (*i.e.*, in less than a moderate state of decomposition as described in the next paragraph), SAE will immediately report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, her designees, and the NMFS Alaska Stranding Hotline. The report must include the same information identified in the paragraph above. Activities may continue while NMFS reviews the circumstances of the incident. NMFS will work with SAE to determine whether modifications in the activities are appropriate.

In the event that SAE discovers an injured or dead marine mammal, and the lead PSO determines that the injury or death is not associated with or related to the authorized activities (*e.g.*, previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), SAE shall report the incident to the Chief of the Permits and Conservation Division, Office of Protected Resources, NMFS, her designees, the NMFS Alaska Stranding Hotline, and the Alaska

Regional Stranding Coordinators within 24 hours of the discovery. SAE shall provide photographs or video footage (if available) or other documentation of the stranded animal sighting to NMFS and the Marine Mammal Stranding Network. Activities may continue while NMFS reviews the circumstances of the incident.

Monitoring Results From Previously Authorized Activities

While SAE has previously applied for Authorizations for work in Cook Inlet, Alaska, work was not conducted upon receiving the Authorization. SAE has previously conducted work under Incidental Harassment Authorizations in the Beaufort Sea.

Estimated Take by Incidental Harassment

Except with respect to certain activities not pertinent here, section 3(18) of the MMPA defines "harassment" as: Any act of pursuit, torment, or annoyance which (i) has the potential to injure a marine mammal or marine mammal stock in the wild; or (ii) has the potential to disturb a marine mammal or marine mammal stock in the wild by causing disruption of behavioral patterns, including, but not limited to, migration, breathing, nursing, breeding, feeding, or sheltering [Level B harassment]. Only take by Level B behavioral harassment is anticipated as a result of the seismic survey program with mitigation measures. Anticipated impacts to marine mammals are associated with noise propagation from the sound sources (*e.g.*, airguns and pingers) used in the seismic survey; no take is expected to result from vessel strikes because of the slow speed of the vessels (4–5 knots).

SAE requests authorization to take nine marine mammal species by Level B harassment. These nine marine mammal species are: Cook Inlet beluga whale; humpback whale; minke whale; killer whale; harbor porpoise; Dall's porpoise; gray whale; harbor seal; and Steller sea lion.

For impulse sounds, such as those produced by airgun(s) used in the seismic survey, NMFS uses the 160 dB re 1 μ Pa (rms) isopleth to indicate the onset of Level B harassment. The current Level A (injury) harassment threshold is 180 dB (rms) for cetaceans and 190 dB (rms) for pinnipeds. The NMFS annual aerial survey data from 2002–2012 was used to derive density estimates for each species (number of individuals/km²), and is a large source of the data in the Goetz *et al* 2012 model used for beluga density estimation in this Authorization.

Applicable Zones for Estimating "Take by Harassment"

To estimate potential takes by Level B harassment for this Authorization, as well as for mitigation radii to be implemented by PSOs, ranges to the 160 dB (rms), 180 dB, and 190 dB isopleths were estimated at three different water depths (5 m, 25 m, and 45 m). The distances to this threshold for the nearshore survey locations are provided in Table 4 in SAE's application. The distances to the thresholds provided in Table 4 in SAE's application correspond to the broadside and endfire directions.

Compared to the airguns, the relevant isopleths for the positioning pinger are quite small. The distances to the 190, 180, and 160 dB (rms) isopleths are 1 m, 3 m, and 25 m (3.3, 10, and 82 ft), respectively.

Estimates of Marine Mammal Density

SAE used one method to estimate densities for Cook Inlet beluga whales and another method for the other marine mammals in the area expected to be taken by harassment. Both methods are described in this document.

1. Beluga Whale Density Estimates

In similar fashion to a previous IHA issued to Apache, SAE used a habitat-based model developed by Goetz *et al.* (2012a). Information from that model has once again been used to estimate densities of beluga whales in Cook Inlet and we consider it to be the best available information on beluga density. A summary of the model is provided here, and additional detail can be found in Goetz *et al.* (2012a). To develop NMML's estimated densities of belugas, Goetz *et al.* (2012a) developed a model based on aerial survey data, depth soundings, coastal substrate type, environmental sensitivity index, anthropogenic disturbance, and anadromous fish streams to predict beluga densities throughout Cook Inlet. The result of this work is a beluga density map of Cook Inlet, which easily sums the belugas predicted within a given geographic area. NMML developed its predictive habitat model from the distribution and group size of beluga whales observed between 1994 and 2008. A 2-part "hurdle" model (a hurdle model in which there are two processes, one generating the zeroes and one generating the positive values) was applied to describe the physical and anthropogenic factors that influence (1) beluga presence (mixed model logistic regression) and (2) beluga count data (mixed model Poisson regression). Beluga presence was negatively associated with sources of

anthropogenic disturbance and positively associated with fish availability and access to tidal flats and sandy substrates. Beluga group size was positively associated with tidal flats and proxies for seasonally available fish. Using this analysis, Goetz *et al.* (2012) produced habitat maps for beluga presence, group size, and the expected number of belugas in each 1 km² cell of Cook Inlet. The habitat-based model developed by NMML uses a Geographic Information System (GIS). A GIS is a computer system capable of capturing, storing, analyzing, and displaying geographically referenced information; that is, data identified according to location. However, the Goetz *et al.* (2012) model does not incorporate seasonality into the density estimates. Rather, SAE factors in seasonal considerations of beluga density into the design of the survey tracklines and locations (as discussion in more detail later in this document) in addition to other factors such as weather, ice conditions, and seismic needs.

2. Non-Beluga Whale Species Density Estimates

Densities of other marine mammal species in the project area were estimated from the annual aerial surveys conducted by NMFS for Cook Inlet beluga whale between 2000 and 2012 in June (Rugh *et al.*, 2000, 2001, 2002, 2003, 2004b, 2005b, 2006, 2007; Sheldon *et al.*, 2008, 2009, 2010, 2012; Hobbs *et al.*, 2011). These surveys were flown in June to collect abundance data of beluga whales, but sightings of other marine mammals were also reported. Although these data were only collected in one month each year, these surveys provide the best available relatively long term data set for sighting information in the project area. The general trend in marine mammal sighting is that beluga whales and harbor seals are the species seen most frequently in upper Cook Inlet, with concentrations of harbor seals near haul out sites on Kalgin Island and of beluga whales near river mouths, particularly the Susitna River. The other marine mammals of interest for this authorization (humpback whales, gray whales, minke whales, killer whales, harbor porpoises, Dall's porpoises, Steller sea lions) are observed infrequently in upper Cook Inlet and more commonly in lower Cook Inlet. In addition, these densities are calculated based on a relatively large area that was surveyed, much larger than the proposed area for a given year of seismic data acquisition. Furthermore, these annual aerial surveys are conducted only in June (numbers from August surveys were not used because the area

surveyed was not provided), so it does not account for seasonal variations in distribution or habitat use of each species.

Table 5 in SAE's application provides a summary of the results of NMFS aerial survey data collected in June from 2000 to 2012. To estimate density of marine mammals, total number of individuals (other species) observed for the entire survey area by year (surveys usually last several days) was divided by the approximate total area surveyed for each year (density = individuals/km²). As noted previously, the total number of animals observed for the entire survey includes both lower and upper Cook Inlet, so the total number reported and used to calculate density is higher than the number of marine mammals anticipated to be observed in the project area. In particular, the total number of harbor seals observed on several surveys is very high due to several large haul outs in lower and middle Cook Inlet. The table below (Table 2) provides average density estimates for gray whales, harbor seals, harbor porpoises, killer whales, and Steller sea lions over the 2000–2012 period.

TABLE 2—ANIMAL DENSITIES IN COOK INLET

Species	Average density (animals/km ²)
Humpback whale	0.0024
Gray whale	9.45E-05
Minke whale	1.14E-05
Killer whale	0.0008
Dall's porpoise	0.0002
Harbor porpoise	0.0033
Harbor seal	0.28
Steller sea lion	0.008

Calculation of Takes by Harassment

1. Beluga Whales

As a result of discussions with NMFS, SAE has used the NMML model (Goetz *et al.*, 2012a) for the estimate of takes in this Authorization. SAE has established two zones (Zone 1 and Zone 2) and proposes to conduct seismic surveys within all, or part of these zones; to be determined as weather, ice, and priorities dictate, which can be found in the attached figure which will be posted at <http://www.nmfs.noaa.gov/pr/permits/incidental/oilgas.htm>

Based on information using Goetz *et al.* model (2012a), SAE derived one density estimate for beluga whales in Upper Cook Inlet (*i.e.*, north of the

Forelands) and another density estimate for beluga whales in Lower Cook Inlet (*i.e.*, south of the Forelands). The density estimate for Upper Cook Inlet is 0.0212 and is 0.0056 for Lower Cook Inlet. SAE's seismic operational area will be determined as weather, ice, and priorities dictate. SAE has requested a maximum allowed take for Cook Inlet beluga whales of 30 individuals. SAE will operate in a portion of the total seismic operation area of 3,934 km² (1,519 mi²), such that when one multiplies the anticipated beluga whale density based on the seismic survey operational area times the area to be ensonified to the 160-dB isopleth of 9.5 km (5.9 mi) and takes the number of days into consideration, estimated takes will not exceed 30 beluga whales.

In order to estimate when that level is reached, SAE is using a formula based on the total potential area of each seismic survey project zone (including the 160 dB buffer) and the average density of beluga whales for each zone. Daily take is calculated as the product of a daily ensonified area times the density in that area. Then daily take is summed across all the days of the survey until the survey approaches 30 takes.

TABLE 3—EXPECTED BELUGA WHALE TAKES, TOTAL AREA OF ZONE, AND AVERAGE BELUGA WHALE DENSITY ESTIMATES

	Expected Beluga takes from NMML model (including the 160 dB buffer)	Total area of zone (km ²) (including the 160 dB buffer)	Average take density (dx)
Zone 1—Upper Inlet	28	2,126	d ₁ = 0.0212
Zone 2—Lower Inlet	29	1,808	d ₂ = 0.0056

SAE will limit surveying in the seismic survey area (Zones 1 and 2 presented in Figures 1 and 2 of SAE's

application) to ensure a maximum of 30 beluga takes during the open water season. In order to ensure that SAE does

not exceed 30 beluga whale takes, the following equation is being used:

$$* d_x = \frac{\text{Expected Beluga Density from the NMML model in Zone X}}{\text{Total Area of Zone X including 160 dB buffer}}$$

$$* A_x = \text{Actual Area Surveyed (km}^2\text{) including 160 dB buffer in Zone X}$$

This formula also allows SAE to have flexibility to prioritize survey locations in response to local weather, ice, and operational constraints. SAE may choose to survey portions of a zone or a zone in its entirety, and the analysis in this Authorization takes this into account. Using this formula, if SAE surveys the entire area of Zone 1 (1,319 km²), then essentially none of Zone 2 will be surveyed because the input in the calculation denoted by d₂A₂ will essentially need to be zero to ensure that

the total allotted take of beluga whales is not exceeded. The use of this formula will ensure that SAE's seismic survey will not exceed 30 calculated beluga takes.

Operations are required to cease once SAE has conducted seismic data acquisition in an area where multiplying the applicable density by the total ensonified area out to the 160-dB isopleth equaled 30 beluga whales, using the equation provided above. If 30 belugas are visually observed before the

calculation reaches 30 belugas, SAE is also required to cease survey activity.

2. Humpback Whales

Although the density for humpback whales in Cook Inlet according to NMML surveys is 0.0024 animals per km², it is widely known that humpbacks occur with greater frequency in the lower inlet, and are rarely sighted in the upper inlet. Apache data has indicated that take of two humpback whales is possible, but existing observation data of humpback whales in Cook Inlet

supports that this is extremely unlikely. No more than two humpback whales have ever been recorded in a single season by NMFS observers or PSOs on board seismic vessels in Cook Inlet. Therefore, while the occurrence of two humpbacks is rare but possible, it is unlikely that more than five humpbacks will be exposed by Level B harassment based on known distribution of humpbacks in Cook Inlet.

3. Steller Sea Lions

The density estimate used in the Authorization for Steller sea lions included NMFS data that includes animals at sea lion haulouts that are within Cook Inlet, but are well south of the action area. An anomalous sighting of 20 animals occurred along the southern edge of the action area, far from any known haulouts or rookeries (such a large congregation of Steller sea lions far from haulouts or rookeries is unusual) which is included in NMFS' revised estimate of Steller sea lion take, but does not include animals observed outside of the action area. Based on monitoring reports of other seismic activities in Cook Inlet, there are typically one or two Steller sea lions within the action area per year. Two individuals were observed by Apache PSOs in 2014 and three groups totaling about four animals were observed in 2012. Because of this data, NMFS has revised its take estimate to 25 individuals, which will account for what one may expect seismic vessels implementing mitigation measures to encounter in a year, but allows for the possibility that the survey may encounter an anomalously large group such as was observed by NMFS aerial observers near the southern portion of the action area in 2006.

While the NMML survey data reports an average density of 0.008281 Steller sea lions per km² in the action area, NMFS aerial survey data indicate a maximum density of 0.003518 Steller sea lions per km² with in the action area (20 animals/5,684 km²). Given the size and location of the action area, we have determined that authorizing take of 25 Steller sea lions is most appropriate and reflects appropriate use of the best available scientific data.

4. Harbor seals

As noted above, using the daily ensonified area \times number of survey days \times density method results in a reasonable estimate of the instances of take, but likely significantly overestimates the number of individual animals expected to be taken. With most species, even this overestimated number is still very small, and additional analysis is not

really necessary to ensure minor impacts. However, because of the number and density of harbor seals in the area, a more accurate understanding of the number of individuals likely taken is necessary to fully analyze the impacts and ensure that the total number of harbor seals taken is small.

As described below, we believe that the modeled number of estimated instances of take referenced above may actually be high, based on monitoring results from the area. The density estimate from NMFS aerial surveys includes harbor seal haulouts far south of the action area that may never move to an ensonified area. Further, we believe that we can reasonably estimate the comparative number of individual harbor seals that will likely be taken, based both on monitoring data, operational information, and an general understanding of harbor seal habitat use.

Using the daily ensonified area \times number of survey days \times density formula (based on surveying 6.7 source lines per day), the number of instances of exposure above the 160-dB threshold estimated for SAE's activity in Cook Inlet is 19,315. However, when we examine monitoring data from previous activities, it is clear this number is an overestimate—compared to both aerial and vessel based observation efforts. Apache's monitoring report from 2012 details that they saw 2,474 harbor seals from 29 aerial flights (over 29 days) in the vicinity of the survey during the month of June, which is the peak month for harbor seal haulout. In surveying the literature, correction factors to account for harbor seals in water based on land counts vary from 1.2 to 1.65 (CITE). Using the most conservative factor of 1.65 (allowing us to consider that some of the other individuals on land may have entered the water at other points in day), if Apache saw 2,474 seals hauled out then there were an estimated 1,500 seals in the water during those 29 days. If, because there were only 29 surveys, we conservatively multiply by 5.5 to estimate the number of seals that might have been seen if the aerial surveys were conducted for 160 days, this yields an estimate of 8,250 instances of seal exposure in the water, which is far less than the estimated 19,315. That the number of potential instances of exposure is likely less than 19,315 is also supported by the visual observations from PSOs on board vessels. PSOs sighted a total of 285 seals in water over 147 days of activity which would rise to about 310 is adjusted to reflect 160 days of effort. Given the size of the disturbance zone for these activities, it is likely that not all harbor

seals that were exposed were seen by PSOs, however 310 is still far less than the estimate of 19,315 given by the density calculations.

Further, based on the residential nature of harbor seals and the number of patches SAE plans to shoot, it is possible to reasonably estimate the number of individual harbor seals exposed, given the instances of exposures. Based on an estimate of 32 patches in 160 days, SAE will shoot one patch in 5 days. If seals are generally returning to haulouts in the survey area over the 5 days of any given patch shoot, than any given seal in the area could be exposed a minimum of one day and a maximum of all five days, with an average of 3 days. If the original exposure estimate using density is 19,315 exposures, then when divided by three (the average number of times an animal could be exposed during the shooting of one patch), the expected number of individuals exposed is 6,438, which is approximately 28% of the population. This number is also likely an overestimate given that adjoining patches may be shot, meaning the same seals could be exposed over multiple patches. Given these multiple methods, as well as the behavioral preferences of harbor seals for haulouts in certain parts of the Inlet (Montgomery *et al.*, 2007), and high concentrations at haulouts in the lower Inlet (Boveng *et al.*), it is unreasonable to expect that more than 25% of the population, or 5,725 individuals, will be taken by Level B harassment during SAE's activity.

5. Other Marine Mammal Species

The estimated takes of other Cook Inlet marine mammals that may be potentially harassed during the seismic surveys was calculated by multiplying the following:

- Average density estimates (derived from NMFS aerial surveys from 2000–2012 and presented in Table 3 in this document)
- the area ensonified by levels ≥ 160 dB re μ Pa rms in one day (calculated using the total ensonified area per day of 414.92 km², which is derived by applying the buffer distance to the 160 dB isopleth to the area of 6 survey tracklines),
- the number of potential survey days (160).

This equation provides the number of instances of take that will occur in the duration of the survey, but overestimates the number of individual animals taken because not every exposure on every successive day is expected to be a new individual. Especially with resident species, re-

exposures of individuals are expected across the months of the survey.

SAE anticipates that a crew will collect seismic data for 8–10 hours per day over approximately 160 days over the course of 8 to 9 months each year. It is assumed that over the course of these 160 days, no more than 777 km² will be surveyed in total, but areas can

be surveyed more than once. It is important to note that environmental conditions (such as ice, wind, fog) will play a significant role in the actual operating days; therefore, these estimates are conservative in order to provide a basis for probability of encountering these marine mammal species in the project area.

Summary of Level B Harassment Takes

Table 4 outlines the density estimates used to estimate Level B harassment takes, the requested Level B harassment take levels, the abundance of each species in Cook Inlet, the percentage of each species or stock estimated to be taken, and current population trends.

TABLE 4—DENSITY ESTIMATES, LEVEL B HARASSMENT TAKE LEVELS, SPECIES OR STOCK ABUNDANCE, PERCENTAGE OF POPULATION TO BE TAKEN, AND SPECIES TREND STATUS

Species	Average density (#individuals/km ²)	Level B take	Abundance	Percentage of population	Trend
Beluga whale	Upper=0.0212; Lower=0.0056.	30	312	9.6	Decreasing.
Humpback whale	0.0024	5	7,469	0.067	Southeast Alaska increasing.
Minke whale	1.14E-05	1	1,233	0.06	No reliable information.
Gray whale	5.33E-05	7	19,126	0.033	Stable/increasing.
Killer whale	0.00082	55	2,347 (resident)	2.34	Resident stock possibly increasing.
			345 (transient)	15.9	Transient stock stable.
Harbor porpoise	0.0033	219	31,046	0.70	No reliable information.
Dall's porpoise	0.0002	14	83,400	0.016	No reliable information.
Harbor seal	0.28	5,725	22,900	25	Stable.
Steller sea lion	0.0082	25	45,649	0.055	Decreasing but with regional variability (some stable or increasing).

Analyses and Determinations

Negligible Impact Analysis

Negligible impact is “an impact resulting from the specified activity that cannot be reasonably expected to, and is not reasonably likely to, adversely affect the species or stock through effects on annual rates of recruitment or survival” (50 CFR 216.103). A negligible impact finding is based on the lack of likely adverse effects on annual rates of recruitment or survival (*i.e.*, population-level effects). An estimate of the number of Level B harassment takes, alone, is not enough information on which to base an impact determination. In addition to considering estimates of the number of marine mammals that might be “taken” through behavioral harassment, NMFS must consider other factors, such as the likely nature of any responses (their intensity, duration, etc.), the context of any responses (critical reproductive time or location, feeding, migration, etc.), as well as the number and nature of estimated Level A harassment takes, the number of estimated mortalities, effects on habitat, and the status of the species.

To avoid repetition, the discussion of our analyses applies to all the species listed in Table 4, divided in some places by group, given that the anticipated effects of the seismic survey on marine mammals are expected to be relatively similar in nature. Where there is

information about the size, status, or structure of any species or stock that would lead to a different analysis (*e.g.* beluga whales), species-specific factors have been identified. In some cases however, we add species-specific information regarding effects (including on habitat) that also informed our analysis.

Given the required mitigation and related monitoring, no injuries or mortalities are anticipated to occur as a result of SAE's seismic survey in Cook Inlet, and none are authorized. Additionally, animals in the area are not expected to incur hearing impairment (*i.e.*, TTS or PTS) or non-auditory physiological effects. The number of takes that are authorized are expected to be limited to short-term Level B behavioral harassment. The seismic airguns do not operate continuously over a 24-hour period. Rather airguns are operational for a few hours at a time totaling about 10 hours a day.

The addition of nine vessels, and noise due to vessel operations associated with the seismic survey, is not outside the present experience of marine mammals in Cook Inlet, although levels may increase locally. Given the large number of vessels in Cook Inlet and the apparent habituation to vessels by Cook Inlet beluga whales and the other marine mammals that may occur in the area, vessel activity and noise is not expected to have effects that

could cause significant or long-term consequences for individual marine mammals or their populations.

Cook Inlet beluga whales, the western DPS of Steller sea lions, and Central North Pacific humpback whales are listed as endangered under the ESA. These stocks are also considered depleted under the MMPA. The estimated annual rate of decline for Cook Inlet beluga whales was 0.6 percent between 2002 and 2012. Steller sea lion trends for the western stock are variable throughout the region with some decreasing and others remaining stable or even indicating slight increases. The Central North Pacific population of humpbacks is known to be increasing, with different techniques predicting abundance increases between 4.9 to 7 percent annually. The other seven species that may be taken by harassment during SAE's seismic survey program are not listed as threatened or endangered under the ESA nor as depleted under the MMPA.

Cetaceans. Odontocete (including Cook Inlet beluga whales, killer whales, and harbor porpoises) reactions to seismic energy pulses are usually thought to be limited to shorter distances from the airgun(s) than are those of mysticetes, in part because odontocete low-frequency hearing is assumed to be less sensitive than that of mysticetes. Belugas in the Canadian Beaufort Sea in summer appear to be

fairly responsive to seismic energy, with few being sighted within 10–20 km (6–12 mi) of seismic vessels during aerial surveys (Miller *et al.*, 2005). However, Cook Inlet belugas are more accustomed to anthropogenic sound than beluga whales in the Beaufort Sea. Therefore, the results from the Beaufort Sea surveys do not directly translate to potential reactions of Cook Inlet beluga whales. Also, due to the dispersed distribution of beluga whales in Cook Inlet during winter and the concentration of beluga whales in upper Cook Inlet from late April through early fall, belugas will likely occur in small numbers in the majority of SAE's survey area during the majority of SAE's annual operational timeframe of April through December. For the same reason, as well as mitigation measures, it is unlikely that animals will be exposed to received levels capable of causing injury.

Potential impacts to marine mammal habitat were discussed previously in this document (see the "Anticipated Effects on Habitat" section). Although some disturbance is possible to food sources of marine mammals, the impacts are anticipated to be minor enough as to not affect annual rates of recruitment or survival of marine mammals in the area. Based on the size of Cook Inlet where feeding by marine mammals occurs versus the localized area of the marine survey activities, any missed feeding opportunities in the direct project area will be minor based on the fact that other feeding areas exist elsewhere. Taking into account the mitigation measures that are planned, effects on cetaceans are generally expected to be restricted to avoidance of a limited area around the survey operation and short-term changes in behavior, falling within the MMPA definition of "Level B harassment". Animals are not expected to permanently abandon any area that is surveyed, and any behaviors that are interrupted during the activity are expected to resume once the activity ceases. Only a small portion of marine mammal habitat will be affected at any time, and other areas within Cook Inlet will be available for necessary biological functions.

In addition, of specific importance to belugas, NMFS seasonally restricts seismic survey operations in the area known to be important for beluga whale feeding, calving, or nursing. The primary location for these biological life functions occurs in the Susitna Delta region of upper Cook Inlet. NMFS proposes to implement a 16 km (10 mi) seasonal exclusion from seismic survey operations in this region from April 15–October 15. The highest concentrations

of belugas are typically found in this area from early May through September each year. NMFS has incorporated a 2-week buffer on each end of this seasonal use timeframe to account for any anomalies in distribution and marine mammal usage. Additionally, in the event that a beluga is seen outside of the seasonal restricted area and buffer, seismic operations are required to shut down if a beluga is seen anywhere in the 160dB disturbance zone.

Mitigation measures such as controlled vessel speed, dedicated marine mammal observers, speed and course alterations, and shutdowns or power downs when marine mammals are seen within defined ranges designed both to avoid injury and disturbance will further reduce short-term reactions and minimize any effects on hearing sensitivity. In all cases, the effects of the seismic survey are expected to be short-term, with no lasting biological consequence. Therefore, the exposure of cetaceans to SAE's seismic survey activity, operation is not anticipated to have an adverse effect on annual rates of recruitment or survival of the affected species or stocks of cetaceans, and therefore will have a negligible impact on them.

Pinnipeds (harbor seals, Steller sea lions). Some individual pinnipeds may be exposed to sound from the seismic surveys more than once during the timeframe of the project. Taking into account the mitigation measures that are planned, effects on pinnipeds are generally expected to be restricted to avoidance of a limited area around the survey operation and short-term changes in behavior, falling within the MMPA definition of "Level B harassment." Animals are not expected to permanently abandon any area that is surveyed, and any behaviors that are interrupted during the activity are expected to resume once the activity ceases. Only a small portion of pinniped habitat will be affected at any time, and other areas within Cook Inlet will be available for necessary biological functions. In addition, the area where the survey will take place is not known to be an important location where pinnipeds haul out. The closest known haul-out site is located on Kalgin Island, which is about 22 km from the McArthur River. More recently, some large congregations of harbor seals have been observed hauling out in upper Cook Inlet. However, mitigation measures, such as vessel speed, course alteration, and visual monitoring, and restrictions will be implemented to help reduce impacts to the animals. Therefore, the exposure of pinnipeds to sounds produced by this phase of SAE's

seismic survey is not anticipated to have an adverse effect on annual rates of recruitment or survival on those pinniped species or stocks, and therefore will have a negligible impact.

Based on the analysis contained herein of the likely effects of the specified activity on marine mammals and their habitat, and taking into consideration the implementation of the monitoring and mitigation measures, NMFS finds that SAE's seismic survey will have a negligible impact on the affected marine mammal species or stocks.

Small Numbers Analysis

The requested takes authorized annually represent 9.6 percent of the Cook Inlet beluga whale population of approximately 312 animals (Allen and Angliss, 2014), 2.34 percent of the Alaska resident stock and 15.9 percent of the Gulf of Alaska, Aleutian Island and Bering Sea stock of killer whales (1,123 residents and 345 transients), 0.70 percent of the Gulf of Alaska stock of approximately 31,046 harbor porpoises, 0.067 percent of the 7,469 Central North Pacific humpback whales, 0.06 percent of the 1,233 Alaska minke whales, 0.016 percent of the 83,400 Gulf of Alaska Dall's porpoise, and 0.033 percent of the eastern North Pacific stock of approximately 19,126 gray whales. The take requests presented for harbor seals represent 25 percent of the Cook Inlet/Shelikof stock of approximately 22,900 animals. The requested takes for Steller sea lions represent 0.055 percent of the U.S. portion of the western stock of approximately 45,649 animals. These take estimates represent the percentage of each species or stock that could be taken by Level B behavioral harassment.

NMFS finds that any incidental take reasonably likely to result from the effects of the activity, as authorized to be mitigated through this IHA, will be limited to small numbers relative to the affected species or stocks. In addition to the quantitative methods used to estimate take, NMFS also considered qualitative factors that further support the "small numbers" determination, including: (1) The seasonal distribution and habitat use patterns of Cook Inlet beluga whales, which suggest that for much of the time only a small portion of the population will be accessible to impacts from SAE's activity, as most animals are found in the Susitna Delta region of Upper Cook Inlet from early May through September; (2) other cetacean species and Steller sea lions are not common in the seismic survey area; (3) the mitigation requirements, which provide spatio-temporal

limitations that avoid impacts to large numbers of belugas feeding and calving in the Susitna Delta and limit exposures to sound levels associated with Level B harassment; (4) the monitoring requirements and mitigation measures described earlier in this document for all marine mammal species that will further reduce the amount of takes; and (5) monitoring results from previous activities that indicated low numbers of beluga whale sightings within the Level B disturbance exclusion zone and low levels of Level B harassment takes of other marine mammals. Therefore, NMFS determined that the numbers of animals likely to be taken are small.

Impact on Availability of Affected Species for Taking for Subsistence Uses

Relevant Subsistence Uses

The subsistence harvest of marine mammals transcends the nutritional and economic values attributed to the animal and is an integral part of the cultural identity of the region's Alaska Native communities. Inedible parts of the whale provide Native artisans with materials for cultural handicrafts, and the hunting itself perpetuates Native traditions by transmitting traditional skills and knowledge to younger generations (NOAA, 2007).

The Cook Inlet beluga whale has traditionally been hunted by Alaska Natives for subsistence purposes. For several decades prior to the 1980s, the Native Village of Tyonek residents were the primary subsistence hunters of Cook Inlet beluga whales. During the 1980s and 1990s, Alaska Natives from villages in the western, northwestern, and North Slope regions of Alaska either moved to or visited the south central region and participated in the yearly subsistence harvest (Stanek, 1994). From 1994 to 1998, NMFS estimated 65 whales per year (range 21–123) were taken in this harvest, including those successfully taken for food and those struck and lost. NMFS concluded that this number was high enough to account for the estimated 14 percent annual decline in the population during this time (Hobbs *et al.*, 2008). Actual mortality may have been higher, given the difficulty of estimating the number of whales struck and lost during the hunts. In 1999, a moratorium was enacted (Pub. L. 106–31) prohibiting the subsistence take of Cook Inlet beluga whales except through a cooperative agreement between NMFS and the affected Alaska Native organizations. Since the Cook Inlet beluga whale harvest was regulated in 1999 requiring cooperative agreements, five beluga whales have been struck and harvested. Those beluga whales were

harvested in 2001 (one animal), 2002 (one animal), 2003 (one animal), and 2005 (two animals). The Native Village of Tyonek agreed not to hunt or request a hunt in 2007, when no co-management agreement was to be signed (NMFS, 2008a).

On October 15, 2008, NMFS published a final rule that established long-term harvest limits on Cook Inlet beluga whales that may be taken by Alaska Natives for subsistence purposes (73 FR 60976). That rule prohibits harvest for a 5-year interval period if the average stock abundance of Cook Inlet beluga whales over the prior five-year interval is below 350 whales. Harvest levels for the current 5-year planning interval (2013–2017) are zero because the average stock abundance for the previous five-year period (2008–2012) was below 350 whales. Based on the average abundance over the 2002–2007 period, no hunt occurred between 2008 and 2012 (NMFS, 2008a). The Cook Inlet Marine Mammal Council, which managed the Alaska Native Subsistence fishery with NMFS, was disbanded by a unanimous vote of the Tribes' representatives on June 20, 2012. At this time, no harvest is expected in 2015 or, likely, in 2016.

Data on the harvest of other marine mammals in Cook Inlet are lacking. Some data are available on the subsistence harvest of harbor seals, harbor porpoises, and killer whales in Alaska in the marine mammal stock assessments. However, these numbers are for the Gulf of Alaska including Cook Inlet, and they are not indicative of the harvest in Cook Inlet.

There is a low level of subsistence hunting for harbor seals in Cook Inlet. Seal hunting occurs opportunistically among Alaska Natives who may be fishing or travelling in the upper Inlet near the mouths of the Susitna River, Beluga River, and Little Susitna River. Some data are available on the subsistence harvest of harbor seals, harbor porpoises, and killer whales in Alaska in the marine mammal stock assessments. However, these numbers are for the Gulf of Alaska including Cook Inlet, and they are not indicative of the harvest in Cook Inlet. Some detailed information on the subsistence harvest of harbor seals is available from past studies conducted by the Alaska Department of Fish & Game (Wolfe *et al.*, 2009). In 2008, 33 harbor seals were taken for harvest in the Upper Kenai-Cook Inlet area. In the same study, reports from hunters stated that harbor seal populations in the area were increasing (28.6%) or remaining stable (71.4%). The specific hunting regions identified were Anchorage, Homer,

Kenai, and Tyonek, and hunting generally peaks in March, September, and November (Wolfe *et al.*, 2009).

Potential Impacts on Availability for Subsistence Uses

Section 101(a)(5)(D) also requires NMFS to determine that the taking will not have an unmitigable adverse effect on the availability of marine mammal species or stocks for subsistence use. NMFS has defined "unmitigable adverse impact" in 50 CFR 216.103 as an impact resulting from the specified activity: (1) That is likely to reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by: (i) Causing the marine mammals to abandon or avoid hunting areas; (ii) Directly displacing subsistence users; or (iii) Placing physical barriers between the marine mammals and the subsistence hunters; and (2) That cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met.

The primary concern is the disturbance of marine mammals through the introduction of anthropogenic sound into the marine environment during the seismic survey. Marine mammals could be behaviorally harassed and either become more difficult to hunt or temporarily abandon traditional hunting grounds. The other anthropogenic activities proposed for Cook Inlet in the 2015 open water season that require an Authorization are spread throughout the Inlet and not concentrated in the area of SAE's activity, lessening the concern about spatial overlap. However, the seismic survey will not have any impacts to beluga harvests as none currently occur in Cook Inlet. Additionally, subsistence harvests of other marine mammal species are limited in Cook Inlet.

Plan of Cooperation or Measures To Minimize Impacts to Subsistence Hunts

Regulations at 50 CFR 216.104(a)(12) require IHA applicants for activities that take place in Arctic waters to provide a Plan of Cooperation or information that identifies what measures have been taken and/or will be taken to minimize adverse effects on the availability of marine mammals for subsistence purposes. The entire upper Cook unit and a portion of the lower Cook unit falls north of 60° N, or within the region NMFS has designated as an Arctic subsistence use area. There are several villages in SAE's project area that have traditionally hunted marine mammals, primarily harbor seals. Tyonek is the only tribal village in upper Cook Inlet with a tradition of hunting marine

mammals, in this case harbor seals and beluga whales. However, for either species the annual recorded harvest since the 1980s has averaged about one or fewer of either species (Fall *et al.* 1984, Wolfe *et al.* 2009, SRBA and HC 2011), and there is currently a moratorium on subsistence harvest of belugas. Further, many of the seals that are harvested are done incidentally to salmon fishing or moose hunting (Fall *et al.* 1984, Merrill and Orpheim 2013), often near the mouths of the Susitna Delta rivers (Fall *et al.* 1984) north of SAE's seismic survey area.

Villages in lower Cook Inlet adjacent to SAE's seismic area (Kenai, Salamatof, and Ninilchik) have either not traditionally hunted beluga whales, or at least not in recent years, and rarely do they harvest sea lions. Between 1992 and 2008, the only reported sea lion harvests from this area were two Steller sea lions taken by hunters from Kenai (Wolfe *et al.* 2009). These villages more commonly harvest harbor seals, with Kenai reporting an average of about 13 per year between 1992 and 2008 (Wolfe *et al.* 2009). According to Fall *et al.* (1984), many of the seals harvested by hunters from these villages were taken on the west side of the inlet during hunting excursions for moose and black bears (or outside SAE's lower Cook unit). Although marine mammals remain an important subsistence resource in Cook Inlet, the number of animals annually harvested are low, and are primarily harbor seals. Much of the harbor seal harvest occurs incidental to other fishing and hunting activities, and at areas outside of the SAE's seismic areas such as the Susitna Delta or the west side of lower Cook Inlet. Also, SAE is unlikely to conduct seismic activity in the vicinity of any of the river mouths where large numbers of seals haul out.

SAE has identified the following features that are intended to reduce impacts to subsistence users:

- In-water seismic activities will follow mitigation procedures to minimize effects on the behavior of marine mammals and, therefore, opportunities for harvest by Alaska Native communities.

SAE and NMFS recognize the importance of ensuring that ANOs and federally recognized tribes are informed, engaged, and involved during the permitting process and will continue to work with the ANOs and tribes to discuss operations and activities.

From mid-March through April 2015, SAE met with the following communities and organizations: Nikiski, Ninilchik Native Association Inc., Tyonek Native Corporation, Tyonek Village, Ninilchik, Nikiski Facilities Group, and United Cook Inlet Drift Association. These meetings were meant to inform the audience about the project as well as listen to concerns and comments. There will also be a review of permit stipulations and a permit matrix developed for the crews. The means of communications and contacts list is developed and implemented into the project, found in SAE's Plan of Cooperation. The use of PSOs/MMO's on board the vessels will ensure that appropriate precautions are taken to avoid harassment of marine mammals. If a conflict does occur with project activities involving subsistence or fishing, the project manager will immediately contact the affected party to resolve the conflict. If avoidance is not possible, the project manager will initiate communication with the Operations Supervisor to resolve the issue and plan an alternative course of action. The communications will involve the Permits Manager and the Anchorage Office of SAE.

Unmitigable Adverse Impact Analysis and Determination

The project will not have any effect on beluga whale harvests because no beluga harvest will take place in 2015. Additionally, the seismic survey area is not an important native subsistence site for other subsistence species of marine mammals, and Cook Inlet contains a relatively small proportion of marine mammals utilizing Cook Inlet; thus, the number harvested is expected to be extremely low. The timing and location of subsistence harvest of Cook Inlet harbor seals may coincide with SAE's project, but because this subsistence hunt is conducted opportunistically and at such a low level (NMFS, 2013c), SAE's program is not expected to have an impact on the subsistence use of harbor seals. Moreover, the survey will result in only temporary disturbances. Accordingly, the specified activity will not impact the availability of these other marine mammal species for subsistence uses.

NMFS anticipates that any effects from SAE's seismic survey on marine mammals, especially harbor seals and Cook Inlet beluga whales, which are or

have been taken for subsistence uses, will be short-term, site specific, and limited to inconsequential changes in behavior and mild stress responses. NMFS does not anticipate that the authorized taking of affected species or stocks will reduce the availability of the species to a level insufficient for a harvest to meet subsistence needs by: (1) Causing the marine mammals to abandon or avoid hunting areas; (2) directly displacing subsistence users; or (3) placing physical barriers between the marine mammals and the subsistence hunters; and that cannot be sufficiently mitigated by other measures to increase the availability of marine mammals to allow subsistence needs to be met. Based on the description of the specified activity, the measures described to minimize adverse effects on the availability of marine mammals for subsistence purposes, and the required mitigation and monitoring measures, NMFS has determined that there will not be an unmitigable adverse impact on subsistence uses from SAE's activities.

Endangered Species Act (ESA)

There are three marine mammal species listed as endangered under the ESA with confirmed or possible occurrence in the project area: The Cook Inlet beluga whale, the western DPS of Steller sea lion, and the Central North Pacific humpback whale. In addition, the action could occur within 10 miles of designated critical habitat for the Cook Inlet beluga whale. NMFS's Permits and Conservation Division has initiated consultation with NMFS' Alaska Region Protected Resources Division under section 7 of the ESA. This consultation concluded on May 7, 2015, when a Biological Opinion was issued. The Biological Opinion determined that the issuance of an IHA is not likely to jeopardize the continued existence of the Cook Inlet beluga whales, Central North Pacific humpback whales, or western distinct population segment of Steller sea lions or destroy or adversely modify Cook Inlet beluga whale critical habitat. Finally, the Alaska region issued an Incidental Take Statement (ITS) for Cook Inlet beluga whales, humpback whales, and Steller sea lions. The ITS contains reasonable and prudent measures implemented by the terms and conditions to minimize the effect of this take.

National Environmental Policy Act (NEPA)

NMFS prepared an EA that includes an analysis of potential environmental effects associated with NMFS' issuance of an IHA to SAE to take marine mammals incidental to conducting a 3D seismic survey program in Cook Inlet, Alaska. NMFS has finalized the EA and prepared a FONSI for this action.

Therefore, preparation of an Environmental Impact Statement is not necessary.

Authorization

As a result of these determinations, NMFS has issued an IHA to SAE for the take of marine mammals incidental to conducting a seismic survey program in Cook Inlet, Alaska, from May 13, 2015

through May 12, 2016, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated.

Dated: May 12, 2015.

Donna S. Wieting,

*Director, Office of Protected Resources,
National Marine Fisheries Service.*

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Part III

The President

Proclamation 9280—National Safe Boating Week, 2015

Proclamation 9281—Emergency Medical Services Week, 2015

Proclamation 9282—World Trade Week, 2015

Proclamation 9283—Armed Forces Day, 2015

Memorandum of May 15, 2015—Delegation of Functions Under the Foreign
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Presidential Documents

Title 3—

Proclamation 9280 of May 15, 2015

The President

National Safe Boating Week, 2015

By the President of the United States of America**A Proclamation**

America's waterways are conduits to creating lasting memories, to discovering worlds of adventure, and to generating economic opportunity. On our rivers, lakes, and oceans, a father brings his daughter fishing for the first time, and a young man learns his ancestors' trade; a family takes a hard-earned vacation, and a captain cares for her prized vessel. During National Safe Boating Week, we remember that protecting the promise of our waterways rests on each of us.

Before embarking on any journey on the water, Americans should prepare for potential hazards by remembering to check the forecast, filing a float plan with a family member or friend, performing a vessel safety check, and confirming their boat has essential safety equipment and communications tools, including life jackets, fire extinguishers, and weather radios. Operators should also be ready for sudden weather changes that can affect a voyage—fog, thunderstorms, and wind shifts can often occur without warning, and knowing how to respond to dangerous weather can save lives. By always wearing life jackets and never drinking while boating, boaters and passengers can further ensure their safety and well-being and help guarantee a great day out on the water does not end in tragedy.

At times, disaster still strikes, even when we are prepared. But thanks to the courageous women and men who serve our Nation and protect our waters, the United States Coast Guard stands always ready to help keep Americans safe at sea. As we look forward to spending time with loved ones this summer and taking advantage of all our scenic waterways have to offer, I encourage everyone to visit www.USCGBoating.org to learn more about responsible boating. Together, we can enjoy the beauty and bounty of the water and avoid preventable injuries and property damage.

In recognition of the importance of safe boating practices, the Congress, by joint resolution approved June 4, 1958 (36 U.S.C. 131), as amended, has authorized and requested the President to proclaim annually the 7-day period prior to Memorial Day weekend as "National Safe Boating Week."

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, do hereby proclaim May 16 through May 22, 2015, as National Safe Boating Week. I encourage all Americans who participate in boating activities to observe this occasion by learning more about safe boating practices and taking advantage of boating education.

IN WITNESS WHEREOF, I have hereunto set my hand this fifteenth day of May, in the year of our Lord two thousand fifteen, and of the Independence of the United States of America the two hundred and thirty-ninth.

A handwritten signature in black ink, appearing to be Barack Obama's signature, consisting of a large 'B' followed by 'arack' and 'Obama' in a cursive style.

Presidential Documents

Proclamation 9281 of May 15, 2015

Emergency Medical Services Week, 2015

By the President of the United States of America

A Proclamation

Few moments are as terrifying as those when medical emergencies strike. But thanks to the courageous efforts of all who provide emergency medical services (EMS), Americans know they and their loved ones will be cared for in their hours of greatest need. As we mark Emergency Medical Services Week, we thank these selfless women and men, and we recommit to upholding an EMS system that is ready every day for every emergency.

Time and again, our Nation has witnessed the critical role EMS professionals play in the lives of our people. Whether 911 dispatchers, emergency medical technicians, paramedics, EMS medical directors, law enforcement officers, firefighters, or nurses, they are dedicated first responders who operate at the crossroads between health care, public safety, and public health—often without pay as volunteers. In intense, high-stress situations, these professionals and volunteers come to the aid of their fellow Americans, easing suffering and frequently making the difference between life and death.

This week, we celebrate the EMS providers who risk their own lives and health to protect the well-being of others. At scenes of accidents and natural disasters, in times of personal crisis and national tragedy, they offer essential services and demonstrate the strength and resilience of the American people. As these heroes rush forward for us, may we remember to stand for them, and may we never forget that an efficient, high-quality EMS system is crucial to ensuring care during any emergency.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim May 17 through May 23, 2015, as Emergency Medical Services Week. I encourage all Americans to observe this occasion by showing their support for their local EMS providers and taking steps to improve their personal safety and preparedness.

IN WITNESS WHEREOF, I have hereunto set my hand this fifteenth day of May, in the year of our Lord two thousand fifteen, and of the Independence of the United States of America the two hundred and thirty-ninth.

A handwritten signature in black ink, appearing to be Barack Obama's signature, consisting of a large 'B' followed by 'arack' and 'Obama' in a cursive style.

Presidential Documents

Proclamation 9282 of May 15, 2015

World Trade Week, 2015

By the President of the United States of America

A Proclamation

After 6 years of tremendous progress, America has fought its way back from the worst recession of our lifetimes. With the grit and determination of working families, we have rebuilt our economy, retooled the auto industry, and revitalized American manufacturing. Our economy is growing and creating jobs at the fastest pace in over a decade, and as this progress continues, we must ensure that all Americans can share in our Nation's prosperity. This conviction is at the core of middle-class economics, and few things are as vital to ensuring that our economy benefits all Americans as trade. Trade allows our people to work, our businesses to thrive, and our goods and services to compete on a global scale. This week, we reaffirm the importance of trade, and we redouble our efforts to position our workers, farmers, manufacturers, and businesses at the center of the 21st-century global economy.

America's future depends on unlocking economic opportunities beyond our borders, where 95 percent of the world's customers live. Last year was the fifth straight record-breaking year for United States exports, supporting 11.7 million American jobs and contributing nearly one-third of our country's overall economic growth since 2009. Continuing this steady progress will strengthen America's middle class because businesses that export tend to hire more, pay their workers more, and invest more in innovation and research.

Americans prosper when foreign markets are open and our trading partners play by the rules. My Administration's efforts to advance trade are focused on opening markets to American products and ensuring the rules of the trading system are fair and reflect our values, including on issues such as workers' rights and the environment. That is why I am committed to leading on trade—creating a race to the top for higher wages and better working conditions—with a progressive, values-driven agenda that will ensure the United States is able to shape the rules of the global economy to benefit our workers and create economic opportunities for our people and all those around the globe.

In the Asia-Pacific, the Trans-Pacific Partnership (TPP) agreement will open new doors of opportunity for American workers and businesses in the world's fastest growing region. Through the TPP, the United States is updating NAFTA, instituting stronger, fully enforceable labor and environmental standards, and ensuring our trade partners play by the rules. With American leadership, this agreement will remove trade barriers and provide our Nation's exporters and innovators access to these markets. And to protect our workers and improve the lives of workers across the globe, it will advance labor protections—including a minimum wage, a prohibition on child labor and forced labor, and the right to form unions. This agreement will level the playing field for our workers and increase exports of products stamped "Made in the USA."

Smart trade agreements are important to helping middle-class families get ahead. My Administration has redoubled our efforts to enforce existing trade agreements, and we are working to ensure all Americans have the

knowledge and skills to succeed in an export-driven economy. Our work has produced real results, protecting jobs here at home and making it easier for businesses to reach consumers living outside our borders, and it has demonstrated that when the playing field is level, American workers and businesses do not just compete—they win.

During World Trade Week, we renew our commitment to leading on trade in order to support more jobs and increase wages here at home. For nearly a century, a key component of this leadership has been strong bipartisan support for trade negotiating authority, which the Congress now has an opportunity to upgrade and, in so doing, shape how the United States and our trading partners engage on trade in the 21st century. Generations of hardworking Americans have made our economy the greatest in the world, and together, we can ensure that trade safeguards our country's promise as a land of opportunity where everyone can make it if they try.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, by virtue of the authority vested in me by the Constitution and the laws of the United States, do hereby proclaim May 17 through May 23, 2015, as World Trade Week. I encourage all Americans to visit www.WhiteHouse.gov/Trade and to observe this week with events, trade shows, and educational programs that celebrate and inform Americans about the benefits of trade to our Nation and the global economy.

IN WITNESS WHEREOF, I have hereunto set my hand this fifteenth day of May, in the year of our Lord two thousand fifteen, and of the Independence of the United States of America the two hundred and thirty-ninth.

A handwritten signature in black ink, appearing to be "Barack Obama", written in a cursive style. The signature is positioned to the right of the main text block.

Presidential Documents

Proclamation 9283 of May 15, 2015

Armed Forces Day, 2015

By the President of the United States of America

A Proclamation

At the heart of our Nation is the idea that we are each endowed with certain unalienable rights. We hold this truth to be self-evident, but from the moment a small band of patriots first came together to declare independence, we have never believed it to be self-executing. From Lexington and Concord to Iraq and Afghanistan, brave women and men have fought to defend the blessings of liberty and freedom and to protect the way of life we cherish. On Armed Forces Day, we salute the unbroken chain of Soldiers, Sailors, Airmen, Marines, and Coast Guardsmen who have continuously secured and renewed the promise of our Nation.

This year, as we celebrate the 70th anniversary of the end of World War II, we honor the generation that triumphed over tyranny and laid a foundation for peace around the world. In the face of oppression, more than 16 million Americans left everything they knew and everyone they loved to fight for freedom far from home. Today, this legacy of extraordinary service is carried forward by patriots who protect the same liberties our parents and grandparents fought for. Year after year, tour after tour, the members of our Armed Forces serve with honor and distinction. Their sacrifice makes our Nation more free and more safe, and in their example, we see the best of America.

As we pay tribute to today's servicemen and women, we acknowledge the obligations we have to all who serve in our name. This sacred trust requires that we fulfill our promise and guarantee that these patriots, and the families who serve alongside them, have all the resources and benefits they have earned and deserve—supporting them as they carry out their missions and ensuring they get their shot at the American dream they helped to defend. As a Nation, we are called to recognize the enormous debt of gratitude we owe the members of our Armed Forces, and we must never forget those who laid down their lives to safeguard our freedoms, or their loved ones who carry their legacies forward.

Today and every day, let us celebrate the women and men who make our military the greatest fighting force the world has ever known. As a grateful Nation, let us show our appreciation by working to uphold the values they protect every day and by continuing to strive to build a country worthy of their enormous sacrifice.

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, and Commander in Chief of the Armed Forces of the United States, continuing the precedent of my predecessors in office, do hereby proclaim the third Saturday of each May as Armed Forces Day. I direct the Secretary of Defense on behalf of the Army, Navy, Air Force, and Marine Corps, and the Secretary of Homeland Security on behalf of the Coast Guard, to plan for appropriate observances each year, with the Secretary of Defense responsible for encouraging the participation and cooperation of civil authorities and private citizens.

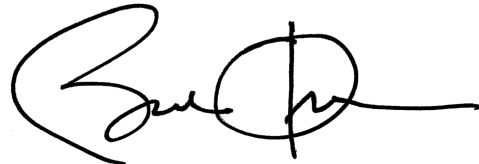
I invite the Governors of the United States and its Territories, and appropriate officials of all units of government, to provide for the observance of Armed Forces Day within their jurisdiction each year in an appropriate manner

designed to increase public understanding and appreciation of the Armed Forces of the United States. I also invite veterans, civic leaders, and organizations to join in the observance of Armed Forces Day.

Finally, I call upon all Americans to display the flag of the United States at their homes on Armed Forces Day, and I urge citizens to learn more about military service by attending and participating in the local observances of the day. I also encourage Americans to volunteer at organizations that provide support to our troops and their families.

Proclamation 9129 of May 16, 2014, is hereby superseded.

IN WITNESS WHEREOF, I have hereunto set my hand this fifteenth day of May, in the year of our Lord two thousand fifteen, and of the Independence of the United States of America the two hundred and thirty-ninth.



Presidential Documents

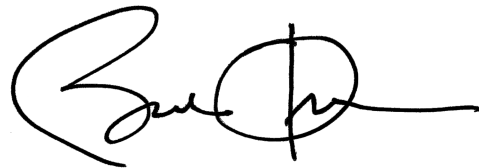
Memorandum of May 15, 2015

Delegation of Functions Under the Foreign Narcotics Kingpin Designation Act

Memorandum for the Secretary of the Treasury

By the authority vested in me as President by the Constitution and the laws of the United States of America, including section 301 of title 3, United States Code, I hereby delegate the functions conferred upon the President by sections 804(b), (c), (g), and (h) of the Foreign Narcotics Kingpin Designation Act (21 U.S.C. 1903(b), (c), (g), and (h)), to the Secretary of the Treasury.

You are authorized and directed to publish this memorandum in the *Federal Register*.

A handwritten signature in black ink, appearing to be Barack Obama's signature, consisting of a large 'B' followed by a circle and a horizontal line.

THE WHITE HOUSE,
Washington, May 15, 2015

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