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Contents

Federal Register

Vol. 80, No. 236

Wednesday, December 9, 2015

Separate Parts In This Issue

Part II
Presidential Documents, 76623–76628

Reader Aids
Consult the Reader Aids section at the end of this issue for phone numbers, online resources, finding aids, and notice of recently enacted public laws.

To subscribe to the Federal Register Table of Contents LISTSERV electronic mailing list, go to http://listserv.access.gpo.gov and select Online mailing list archives, FEDREGTOC-L, Join or leave the list (or change settings); then follow the instructions.

CFR PARTS AFFECTED IN THIS ISSUE

A cumulative list of the parts affected this month can be found in the Reader Aids section at the end of this issue.

2 CFR
5900 76355

3 CFR
Proclamations:
9378 76625
9379 76627

10 CFR
431 76355
Proposed Rules:
26 76394

12 CFR
217 76374

14 CFR
23 76379
39 76381
Proposed Rules:
39 (3 documents) 76398, 76400, 76402

15 CFR
730 76383
734 76383
736 76383
742 76383
744 76383
745 76383

21 CFR
510 76384
520 (2 documents) 76384, 76387
522 76384
524 76384
558 (2 documents) 76384, 76387

40 CFR
180 76388
Proposed Rules:
52 76403

44CFR
64 76391

50CFR
Proposed Rules:
679 (2 documents) 76405, 76425

Rules and Regulations

Federal Register
Vol. 80, No. 236
Wednesday, December 9, 2015

GULF COAST ECOSYSTEM RESTORATION COUNCIL

2 CFR Part 5900

[Docket Number: 112092015–1111–09]

Federal Awarding Agency Regulatory Implementation of Office of Management and Budget's Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards

AGENCY: Gulf Coast Ecosystem Restoration Council.

ACTION: Final rule.

SUMMARY: The Gulf Coast Ecosystem Restoration Council publishes this rule to adopt as a final rule, without change, a joint interim final rule published with the Office of Management and Budget (OMB) for all Federal award-making agencies that implemented guidance on Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (Uniform Guidance). This rule is necessary to incorporate into a regulation and thus bring into effect the Uniform Guidance as required by OMB for the Gulf Coast Ecosystem Restoration Council.

DATES: This rule is effective January 8, 2016.

FOR FURTHER INFORMATION CONTACT: Kristin Smith at 504–444–3558 or *Kristin.smith@restorethegulf.gov.*

SUPPLEMENTARY INFORMATION: On December 19, 2014, OMB issued an interim final rule that implemented for all Federal award-making agencies the final guidance on Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards (Uniform Guidance). In that interim final rule, Federal awarding agencies, including the Gulf Coast Ecosystem Restoration Council (Council), joined together to implement the Uniform Guidance in their respective chapters of title 2 of the CFR, and, where approved by OMB, implemented any exceptions to the Uniform Guidance by including the relevant language in their regulations. The interim final rule went into effect on December 26, 2014. The public comment period for the interim final rule closed on February 17, 2015. The interim final rule was modified on July 22, 2015 (80 FR 43310) to add Appendix XII (Award Term and Condition for Recipient Integrity and Performance Matters) as required by section 872 of Public Law 110–417, as amended (41 U.S.C. 2313).

The Council publishes this final rule to adopt the provisions of the interim final rule. The Council did not request any exceptions to the Uniform Guidance and did not provide any language beyond what was included in 2 CFR part 200. The Council did not receive any public comments on its regulations. Accordingly, the Council makes no changes to the interim final rule.

Classification

Paperwork Reduction Act

This rule contains no collections of information subject to the requirements of the Paperwork Reduction Act (44 U.S.C. 3506). 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 Paperwork Reduction Act unless that collection displays a currently valid OMB Control Number.

Regulatory Flexibility Act

Because notice and opportunity for comment are not required pursuant to 5 U.S.C. 553 or any other law, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are inapplicable. Therefore, a regulatory flexibility analysis is not required and has not been prepared.

Executive Order 12868

Pursuant to Executive Order 12866, OMB has determined this final rule to be not significant.

Accordingly, the interim rule amending 2 CFR part 5900 which was published at 79 FR 75867 on December 19, 2014, is adopted as a final rule without change.

Will D. Spoon,

Program Analyst, Gulf Coast Ecosystem Restoration Council.

[FR Doc. 2015–30922 Filed 12–8–15; 8:45 am]

BILLING CODE 3510–EA–P

DEPARTMENT OF ENERGY

10 CFR Part 431

[Docket Number EERE–2010–BT–STD–0043]

RIN 1904–AC36

Energy Conservation Program: Energy Conservation Standards for High-Intensity Discharge Lamps

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Final determination.

SUMMARY: The Energy Policy and Conservation Act of 1975 (EPCA), as amended, requires DOE to prescribe test procedures and energy conservation standards for high-intensity discharge (HID) lamps for which it has determined that standards would be technologically feasible and economically justified, and would result in significant energy savings. In this final determination, DOE determines that energy conservation standards for high-intensity discharge (HID) lamps do not meet these criteria.

DATES: This final determination is effective December 9, 2015.

ADDRESSES: The docket, which includes **Federal Register** notices, framework documents, public meeting attendee lists and transcripts, comments, and other supporting documents/materials, is available for review at 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 publicly available, such as information that is exempt from public disclosure.

The docket Web page can be found at: *https://www1.eere.energy.gov/buildings/appliance_standards/rulemaking.aspx/ruleid/23.* This Web page contains a link to the docket for this final determination on the regulations.gov site. The regulations.gov Web page contains

simple instructions on how to access all documents, including public comments, in the docket.

For further information on how to review the docket, contact Ms. Brenda Edwards at (202) 586–2945 or by email: *Brenda.Edwards@ee.doe.gov.*

FOR FURTHER INFORMATION CONTACT:

Ms. Lucy deButts, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Program, EE–2J, 1000 Independence Avenue SW., Washington, DC, 20585–0121. Telephone: (202) 287–1604. Email: *high_intensity_discharge_lamps@ee.doe.gov.*

Ms. Francine Pinto, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW., Washington, DC, 20585–0121. Telephone: (202) 586–7432. Email: *francine.pinto@hq.doe.gov.*

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Synopsis of the Determination

DOE determines that energy conservation standards for HID lamps do not meet the EPCA requirements described in section II.A, that such standards be technologically feasible, economically justified, and result in a significant conservation of energy. (42 U.S.C. 6317(a)(1)) Specifically, DOE concludes that standards for high-pressure sodium (HPS) lamps are not technologically feasible, and that standards for mercury vapor (MV) and metal halide (MH) lamps are not economically justified (HPS, MV, and MH lamps are subcategories of HID lamps). DOE's determination is based on analysis of several efficacy levels (ELs) as a means of conserving energy. These analyses and DOE's results are described in the following sections of this final determination and in the final determination technical support document (TSD).

II. Introduction

A. Legal Authority

Title III of EPCA (42 U.S.C.6291, *et seq.*), Public Law 94–163, sets forth a variety of provisions designed to improve energy efficiency. Part C of title III, which for editorial reasons was re-designated as Part A–1 upon incorporation into the U.S. Code (42 U.S.C. 6311–6317), establishes the ''Energy Conservation Program for Certain Industrial Equipment,'' a program covering certain industrial equipment, which include the HID lamps that are the subject of this determination. Pursuant to EPCA, DOE must prescribe test procedures and energy conservation standards for HID lamps for which DOE has determined that standards would be technologically feasible, economically justified, and would result in a significant conservation of energy. (42 U.S.C. 6317(a)(1))

B. Background

1. Current Standards

There are currently no Federal energy conservation standards for HID lamps.

2. History of Standards Rulemaking for High-Intensity Discharge Lamps

Pursuant to EPCA, in 2010 DOE published a final determination [1] (hereafter the ''2010 determination'') that standards for certain HID lamps are technologically feasible, economically justified, and would result in significant energy savings (a positive determination). 75 FR 37975 (July 1, 2010). As a result of the 2010 determination, DOE initiated a test procedure rulemaking for the specified lamps (see section IV.A).

DOE also initiated an energy conservation standards rulemaking in response to the 2010 determination. On February 28, 2012, DOE published in the **Federal Register** an announcement of the availability of a framework document for energy conservation standards for HID lamps, as well as a notice of a public meeting. 77 FR 11785. DOE held a public meeting on March 29, 2012, to receive feedback in response to the framework document.

DOE gathered additional information and performed interim analyses to develop potential energy conservation standards for HID lamps. On February 28, 2013, DOE published in the **Federal Register** an announcement of the availability of the interim technical support document (the interim TSD)

[1] The final determination is available at: *http://www.regulations.gov/#!documentDetail;D=EERE-2006-DET-0112-0002.*

and notice of a public meeting (hereafter, the ''February 2013 notice'') to discuss and receive comments on the following matters: (1) The equipment classes DOE planned to analyze; (2) the analytical framework, models and tools that DOE used to evaluate standards; (3) the results of the interim analyses performed by DOE; and (4) potential standard levels that DOE could consider. 78 FR 13566. In the February 2013 notice, DOE requested comment on issues that would affect energy conservation standards for HID lamps or that DOE should address in the following analysis stage. The interim TSD is available at: *http://www.regulations.gov/#!documentDetail;D=EERE-2010-BT-STD-0043-0016.*

The interim TSD summarized the activities DOE undertook in developing standards for HID lamps. It also described the analytical framework that DOE uses in a typical energy conservation standards rulemaking, including a description of the methodology, the analytical tools, and the relationships among the various analyses that are part of the rulemaking. The interim TSD presented and described in detail each analysis DOE performed, including descriptions of inputs, sources, methodologies, and results.

The public meeting for the interim analysis took place on April 2, 2013. At this meeting, DOE presented the methodologies and results of the analyses set forth in the interim TSD. Interested parties discussed the following major issues at the public meeting: The scope of the interim analysis, equipment classes, sapphire arc tube technology, the engineering analysis (including representative units, baselines, and candidate standard levels [CSLs]), the life-cycle cost (LCC) and payback period (PBP) analysis, and the shipment analysis.

On October 21, 2014, DOE published a notice of proposed determination (NOPD) in the **Federal Register** which proposed that energy conservations standards for HID lamps were not justified. 79 FR 62910. In conjunction with the NOPD, DOE also published on its Web site the complete TSD for the NOPD, which incorporated the analyses DOE conducted and technical documentation for each analysis. The NOPD TSD was accompanied by the LCC spreadsheet, the national impact analysis (NIA) spreadsheet, and the manufacturer impact analysis (MIA) spreadsheet—all of which are available in the rulemaking docket EERE–2010–BT–STD–0043 at: *http://www.regulations.gov/#!docketDetail;D=EERE-2010-BT-STD-0043.*

In the NOPD, DOE invited comment, particularly on the following issues: (1) The HID lamps selected for and excluded from analysis of economic justification for standards, (2) the decision to analyze equal wattage replacement lamps, as well as the methodology used to select the equal wattage replacement lamps, (3) the decision to include replacement pathways other than full fixture replacement, and (4) the proposal of a negative determination stating that standards for HID lamps were not justified. 79 FR 62910 (October 21, 2014).

The NOPD detailed that there would not be a public meeting unless one was requested by stakeholders. Because a public meeting was not requested, DOE did not hold a public meeting for the NOPD.

All comments received by DOE in response to the NOPD were considered in this final determination, including those received during the reopened comment period. 80 FR 6016 (February 4, 2015). Chapter 2 of this TSD summarizes and responds to comments received on the NOPD.

DOE concludes in this final determination that standards for HID lamps do not meet the statutory requirements for the establishment of standards, based either upon lack of technological feasibility, economic justification, or significant energy savings.

3. Changes From the 2010 Determination

As discussed previously, DOE published a determination in 2010 that concluded that standards for certain HID lamps would be technologically feasible, economically justified, and would result in significant energy savings. 75 FR 37975 (July 1, 2010) Since the publication of the 2010 determination, DOE held public meetings, received written comments, conducted interviews with manufacturers, and conducted additional research. Based upon this new information, DOE revised its analyses for potential HID lamp energy conservation standards. The following sections summarize the major changes in assumptions and analyses between the 2010 determination and this final determination, in which DOE concludes that standards for HID lamps are either not technologically feasible or not economically justified.

a. Color

In contrast to the 2010 determination, DOE established separate equipment classes based on correlated color temperature (CCT) in this final determination. CCT represents the color appearance of a light source and is expressed in kelvin (K). The higher the CCT, the cooler or more blue the light appears, and the lower the CCT, the warmer or more red the light appears. HID lamps are available with a wide range of CCT values depending on lamp type and design. DOE's analysis of commercially available lamp manufacturer catalog data concluded that CCT is correlated with lamp efficacy. DOE determined that higher-CCT lamps are less efficacious than lower CCT lamps of the same wattage. Because CCT is an approximation of the color appearance of a lamp, commercial consumers typically specify different CCTs for different applications. Some lamp substitutions are not suitable because certain applications have specific color requirements (typically indoor applications that demand white light). Because CCT affects HID lamp efficacy and impacts consumer utility, DOE established separate equipment classes based on CCT.

DOE established two different equipment classes based on CCT for MH and MV lamps, ≥2800 K to ≤4500 K range (hereafter referred to as the 2800–4500 K CCT range) and >4500 and <7000 K (hereafter referred to as the 4501–6999 K CCT range). HPS lamps are the only HID lamps available below 2800 K. DOE investigated higher efficacy replacement options for HPS lamps such that commercial consumers could save energy while maintaining the utility (*e.g.,* CCT) of the lamp type. As discussed in section V.A.3, DOE concluded no technology options exist for improving the efficacy of HPS lamps. Therefore, DOE determined standards for HPS lamps are not technologically feasible and did not conduct a full economic analysis on standards for HID lamps below 2800 K in this final determination.

b. Replacement Options

In the 2010 determination, DOE assumed that any commercial consumer purchasing a compliant lamp would choose a reduced-wattage lamp more efficacious than their existing non-compliant lamp. However, DOE received feedback from manufacturer interviews that not all commercial consumers would choose to reduce wattage in response to standards for HID lamps. Some commercial consumers would choose to continue using their

existing wattage (*e.g.,* a more-efficacious, increased lumen output lamp that complies with standards, but has the same wattage) for the convenience and lower cost of not purchasing a new fixture and/or ballast that may be necessary for use with the reduced-wattage lamp. During interviews, manufacturers also indicated that some commercial consumers may not understand the metrics used to measure light output and would opt to keep lamps at their existing wattage because wattage is the metric they most commonly consider for lighting. These commercial consumers would experience an increase in light output, but no energy savings. As a result of this information, DOE modeled a portion of commercial consumers replacing lamps with more efficacious, equal wattage lamps in addition to commercial consumers replacing lamps with reduced wattage lamps in this final determination. This change reduced potential energy savings and corresponding operating cost savings associated with HID lamp standards. See chapter 5 of the final determination TSD for more details about the engineering analysis and chapter 11 of the final determination TSD for more detail about the NIA.

c. Shipments

For the 2010 determination, DOE calculated the installed base of HID lamps using historical shipments data provided by the National Electrical Manufacturers Association (NEMA). DOE projected future lamp shipments based on the lamp lifetimes and operating scenarios developed for the LCC and PBP analysis, as well as estimated market and substitution trends in the no-new-standards case and standards case. 75 FR 37975, 37981 (July 1, 2010). The shipments analysis and NIA for this final determination (see sections V.H and V.I) draw upon the same historical NEMA lamp shipments data in calculating the installed base of HID lamps, supplemented with additional shipments data and manufacturer input on HID market trends. DOE's current projections illustrate a sharper decline in and lower overall shipments of HID lamps than projected in the 2010 determination.

d. Summary of Changes

Since the publication of the 2010 determination, DOE received additional information from public meetings, written comments, manufacturer interviews, and further research. This new information led to the following major changes presented in this final determination: (1) The determination that equipment classes should be separated based on CCT; (2) the introduction of a percentage of commercial consumers replacing lamps with more efficacious, equal wattage lamps in response to potential standards; and (3) the revision downward of projected HID lamp shipments in the shipments analysis, based on supplemental data and manufacturer input collected on HID market trends. By creating separate equipment classes for CCT, DOE determined that standards for HPS lamps are not technologically feasible. Additionally, in modeling some commercial consumers replacing lamps with more efficacious, equal wattage lamps and revising downward projected shipments of HID lamps, the NIA yielded negative NPVs for all analyzed levels in this final determination (see section VI.C for a discussion of NIA results in the final determination). As such, DOE determined that standards for MV and MH lamps would not be economically justified.

III. Issues Affecting the Lamps Analyzed by This Determination

A. Lamps Analyzed by This Determination

HID is the generic name for a family of lamps including MV, MH, and HPS lamps. Although low-pressure sodium lamps are often included in the family, the definition of HID lamp set forth in EPCA requires the arc tube wall loading to be greater than three watts per square centimeter. (42 U.S.C. 6291(46)) Because low-pressure sodium lamps do not satisfy this requirement, they are not considered HID lamps according to the statute, and are therefore not considered in this final determination. Definitions for these lamps are discussed in chapter 2 of the final determination TSD.

DOE first analyzed the potential energy savings of the HID lamp types that fall within the EPCA definition of ''HID lamp,'' as well as the technological feasibility of more efficient lamps for each lamp type. For the HID lamps that met these ladder EPCA criteria, DOE conducted a full economic analysis with the LCC analysis, NIA, and MIA (see sections V.G, V.I, and V.J below) to determine whether standards would be economically justified.

After considering the comments on the NOPD, DOE determined that there are no design options to increase the efficacy of HPS lamps, indicating that standards for this lamp technology are not technologically feasible. Specifically, DOE determined that sapphire arc tube technology is not a valid technology option for increased efficacy in HPS lamps (see section V.A.3.b below for further details).

Regarding MV and MH lamps, available information indicated that energy conservation standards for certain MV and MH lamps were both technologically feasible and would save a significant amount of energy. Therefore, DOE conducted the full economic analysis for those lamp types to determine whether standards would be economically justified. Specifically, DOE analyzed the economic justification of potential energy conservation standards for MH lamps with a rated wattage greater than or equal to 50 watts (W) and less than or equal to 2000 W, and CCTs greater than or equal to 2800 K and less than 7000 K. DOE also analyzed the economic justification of energy conservation standards for MV lamps with a rated wattage greater than or equal to 50 W and less than or equal to 1000 W, and CCTs greater than or equal to 3200 K and less than or equal to 6800 K. Table III.1 provides a summary of the HID lamps analyzed.

TABLE III.1—CCT AND WATTAGE RANGES ANALYZED

Lamp Type	Wattage	CCT
MV	50–1000 W	3200–6800 K
MH	50–2000 W	2800–6999 K

In summary, DOE excluded the following HID lamps from analysis of economic justification based on these lamps not meeting the criteria of significant energy savings or technological feasibility:

- HPS lamps;
- directional HID lamps;
- self-ballasted HID lamps;
- lamps designed to operate exclusively on electronic ballasts;
- high-color rendering index (CRI) MH lamps (a CRI greater than or equal to 95);
- colored MH lamps (a CRI of less than 40);
- MV lamps that are double-ended, have a non-screw base, and have no outer bulb;
- HID lamps that have a CCT of 5000–6999 K, have a non-screw base, and have non-T-shaped bulbs; and
- electrodeless HID lamps.

See chapter 2 of the final determination TSD for a more detailed discussion of which HID lamps did and did not meet the criteria for analysis and of the rationale behind those selections.

B. Standby/Off Mode

EPCA defines active mode as the condition in which an energy-using

piece of equipment is connected to a main power source, has been activated, and provides one or more main functions. (42 U.S.C. 6295)(gg)(1)(A)) Standby mode is defined as the condition in which an energy-using piece of equipment is connected to a main power source and offers one or more of the following user-oriented or protective functions: facilitating the activation or deactivation of other functions (including active mode) by remote switch (including remote control), internal sensor, or timer; or providing continuous functions, including information or status displays (including clocks) or sensor-based functions. *Id.* Off mode is defined as the condition in which an energy-using piece of equipment is connected to a main power source, and is not providing any standby or active mode function. *Id.*

DOE conducted an analysis of the applicability of standby mode and off mode energy use for HID lamps. DOE determined that HID lamps that are subject of this final determination do not operate in standby mode or off mode. HID lamps do not offer any secondary user-oriented or protective functions or continuous standby mode functions. Because all energy use of HID lamps is accounted for in the active mode, DOE did not analyze potential standards for lamp operation in standby and off mode in this final determination.

C. Metric

To analyze energy conservation standards related to HID lamps, DOE must select a metric for rating the performance of the lamps. DOE used initial efficacy for consideration and analysis of energy conservation standards for HID lamps. Additionally, because dimming is uncommon for HID lamps, DOE assessed initial efficacy of all lamps while operating at full light output.

D. Coordination of the Metal Halide Lamp Fixture and HID Lamp Rulemakings

For this final determination, DOE used shared data sources between the metal halide lamp fixture (MHLF) standards rulemaking (Docket No. EERE–2009–BT–STD–0018) [2] and this HID lamp determination. DOE's analysis of HID lamps assumed that MHLFs purchased after the compliance date of the MHLF final rule use ballasts compliant with those standards.

IV. General Discussion

A. Test Procedures

EPCA sets forth generally applicable criteria and procedures for DOE's adoption and amendment of test procedures. (42 U.S.C. 6314) Manufacturers of covered equipment must use these test procedures to certify to DOE that their equipment complies with EPCA energy conservation standards and to quantify the efficiency of their equipment. Also, these test procedures must be used whenever testing is required in an enforcement action to determine whether covered equipment complies with EPCA standards.

Based on comments received on a HID lamps test procedure notice of proposed rulemaking (NOPR) published on December 15, 2011 (76 FR 77914) and subsequent additional research, DOE proposed revisions to and clarification of the proposed HID lamp test procedures. DOE published these proposed revisions and clarifications in a test procedure supplemental notice of proposed rulemaking (SNOPR).[3] 79 FR 29631 (May 22, 2014). The analysis in this final determination is based upon the test procedures put forward in the test procedure SNOPR.

B. Technological Feasibility

1. General

In the final determination, DOE conducted a screening analysis based on information gathered on all current technology options and prototype designs that could improve the efficacy of HID lamps. As the first step in such an analysis, DOE developed a list of technology options for consideration in consultation with manufacturers, design engineers, and other interested parties. DOE then determined which of those means for improving efficacy are technologically feasible. DOE considers technologies incorporated in commercially available products or in working prototypes to be technologically feasible, pursuant to 10 CFR part 430, subpart C, appendix A, section 4(a)(4)(i).

After DOE has determined that particular technology options are technologically feasible, it further evaluates each technology option in light of the following additional screening criteria: (1) Practicability to manufacture, install, and service; (2) adverse impacts on product utility or availability; and (3) adverse impacts on health or safety. 10 CFR part 430, subpart C, appendix A, section 4(a)(4)(ii)–(iv). For further details on the screening analysis, see section V.B of this final determination and chapters 2 and 4 of the final determination TSD.

2. Maximum Technologically Feasible Levels

When DOE analyzes a new standard for a type or class of covered product, it must determine the maximum improvement in energy efficiency or maximum reduction in energy use that is technologically feasible for that product. (42 U.S.C. 6295(p)(1)) Accordingly, in the engineering analysis, DOE determined the maximum technologically feasible (''max-tech'') improvements in efficacy for HID lamps, using the design parameters for the most efficacious products available on the market or in working prototypes. (See chapter 5 of the final determination TSD.) The max-tech levels that DOE determined for this final determination are described in chapters 2 and 5 of the final determination TSD.

C. Energy Savings

1. Determination of Savings

For each EL in each equipment class, DOE projected energy savings for the equipment that is the subject of this final determination purchased in the 30-year period that would begin in the expected year of compliance with any new standards (2018–2047). The savings are measured over the entire lifetime of equipment purchased in the 30-year analysis period.[4] DOE quantified the energy savings attributable to each EL as the difference in energy consumption between each standards case and the no-new-standards case. The no-new-standards case represents a projection of energy consumption in the absence of new mandatory efficacy standards, and it considers market forces and policies that affect demand for more efficient equipment.

DOE used its NIA spreadsheet model to estimate energy savings from potential standards for the equipment that are the subject of this final determination. The NIA spreadsheet model (described in section V.I of this final determination) calculates energy

[2] A final rule for MHLF energy conservation standards was published in February 2014. For more information on the MHLF standards rulemaking, see *http://www.regulations.gov/#!docketDetail;D=EERE-2009-BT-STD-0018.*

[3] The HID lamp test procedure SNOPR is available at: *http://www.regulations.gov/#!documentDetail;D=EERE-2010-BT-TP-0044-0013.*

[4] In the past DOE presented energy savings results for only the 30-year period that begins in the year of compliance. In the calculation of economic impacts, however, DOE considered operating cost savings measured over the entire lifetime of equipment purchased in the 30-year period. DOE has chosen to modify its presentation of national energy savings to be consistent with the approach used for its national economic analysis.

savings in site energy, which is the energy directly consumed by equipment at the locations where they are used. DOE reports national energy savings on an annual basis in terms of the source (primary) energy savings, which is the savings in the energy that is used to generate and transmit the site energy. To convert site energy to source energy, DOE derived annual conversion factors from the model used to prepare the Energy Information Administration's (EIA's) *Annual Energy Outlook 2015* (*AEO2015*).

DOE estimated full-fuel-cycle (FFC) energy savings. 76 FR 51281 (August 18, 2011), as amended at 77 FR 49701 (August 17, 2012). The FFC metric includes the energy consumed in extracting, processing, and transporting primary fuels, and thus presents a more complete picture of the impacts of energy efficiency standards. DOE's evaluation of FFC savings is driven in part by the National Academy of Science's (NAS) report on FFC measurement approaches for DOE's Appliance Standards Program.[5] The NAS report discusses that FFC was primarily intended for energy efficiency standards rulemakings where multiple fuels may be used by particular equipment. In the case of this final determination pertaining to HID lamps, only a single fuel—electricity—is consumed by the equipment. DOE's approach is based on the calculation of an FFC multiplier for each of the energy types used by covered equipment. Although the addition of FFC energy savings in rulemakings is consistent with the recommendations, the methodology for estimating FFC does not project how fuel markets would respond to a potential standards rulemaking. The FFC methodology simply estimates how much additional energy may be displaced if the estimated fuel were not consumed by the equipment covered in this final determination. It is also important to note that inclusion of FFC savings does not affect DOE's choice of potential standards. For more information on FFC energy savings, see section V.I of this determination, and chapter 11 and appendix 11A of the final determination TSD.

2. Significance of Savings

To adopt standards that are more stringent for a covered product, DOE must determine that such action would result in ''significant'' energy savings. (42 U.S.C. 6295(o)(3)(B)) Although the term ''significant'' is not defined in the Act, the U.S. Court of Appeals, in *Natural Resources Defense Council* v. *Herrington*, 768 F.2d 1355, 1373 (D.C. Cir. 1985), indicated that Congress intended ''significant'' energy savings in the context of EPCA to be savings that were not ''genuinely trivial.'' DOE analyzed the energy savings for each potential standard level for each equipment class in this final determination (presented below in section VI.C.1).

D. Economic Justification

In determining whether potential energy conservation standards for HID lamps would be economically justified, DOE analyzed the results of the following analyses: (1) The market and technology assessment that characterizes where and how HID lamps are used; (2) an engineering analysis that estimates the relationship between equipment costs and energy use; (3) an LCC and PBP analysis that estimates the costs and benefits to users from increased efficacy in HID lamps; (4) an NIA that estimates potential energy savings on a national scale and potential economic costs and benefits that would result from improving efficacy in the considered HID lamps; and (5) an MIA that determines the potential impact new standards for HID lamps would have on manufacturers.

V. Methodology and Discussion

A. Market and Technology Assessment

1. General

In conducting the market and technology assessment for this final determination, DOE developed information that provides an overall picture of the market for the equipment concerned, including the purpose of the products, the industry structure, and the market characteristics. This activity included both quantitative and qualitative assessments based on publicly available information. The subjects addressed in the market and technology assessment for this final determination include: Equipment classes and manufacturers; historical shipments; market trends; regulatory and non-regulatory programs; and technologies that could improve the efficacy of the HID lamps under examination. See chapter 3 of the final determination TSD for further discussion of the market and technology assessment.

2. Equipment Classes

For this final determination, DOE divided equipment into classes by: (a) The type of energy used, (b) the capacity of the equipment, or (c) any other performance-related features that justifies different standard levels, such as features affecting consumer utility. (42 U.S.C. 6295(q)) DOE then considered establishing separate standard levels for each equipment class based on the criteria set forth in 42 U.S.C. 6317(a).

In this final determination, DOE analyzed CCT, wattage, bulb finish, and luminaire characteristic as the equipment-class-setting factors. DOE analyzed 24 equipment classes for HID lamps, as shown in Table V.1. See chapters 2 and 3 of the final determination TSD for a more detailed discussion on equipment classes analyzed for HID lamps.[6]

TABLE V.1—EQUIPMENT CLASSES ANALYZED IN FINAL DETERMINATION

CCT Range (K)	Wattage (W)	Bulb finish *	Luminaire characteristic **
≥2800 and ≤4500	≥50 and ≤400	Clear	Enclosed.
			Open.
		Coated	Enclosed.
			Open.
	>400 and ≤1000	Clear	Enclosed.

[5] ''Review of Site (Point-of-Use) and Full-Fuel-Cycle Measurement Approaches to DOE/EERE Building Appliance Energy-Efficiency Standards,'' (Academy report) was completed in May 2009 and included five recommendations. A copy of the study can be downloaded at: *http://www.nap.edu/catalog/12670/review-of-site-point-of-use-and-full-fuel-cycle-measurement-approaches-to-doeeere-building-appliance-energy-efficiency-standards-letter-report.*

[6] When delineating the equipment class CCT ranges of ≥2800 K and ≤4500 K and of >4500 K and <7000 K in text, DOE uses the shorthand 2800 K–4500 K and 4501 K–6999 K, respectively. Similarly, when writing out the equipment class wattage ranges of ≥50 W and ≤400 W, >400 W and ≤1000 W, and >1000 W and ≤2000 W in text, DOE uses the shorthand 50 W–400 W, 401 W–1000 W, and 1001 W–2000 W, respectively.

TABLE V.1—EQUIPMENT CLASSES ANALYZED IN FINAL DETERMINATION—Continued

CCT Range (K)	Wattage (W)	Bulb finish *	Luminaire characteristic **
			Open.
		Coated	Enclosed.
			Open.
	>1000 and ≤2000	Clear	Enclosed.
			Open.
		Coated	Enclosed.
			Open.
>4500 and <7000	≥50 and ≤400	Clear	Enclosed.
			Open.
		Coated	Enclosed.
			Open.
	>400 and ≤1000	Clear	Enclosed.
			Open.
		Coated	Enclosed.
			Open.
	>1000 and ≤2000	Clear	Enclosed.
			Open.
		Coated	Enclosed.
			Open.

* MV lamps regardless of bulb finish are placed in the clear equipment classes for their respective CCT and wattage.
** MV lamps are placed in the enclosed equipment classes for their respective wattage and CCT.

3. Technology Options

The following sections detail the technology options that DOE analyzed in this final determination as viable means of increasing the efficacy of HID lamps.

a. Mercury Vapor

MV ballasts, other than specialty application MV ballasts, have been banned from import or production in the United States since January 1, 2008. (42 U.S.C. 6295(ee)) This ban effectively limits the installation of new MV fixtures and ballasts, meaning the only MV lamps currently sold are replacement lamps. DOE understands there is limited industry design emphasis on MV lamps and that there are limited methods to improving the efficacy of MV lamps using MV technology. In this final determination, DOE found that change of technology is the sole method by which commercial consumers of MV lamps can obtain higher lamp efficacies.

b. High-Pressure Sodium Lamps

HPS lamps are already very efficacious (up to 150 lumens per watt), but have intrinsically poor color quality. DOE did not identify any technology options currently utilized in commercially available HPS lamps that increase lamp efficacy. In the interim analysis, DOE identified academic papers that indicated potential increases in efficacy were possible by constructing the arc tubes out of a sapphire material, or single crystal aluminum oxide. Several manufacturers produced HPS lamps with a sapphire arc tube beginning in the late 1970s, but these lamps have since been discontinued.

In the interim analysis, DOE found that sapphire material had five percent greater transmission of light compared to the traditionally used polycrystalline alumina (PCA) material and equated this with a potential five percent increase in lamp efficacy. 78 FR 13566 (Feb. 28, 2013). However, during manufacturer interviews held between the interim analysis and NOPD, DOE received feedback from manufacturers that the increase in transmission associated with using sapphire material instead of PCA does not necessarily result in an equal increase in efficacy. This is because the material does not transmit all wavelengths uniformly, which affects the perceived brightness of the light. Because these lamps are no longer manufactured, DOE cannot empirically validate the potential increase in efficacy using sapphire arc tubes. Additionally, DOE received feedback that HPS lamps using sapphire arc tubes are much more susceptible to catastrophic failure and would require enclosed fixtures for safe operation. Currently, all HPS lamps that are commercially available can be used in open fixtures. An enclosed fixture would reduce the efficacy of the sapphire HPS system (due to absorption in the lens used to enclose the fixture) and likely negate any small increase in efficacy gained from using sapphire arc tubes.

For these reasons, DOE does not believe that the use of sapphire arc tubes would increase the efficacy of HPS lamps in practice. As such, DOE concluded sapphire arc tubes are not a valid technology option for HPS lamps. Further, DOE found no other viable technology options to improve the efficacy of HPS lamps. Therefore, DOE determined standards for HPS lamps are not technologically feasible and did not analyze standards for HPS lamps in the final determination.

c. Metal Halide

DOE identified a number of technology options that could improve MH lamp efficacy. These technology options include improving arc tube design through the use of ceramic arc tubes, optimization of the arc tube, and optimization of the arc tube fill gas.

d. Summary

Table V.2 summarizes the technology options identified for HID lamps in this final determination. For more detail on the technology options that DOE analyzed to improve MV, HPS, and MH lamp efficacy, see chapters 2 and 3 of the final determination TSD.

TABLE V.2—FINAL DETERMINATION HID LAMP TECHNOLOGY OPTIONS

Lamp type	Technology option	Description
HPS	None	No technology options available.
MV	Change lamp type	Use MH technology instead of MV technology.
MH	Ceramic arc tubes	Use CMH technology instead of quartz MH lamps.
	Arc tube optimization	Design the shape of the arc tube so that it facilitates an increase in MH vapor pressure; change the thickness of quartz, optimize electrode positioning, improve the purity of the materials; and improve the manufacturing processes to ensure the consistency and quality of the arc tube construction.
	Fill gas optimization	Optimize the gas fill pressure and chemistry.

B. Screening Analysis

DOE consults with industry, technical experts, and other interested parties to develop a list of technology options for consideration. In the screening analysis, DOE determines which technology options to consider further and which to screen out.

Appendix A to subpart C of 10 CFR part 430, ''Procedures, Interpretations, and Policies for Consideration of New or Revised Energy Conservation Standards for Consumer Products'' (the Process Rule), sets forth procedures to guide DOE in its consideration and promulgation of new or revised energy conservation standards. These procedures elaborate on the statutory criteria provided in 42 U.S.C. 6295(o). In particular, sections 4(b)(4) and 5(b) of the Process Rule provide guidance to DOE for determining which technology options are unsuitable for further consideration: Technological feasibility, practicability to manufacture, install and service, adverse impacts on product utility or product availability, and adverse impacts on health or safety.

For MH lamps, DOE identified ceramic arc tubes as a technology option that can improve lamp efficacy relative to quartz arc tubes. Ceramic arc tubes are a technology option used in all CMH lamps. Although CMH lamps are commercially available from 50–400 W, they are not manufactured from 401–2000 W.[7] DOE learned from manufacturers that it is technologically possible to create 401–1000 W CMH lamps on an individual scale in laboratory conditions. However, manufacturers may have difficulty producing these lamps on a scale large enough to serve the entire market. Because of this, DOE determined that ceramic arc tubes for 401–2000 W MH lamps do not pass the criterion that they be practicable to manufacture, install, and service. In this final determination, DOE did not consider ceramic arc tubes as design options for MH lamps from 401–2000 W.

All other technology options for MV and MH lamps meet the screening criteria and are considered as design options in the engineering analysis. These design options include changing from a MV lamp to a MH lamp, using ceramic arc tubes instead of quartz arc tubes, optimizing the arc tube shape and design, and optimizing the fill gas pressure and chemistry. These design options are summarized in Table V.3. Chapters 2 and 4 of the final determination TSD provide additional information regarding the design options considered in the final determination.

TABLE V.3—FINAL DETERMINATION HID LAMP DESIGN OPTIONS

Lamp type	Design option	Description
HPS	None	No design options available.
MV	Change lamp type	Use MH technology instead of MV technology.
MH	Ceramic arc tubes (50–400 W)	Use CMH technology instead of quartz MH lamps.
	Arc tube optimization	Design the shape of the arc tube so that it facilitates an increase in MH vapor pressure; change the thickness of quartz, alter the fill gas chemistry; optimize electrode positioning; improve the purity of the materials; and improve the manufacturing processes to ensure the consistency and quality of the arc tube construction.
	Fill gas optimization	Optimize the gas fill pressure and chemistry.

C. Engineering Analysis

For this final determination, DOE derived ELs in the engineering analysis and lamp end-user prices in the equipment price determination. The engineering analysis focuses on selecting commercially available lamps that incorporate design options that improve efficacy. The following discussion summarizes the general steps and results of the engineering analysis.

1. Representative Equipment Classes

When multiple equipment classes exist, to streamline analysis, DOE selects certain classes as ''representative,'' primarily because of their high market volumes and unique performance characteristics. DOE then scales the ELs from representative equipment classes to those equipment classes it does not analyze directly. Table V.4 lists the equipment classes that DOE selected as representative.

[7] There is one example of a CMH lamp in this wattage range. It is an 860 W CMH lamp that is designed to be used on a 1000 W ballast and can operate on both probe-start and pulse-start ballasts. Because this lamp employs proprietary technology, DOE does not use this lamp as an example of CMH lamps being commercially available from 401–1000 W.

TABLE V.4—REPRESENTATIVE EQUIPMENT CLASSES FOR HID LAMPS

CCT Range (K)	Wattage (W)	Bulb finish *	Luminaire characteristic **
≥2800 and ≤4500	≥50 and ≤400	Clear	Enclosed.
	>400 and ≤1000	Clear	Enclosed.
	>1000 and ≤2000	Clear	Enclosed.

* MV lamps regardless of bulb finish are placed in the clear equipment classes for their respective CCT and wattage.
** MV lamps are placed in the enclosed equipment classes for their respective wattage and CCT.

2. Baseline Lamps and Representative Lamp Types

Because no Federal energy conservation standards exist for HID lamps, the baseline lamps represent the most common, least efficacious lamps sold within the equipment class. For each baseline lamp, DOE selected more efficacious replacement lamps to measure potential energy-saving improvements. DOE refers to the baseline lamp and its more efficacious replacements collectively herein as a ''representative lamp type.'' The representative lamp type is named by its baseline unit. For example, the 400 W MV representative lamp type refers to the 400 W MV baseline lamp and all of its more efficacious replacements.

DOE used performance data presented in manufacturer catalogs to determine lamp efficacy. DOE also considered other lamp characteristics in choosing the most appropriate baseline for each equipment class. These characteristics include the wattage and technology type (*i.e.*, MH or MV), among others. For some of the representative lamp types, DOE selected multiple baseline models to ensure consideration of different high-volume lamps and their associated commercial consumer economics. For example, although MV lamps are the least efficacious products available, the HID market has largely shifted away from MV lamps and commercial consumers of MH lamp-and-ballast systems incur different costs than commercial consumers of MV lamp-and-ballast systems. For these reasons, DOE selected both MV and MH lamps as baselines for certain equipment classes.

Table V.5 lists the baseline lamps and representative lamp types. See chapters 2 and 5 of the final determination TSD for additional detail.

TABLE V.5—BASELINE LAMPS AND REPRESENTATIVE LAMP TYPES

CCT Range	Wattage	Bulb finish *	Luminaire characteristic **	Representative lamp type	Baseline lamp type	Baseline wattage
2800–4500 K	50–400 W	Clear	Enclosed	100 W MV	MV	100
					MH	70
				175 W MV	MV	175
					MH	150
				250 W MV	MV	250
					MH	175
				400 W MV	MV	400
					MH	250
				400 W MH	MH	400
	401–1000 W	Clear	Enclosed	1000 W MV	MV	1000
					MH	750
				1000 W MH	MH	1000
	1001–2000 W	Clear	Enclosed	2000 W MH	MH	2000

* MV lamps regardless of bulb finish are placed in the clear equipment classes for their respective CCT and wattage.
** MV lamps are placed in the enclosed equipment classes for their respective wattage and CCT.

3. More Efficacious Substitutes

DOE selected commercially available HID lamps with efficacies above the baseline as replacements for the baseline model(s) in each representative equipment class. When selecting more efficacious substitute lamps, DOE considered only design options that meet the criteria outlined in the screening analysis (see section V.B). Depending on the equipment class (see Table V.6), DOE analyzed standard efficacy quartz MH, high efficacy quartz MH, and CMH lamps as more efficacious substitutes for the baseline lamps.

TABLE V.6—MORE EFFICACIOUS SUBSTITUTE LAMP TYPES

Equipment class	More efficacious substitute lamps analyzed
50–400 W	Standard efficacy quartz MH, high efficacy quartz MH, and CMH lamps.
401–1000 W	Standard efficacy quartz MH and high efficacy quartz MH lamps.
1001–2000 W	High efficacy quartz MH lamps.

In this final determination, DOE considered a number of different potential pathways a commercial consumer might choose when identifying replacements that are more efficacious. When purchasing a new and compliant lamp, a commercial consumer can purchase just a new lamp, a new lamp-and-ballast system, or an entirely new fixture. For each of these options, a commercial consumer can also choose between a replacement that

maintains the wattage of the existing system or a reduced wattage replacement. See chapters 2 and 5 of the final determination TSD for additional detail.

4. Determine Efficacy Levels

DOE developed ELs based on: (1) The design options associated with the equipment class studied and (2) the max-tech EL for that class. DOE's ELs for this final determination are based on manufacturer catalog data. Table V.7 summarizes the EL equations for each representative equipment class. More information on the described ELs can be found in chapters 2 and 5 of the final determination TSD.

TABLE V.7—EFFICACY LEVEL EQUATIONS FOR THE REPRESENTATIVE EQUIPMENT CLASSES

Representative equipment class	Minimum initial efficacy † (lm/W)		
	EL 1	EL 2	EL 3
2800–4500 K, 50–400 W, clear */enclosed **	$38.5 \times P^{0.1350}$	$44.4 \times P^{0.1350}$	$40.4 \times P^{0.1809}$.
2800–4500 K, 401–1000 W, clear/enclosed	0.0116×P + 81.8	0.0173×P + 92.8	N/A.
2800–4500 K, 1001–2000 W, clear/enclosed	93.4	N/A	N/A.

* MV lamps are placed in the clear equipment classes for their respective CCT and wattage regardless of bulb finish.
** MV lamps are placed in the enclosed equipment classes for their respective wattage and CCT.
† P is defined as the rated wattage of the lamp.

5. Scaling to Equipment Classes Not Directly Analyzed

For the equipment classes not analyzed directly, DOE scaled the ELs from the representative to non-representative equipment classes based on efficacy ratios observed in manufacturer catalog data. For example, DOE calculated an average percentage difference in efficacy between lamps in different equipment classes (one representative and one non-representative) and used this percentage difference to scale the ELs from the representative to the non-representative equipment classes. Table V.8 lists the scaling factors calculated in the final determination analysis.

TABLE V.8—SCALING FACTORS

Bulb finish	Luminaire characteristic	CCT
0.945	0.950	0.812

* To calculate the efficacy requirement for a scaled equipment class, the representative equipment class equation is multiplied by each scaling factor of the characteristics of the equipment class that differ from the representative class.

6. HID Systems

In this final determination, DOE only analyzed standards for HID lamps. However, HID lamps are just one component of an HID lighting system. HID lamps must be paired with specific ballasts to regulate the current and power supplied to the lamp. These lamp-and-ballast systems are then housed in an HID lamp fixture [8] to protect the components, enable mounting, and direct the light to the target area. When considering changes to HID lamps, DOE recognizes the importance of also analyzing the impact on both the ballast and the fixture. Additional components may also be required if placing a new lamp-and-ballast system in an existing fixture, including an appropriate lamp socket and ballast brackets. See chapter 2, chapter 5, appendix 5A, and appendix 5B of the final determination TSD for additional detail.

D. Equipment Price Determination

The equipment price determination describes the methodology followed in developing end-user prices for HID lamps and manufacturer selling prices (MSPs) for ballasts, fixtures, and retrofit kit components (brackets and sockets) analyzed in this final determination. DOE developed ballast and fixture MSPs in addition to lamp MSPs because a change of ballast and fixture is often required when switching to a more efficacious lamp. In addition, DOE developed MSPs for brackets and sockets packaged in lamp-and-ballast retrofit kits because commercial consumers will sometimes also have the option of keeping the fixture housing and installing a new lamp-and-ballast system. These systems will often require a change in the socket and brackets used for mounting the ballast.

For HID lamps, DOE developed three sets of discounts from blue-book prices, representing low (State procurement), medium (electrical distributors), and high (Internet retailers) end-user lamp prices. For MH ballasts, fixtures, sockets, and brackets, DOE performed teardown analyses to estimate manufacturer production costs (MPCs) and a manufacturer markup analysis to estimate the MSPs. For additional detail on the equipment price determination, see chapters 2, 6, and appendix 6A of the final determination TSD.

E. Markups Analysis

Markups are multipliers that relate MSPs to end-user purchase prices, and vary with the distribution channel through which commercial consumers purchase the equipment. DOE estimated end-user prices for representative HID lamp designs directly, rather than develop MSPs from a bill of materials and manufacturer markup analysis (final determination TSD chapter 6).[9] However, DOE estimated price markups to calculate end-user prices from MSPs for HID ballasts and fixtures as inputs to the LCC and PBP analysis, and the NIA (chapters 9 and 11, respectively, of the final determination TSD). Appendix 6A of the final determination TSD describes the process by which DOE developed MPCs and MSPs for HID ballasts and fixtures. Chapters 2 and 7 of the final determination TSD provides additional detail on the markup analysis for developing end-user prices for HID ballasts and fixtures.

F. Energy Use Analysis

For the energy use analysis, DOE estimated the energy use of HID lamp-and-ballast systems in actual field conditions. The energy use analysis provided the basis for other DOE analyses, particularly assessments of the energy savings and the savings in operating costs that could result from DOE's adoption of potential new standard levels. DOE multiplied annual usage (in hours per year) by the lamp-and-ballast system input power (in watts) to develop annual energy use estimates. Chapters 2 and 8 of the final determination TSD provide a more detailed description of DOE's energy use analysis.

[8] Here, DOE uses the term ''fixture'' to refer to the enclosure that houses the lamp and ballast.

[9] For this final determination, DOE used estimated markups to develop MSPs for HID lamps for the MIA (see chapter 12 of the final determination TSD).

G. Life-Cycle Cost and Payback Period Analysis

DOE conducted the LCC and PBP analysis to evaluate the economic effects of potential energy conservation standards for HID lamps on individual commercial consumers. For any given EL, DOE calculated the PBP and the change in LCC relative to an estimated baseline equipment EL. The LCC is the total commercial consumer expense over the life of the equipment, consisting of purchase, installation, and operating costs (expenses for energy use, maintenance, and repair). To compute the operating costs, DOE discounted future operating costs to the time of purchase and summed them over the lifetime of the equipment. The PBP is the estimated amount of time (in years) it takes commercial consumers to recover the increased purchase cost (including installation) of more efficacious equipment through lower operating costs. DOE calculates the PBP by dividing the change in purchase cost (normally higher) by the change in average annual operating cost (normally lower) that results from the more stringent standard. Chapters 2 and 9, and appendices 9A and 9B, of the final determination TSD provide details on the spreadsheet model and all the inputs to the LCC and PBP analysis.

H. Shipments Analysis

DOE projected equipment shipments to calculate the national effects of potential standards on energy use, NPV, and future manufacturer cash flows. DOE developed shipment projections based on an analysis of key market drivers for each considered HID lamp type. In DOE's shipments model, shipments of equipment are driven by new construction, stock replacements, and other types of purchases. The shipments model takes an accounting approach, tracking market shares of each equipment class and the vintage of units in the existing stock. Stock accounting uses equipment shipments as inputs to estimate the age distribution of in-service equipment stocks for all years. The age distribution of in-service equipment stocks is a key input to calculations of both the NES and the NPV, because operating costs for any year depend on the age distribution of the stock. Chapters 2 and 10 of the final determination TSD provide a more detailed description of DOE's shipments analysis.

I. National Impact Analysis

DOE's NIA assessed the cumulative NES and the cumulative national economic impacts of ELs (*i.e.*, potential standards cases) considered for the equipment classes analyzed. The analysis measures economic impacts using the NPV metric, which presents total commercial consumer costs and savings expected to result from potential standards at specific ELs, discounted to their present value. For a given EL, DOE calculated the NPV, as well as the NES, as the difference between a no-new-standards case projection and the standards-case projections. Chapters 2 and 11, and appendices 11A and 11B, of the final determination TSD provide details on the spreadsheet model and all the inputs to the NIA.

J. Manufacturer Impact Analysis

DOE conducted an MIA for HID lamps to estimate the financial impact of potential energy conservation standards on manufacturers. The MIA has both quantitative and qualitative aspects. The quantitative part of the MIA relies on the Government Regulatory Impact Model (GRIM), an industry cash-flow model customized for HID lamps covered in this final determination. The key GRIM inputs are industry cost structure data, shipment data, equipment costs, and assumptions about markups and conversion costs. The key MIA output is industry net present value (INPV). DOE used the GRIM to calculate cash flows using standard accounting principles and to compare changes in INPV between a no-new-standards case and various ELs at each equipment class (the standards cases). The difference in INPV between the no-new-standards case and standards cases represents the financial impact of potential energy conservation standards on HID lamp manufacturers. Different sets of assumptions (scenarios) produce different INPV results. The qualitative part of the MIA addresses how potential standards could impact manufacturing capacity and industry competition, as well as any differential impact the potential standard could have on any particular subgroup of manufacturers. See chapter 12 of this final determination TSD for additional details on DOE's MIA.

VI. Analytical Results

A. Economic Impacts on Individual Commercial Consumers

To evaluate the net economic impact of standards on commercial consumers, DOE conducted an LCC and PBP analysis for each EL. In general, higher efficacy equipment would affect commercial consumers in two ways: (1) Annual operating expenses would decrease; and (2) purchase prices would increase. Section V.G of this determination discusses the inputs DOE used for calculating the LCC and PBP.

The key outputs of the LCC analysis are mean LCC savings relative to the baseline equipment, as well as a probability distribution or likelihood of LCC reduction or increase, for each efficacy level and equipment class.[10] In its LCC analysis, DOE traditionally assumes that the commercial consumer purchases a covered design upon the compliance date of potential standards (in this case, 2018). The resulting values then necessarily reflect the projected market for HID equipment in 2018, and are reported by equipment class in Table VI.1, Table VI.2, and Table VI.3.

The LCC analysis also estimates the fraction of commercial consumers for which the LCC will decrease (net benefit), remain unchanged (no impact), or increase (net cost) relative to the baseline case. The last column in each table contains the median PBPs for the commercial consumers purchasing a design compliant with the efficacy level.

In evaluating these results relative to cumulative NPV, it is important to note that the LCC and PBP analysis does not reflect the long-term dynamics of the declining market for HID equipment, which are captured in the NIA shipments period (2018—2047). As a result, the average LCC savings—based on the projected 2018 market—may be positive in some cases (*e.g.*, EL 2 and EL 3 for the >2800 K and ≤4500 K and ≥50 W to ≤400 W equipment class), whereas the cumulative NPV results for these ELs are negative (see Table VI.16). DOE explored the effects of the declining HID market on average LCC savings by conducting a sensitivity analysis based on the projected market in 2022, with results reported by equipment class in Table VI.4, Table VI.5, and Table VI.6. These results show a general erosion of average LCC savings, and demonstrate increasing consistency with the cumulative NPV results. For the >2800 K and ≤4500 K and ≥50 W to ≤400 W equipment class, average LCC savings for EL 2 become negative, with a majority of affected commercial consumers remaining negatively impacted. Average LCC savings for EL 3 in this equipment class—while still positive—are significantly diminished, with a majority of affected commercial consumers experiencing a net cost. Following this trend, DOE would expect LCC savings for EL 3 to become increasingly negative for an increasing

[10] Commercial consumers, in the no-new-standards scenario, who buy the equipment at or above the EL under consideration, would be unaffected (no impact) if the potential standard were to be set at that EL.

proportion of affected commercial consumers over the NIA analysis period.

Based on this sensitivity analysis, DOE believes its main LCC and PBP analysis results (including some cases of positive average LCC savings) are consistent with negative cumulative NPV results in the NIA, given the declining market for HID equipment. Chapter 9 of the final determination TSD examines the relationship of the LCC and PBP analysis and projected HID market in further detail.

TABLE VI.1—HID LAMPS >2800 K AND ≤4500 K AND ≥50 W TO ≤400 W—LCC AND PBP RESULTS

Efficacy level	Life-cycle cost (2014$)			Life-cycle cost savings				Median payback period (years)
	Installed cost	Discounted operating cost	LCC	Average savings (2014$)	Percentage of commercial consumers that experience *			
					Net cost	No impact	Net benefit	
Baseline	335.60	1726.95	2062.55	.....	.....	.....	.....	.....
1	340.72	1724.33	2065.05	(2.50)	1	99	0	100.00
2	393.94	1662.25	2056.20	6.35	52	36	12	100.00
3	533.97	1437.77	1971.74	90.81	36	23	42	11.00

* Any minor incongruities among various reported metrics are the result of rounding.

TABLE VI.2—HID LAMPS >2800 K AND ≤4500 K AND >400 AND ≤1000 W—LCC AND PBP RESULTS

Efficacy level	Life-cycle cost (2014$)			Life-cycle cost savings				Median payback period (years)
	Installed cost	Discounted operating cost	LCC	Average savings (2014$)	Percentage of commercial consumers that experience *			
					Net cost	No impact	Net benefit	
Baseline	484.68	6065.71	6550.39	.....	.....	.....	.....	.....
1	484.68	6065.71	6550.39	0.00	0	100	0	** N/A
2	526.13	6100.06	6626.19	(75.80)	90	9	2	100.00

* Any minor incongruities among various reported metrics are the result of rounding.
** Zero impacted commercial consumers (median PBP calculated for affected commercial consumers only).

TABLE VI.3—HID LAMPS >2800 K AND ≤4500 K AND >1000 W TO ≤2000 W—LCC AND PBP RESULTS

Efficacy level	Life-cycle cost (2014$)			Life-cycle cost savings				Median payback period (years)
	Installed cost	Discounted operating cost	LCC	Average savings (2014$)	Percentage of commercial consumers that experience *			
					Net cost	No impact	Net benefit	
Baseline	579.09	680.88	1259.97	.....	.....	.....	.....	.....
1	634.99	639.31	1274.30	(14.33)	7	90	3	29.34

* Any minor incongruities among various reported metrics are the result of rounding.

TABLE VI.4—HID LAMPS >2800 K AND ≤4500 K AND ≥50 W TO ≤400 W—LCC AND PBP RESULTS

[2023 Projected market basis]

Efficacy level	Life-cycle cost (2014$)			Life-cycle cost savings				Median payback period (years)
	Installed cost	Discounted operating cost	LCC	Average savings (2014$)	Percentage of commercial consumers that experience *			
					Net cost	No impact	Net benefit	
Baseline	326.84	1688.79	2015.63	.....	.....	.....	.....	.....
1	327.03	1688.69	2015.72	(0.08)	0	100	0	100.00
2	521.25	1555.77	2077.02	(61.39)	52	37	10	44.38
3	583.73	1401.66	1985.39	30.24	42	23	35	15.60

* Any minor incongruities among various reported metrics are the result of rounding, including cases where the percentage of commercial consumers experiencing a net cost or net benefit are greater than zero, but round to zero.

TABLE VI.5—HID LAMPS >2800 K AND ≤4500 K AND >400 AND ≤1000 W—LCC AND PBP RESULTS

[2023 Projected market basis]

Efficacy level	Life-cycle cost (2014$)			Life-cycle cost savings				Median payback period (years)
	Installed cost	Discounted operating cost	LCC	Average savings (2014$)	Percentage of commercial consumers that experience *			
					Net cost	No impact	Net benefit	
Baseline	478.73	6031.96	6510.69	.....	.....	.....	.....	.....
1	478.73	6031.96	6510.69	0.00	0	100	0	** N/A
2	735.66	5980.27	6715.93	(205.25)	91	9	0	100.00

* Any minor incongruities among various reported metrics are the result of rounding.
** Zero impacted commercial consumers (median PBP calculated for affected commercial consumers only).

TABLE VI.6—HID LAMPS >2800 K AND ≤4500 K AND >1000 W TO ≤2000 W—LCC AND PBP RESULTS

[2023 Projected market basis]

Efficacy level	Life-cycle cost (2014$)			Life-cycle cost savings				Median payback period (years)
	Installed cost	Discounted operating cost	LCC	Average savings (2014$)	Percentage of commercial consumers that experience *			
					Net cost	No impact	Net benefit	
Baseline	639.90	687.87	1327.78	.....	.....	.....	.....	.....
1	716.39	633.18	1349.57	(21.80)	10	86	4	29.60

* Any minor incongruities among various reported metrics are the result of rounding.

B. Economic Impacts on Manufacturers

DOE performed the MIA to estimate the impact of analyzed energy conservation standards on manufacturers of HID lamps. The following sections describe the expected impacts on HID lamp manufacturers at each EL for each equipment class. Chapter 12 of the final determination TSD explains the MIA in further detail.

1. Industry Cash-Flow Analysis Results

The tables in the following sections depict the financial impacts (represented by changes in INPV) of analyzed energy conservation standards on HID lamp manufacturers as well as the conversion costs that DOE estimates HID lamp manufacturers would incur at each EL for each equipment class. To evaluate the range of cash-flow impacts on the HID lamp industry, DOE modeled two markup scenarios that correspond to the range of anticipated market responses to analyzed standards. Each scenario results in a unique set of cash flows and corresponding industry values at each EL for each equipment class. In the following discussion, the INPV results refer to the difference in industry value between the no-new-standards case and the standards cases that result from the sum of discounted cash flows from the reference year (2015) through the end of the analysis period (2047).

To assess the upper (less severe) end of the range of analyzed impacts on HID lamp manufacturers, DOE modeled a flat, or preservation of gross margin, markup scenario. This scenario assumes that in the standards case, manufacturers would be able to pass along all the higher production costs required for more efficacious equipment to their commercial consumers. To assess the lower (more severe) end of the range of potential impacts, DOE modeled a preservation of operating profit markup scenario. The preservation of operating profit markup scenario assumes that in the standards case, manufacturers would be able to earn the same operating margin in absolute dollars as they would in the no-new-standards case. This represents the lower bound of industry profitability in the standards case.

Table VI.7 and Table VI.8 present the projected results of the 50–400 W equipment class under the flat and preservation of operating profit markup scenarios.

TABLE VI.7—MANUFACTURER IMPACT ANALYSIS FOR THE ≥50 W TO ≥400 W EQUIPMENT CLASS—FLAT MARKUP SCENARIO

	Units	No-new-standards case	EL		
			1	2	3
INPV	2014$ millions	290.0	285.3	256.6	311.8
Change in INPV	2014$ millions	.....	(4.7)	(33.3)	21.8
	%	.....	(1.6)	(11.5)	7.5
Product Conversion Costs	2014$ millions	.....	7.4	31.4	55.0
Capital Conversion Costs	2014$ millions	.....	.....	6.0	54.5
Total Conversion Costs	2014$ millions	.....	7.4	37.4	109.5

TABLE VI.8—MANUFACTURER IMPACT ANALYSIS FOR THE ≥50 W TO ≥400 W EQUIPMENT CLASS—PRESERVATION OF OPERATING PROFIT MARKUP SCENARIO

	Units	No-new-standards case	EL		
			1	2	3
INPV	2014$ millions	290.0	284.9	239.8	214.1
Change in INPV	2014$ millions		(5.1)	(50.1)	(75.9)
	%		(1.7)	(17.3)	(26.2)
Product Conversion Costs	2014$ millions		7.4	31.4	55.0
Capital Conversion Costs	2014$ millions			6.0	54.5
Total Conversion Costs	2014$ millions		7.4	37.4	109.5

Table VI.9 and Table VI.10 present the projected results of the 401–1000 W equipment class under the flat and preservation of operating profit markup scenarios.

TABLE VI.9—MANUFACTURER IMPACT ANALYSIS FOR THE ≥400 W TO ≥1000 W EQUIPMENT CLASS—FLAT MARKUP SCENARIO

	Units	No-new-standards case	EL	
			1	2
INPV	2014$ millions	44.6	44.2	44.8
Change in INPV	2014$ millions		(0.3)	0.2
	%		(0.8)	0.6
Product Conversion Costs	2014$ millions		0.5	4.9
Capital Conversion Costs	2014$ millions			0.8
Total Conversion Costs	2014$ millions		0.5	5.7

TABLE VI.10—MANUFACTURER IMPACT ANALYSIS FOR THE ≥400 W TO ≥1000 W EQUIPMENT CLASS—PRESERVATION OF OPERATING PROFIT MARKUP SCENARIO

	Units	No-new-standards case	EL	
			1	2
INPV	2014$ millions	44.6	44.2	40.7
Change in INPV	2014$ millions		(0.3)	(3.9)
	%		(0.8)	(8.7)
Product Conversion Costs	2014$ millions		0.5	4.9
Capital Conversion Costs	2014$ millions			0.8
Total Conversion Costs	2014$ millions		0.5	5.7

Table VI.11 and Table VI.12 present the projected results of the 1001–2000 W equipment class under the flat and preservation of operating profit markup scenarios.

TABLE VI.11—MANUFACTURER IMPACT ANALYSIS FOR THE ≥1000 W TO ≥2000 W EQUIPMENT CLASS—FLAT MARKUP SCENARIO

	Units	No-new-standards case	EL
			1
INPV	2014$ millions	3.0	2.2
Change in INPV	2014$ millions		(0.8)
	%		(25.2)
Product Conversion Costs	2014$ millions		0.6
Capital Conversion Costs	2014$ millions		0.4
Total Conversion Costs	2014$ millions		0.9

TABLE VI.12—MANUFACTURER IMPACT ANALYSIS FOR THE ≥1000 W TO ≥2000 W EQUIPMENT CLASS—PRESERVATION OF OPERATING PROFIT MARKUP SCENARIO

	Units	No-new-standards case	EL
			1
INPV	2014$ millions	3.0	2.3
Change in INPV	2014$ millions		(0.7)
	%		(24.4)
Product Conversion Costs	2014$ millions		0.6
Capital Conversion Costs	2014$ millions		0.4
Total Conversion Costs	2014$ millions		0.9

2. Impacts on Employment

DOE quantitatively assessed the impacts of analyzed energy conservation standards on direct employment. DOE used the GRIM to estimate the domestic labor expenditures and number of domestic production workers in the no-new-standards case and at each EL for the 50–400 W equipment class, since the 50–400 W equipment class represents over 90 percent of all covered HID lamp shipments in 2018. Furthermore, manufacturers stated that most domestic employment decisions would be based on the standards set for the 50–400 W equipment class.

The employment impacts shown in Table VI.13 represent the potential production employment that could result following analyzed energy conservation standards. The upper bound of the results estimates the maximum change in the number of production workers that could occur after compliance with the analyzed energy conservation standards assuming that manufacturers continue to produce the same scope of covered equipment in the same domestic production facilities. It also assumes that domestic production does not shift to lower labor-cost countries. Because there is a real risk of manufacturers evaluating sourcing decisions in response to analyzed energy conservation standards, the lower bound of the employment results includes the estimated total number of U.S. production workers in the industry who could lose their jobs if some or all existing production were moved outside of the United States.

DOE estimates that approximately one third of the HID lamps sold in the United States are manufactured domestically. With this assumption, DOE estimates that in the absence of potential energy conservation standards, there would be approximately 219 domestic production workers involved in manufacturing HID lamps in 2018. The table below shows the range of the impacts of analyzed standards on U.S. production workers in the HID lamp industry.

TABLE VI.13—POTENTIAL CHANGES IN THE TOTAL NUMBER OF DOMESTIC HIGH-INTENSITY DISCHARGE LAMP PRODUCTION WORKERS IN 2018

	No-new-standards case	50–400 W Equipment Class EL		
		1	2	3
Total Number of Domestic Production Workers in 2018 (without changes in production locations)	219	220	228	357
Potential Changes in Domestic Production Workers in 2018 *		0 to 1	(110) to 9	(219) to 138

* DOE presents a range of potential employment impacts. Numbers in parentheses indicate negative numbers.

3. Impacts on Manufacturing Capacity

HID lamp manufacturers stated that they did not anticipate any significant capacity constraints unless all lamps in the 50–400 W equipment class had to be converted to CMH technology. Most manufacturers stated that they do not have the equipment to produce the volume of CMH lamps that would be necessary to satisfy demand. Manufacturers would have to expend significant capital resources to obtain additional equipment that is specific to CMH lamp production. Manufacturers also pointed out that thousands of man-hours would be necessary to redesign specific lamps and lamp production lines at ELs requiring CMH. The combination of obtaining new equipment and the engineering effort that manufacturers would have to undergo could cause significant downtime for manufacturers. Most manufacturers agreed that there would not be any significant capacity constraints at any ELs that did not require CMH technology.

4. Impacts on Subgroups of Manufacturers

Using average cost assumptions to develop an industry cash-flow estimate may not be adequate for assessing differential impacts among manufacturer subgroups. Small manufacturers, niche equipment manufacturers, and manufacturers exhibiting cost structures substantially different from the industry average could be affected disproportionately. DOE did not identify any adversely impacted subgroups for HID lamps for this final determination based on the results of the industry characterization. DOE analyzed the impacts on small manufacturers as required by the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*

5. Cumulative Regulatory Burden

While any one regulation may not impose a significant burden on manufacturers, the combined effects of recent or impending regulations may have serious consequences for some manufacturers, groups of manufacturers, or an entire industry. Assessing the impact of a single regulation may overlook this cumulative regulatory burden. In addition to energy conservation standards, other regulations can significantly affect manufacturers' financial operations. Multiple regulations affecting the same manufacturer can strain profits and lead companies to abandon product lines or markets with lower expected future returns than competing equipment. For

these reasons, DOE conducted a cumulative regulatory burden analysis to make sure that the standards considered in this determination do not create a cumulative regulatory burden that is unacceptable to the overall lighting industry.

C. National Impact Analysis

1. Significance of Energy Savings

For each efficacy level, DOE projected energy savings for HID lamps purchased in the 30-year period that begins in the year 2018, ending in the year 2047. The savings are measured over the entire lifetime of equipment purchased in the 30-year period. DOE quantified the energy savings attributable to each efficacy level as the difference in energy consumption between each standards case and the no-new-standards case. Table VI.14 presents the estimated primary energy savings for each efficacy level analyzed. Table VI.15 presents the estimated FFC energy savings for each efficacy level. Chapter 11 of the final determination TSD describes these estimates in more detail.

TABLE VI.14—CUMULATIVE NATIONAL PRIMARY ENERGY SAVINGS FOR HID LAMP EFFICACY LEVELS FOR UNITS SOLD IN 2018–2047

Equipment class	Efficacy level	National primary energy savings (quads)
≥2800 K and ≤4500 K and ≥50 W to ≤400 W	1	0.003
	2	0.14
	3	1.34
≥2800 K and ≤4500 K and >400 and ≤1000 W	1	0.00
	2	0.002
≥2800 K and ≤4500 K and >1000 W to ≤2000 W	1	0.001

TABLE VI.15—CUMULATIVE NATIONAL FULL-FUEL-CYCLE ENERGY SAVINGS FOR HID LAMP EFFICACY LEVELS FOR UNITS SOLD IN 2018–2047

Equipment class	Efficacy level	National FFC energy savings (quads)
≥2800 K and ≤4500 K and ≥50 W to ≤400 W	1	0.003
	2	0.15
	3	1.40
≥2800 K and ≤4500 K and >400 and ≤1000 W	1	0.00
	2	0.002
≥2800 K and ≤4500 K and >1000 W to ≤2000 W	1	0.001

2. Net Present Value of Commercial Consumer Costs and Benefits

DOE estimated the cumulative NPV of the total costs and savings for commercial consumers that would result from the efficacy levels considered for HID lamps. In accordance with the Office of Management and Budget's (OMB's) guidelines on regulatory analysis,[11] DOE calculated the NPV using both a 7-percent and a 3-percent real discount rate. The 7-percent rate is an estimate of the average before-tax rate of return on private capital in the U.S. economy, and reflects the returns on real estate and small business capital as well as corporate capital. This discount rate approximates the opportunity cost of capital in the private sector (OMB analysis has found the average rate of return on capital to be near this rate). The 3-percent rate reflects the potential effects of standards on private consumption (*e.g.,* through higher prices for products and reduced purchases of energy). This rate represents the rate at which society discounts future consumption flows to their present value. It can be approximated by the real rate of return on long-term government debt (*i.e.,* yield on U.S. Treasury notes), which has averaged about 3 percent for the past 30 years.

Table VI.16 shows the commercial consumer NPV results for each efficacy level DOE considered for HID lamps, using both 7-percent and 3-percent discount rates. In each case, the impacts cover the lifetime of equipment purchased in 2018 through 2047. See chapter 11 of the final determination TSD for more detailed NPV results.

TABLE VI.16—NET PRESENT VALUE OF COMMERCIAL CONSUMER BENEFITS FOR HID LAMP EFFICACY LEVELS FOR UNITS SOLD IN 2018–2047

Equipment class	Efficacy level	Net present value (billion 2014$)	
		7-Percent discount rate	3-Percent discount rate
≥2800 K and ≤4500 K and ≥50 W to ≤400 W	1	(0.03)*	(0.01)
	2	(1.21)	(2.20)
	3	(1.69)	(1.14)
≥2800 K and ≤4500 K and >400 and ≤1000 W	1	0.00	0.00
	2	(0.25)	(0.49)
≥2800 K and ≤4500 K and >1000 W to ≤2000 W	1	(0.012)	(0.02)

* Values in parenthesis are negative values.

D. Determination

As required by EPCA, this final determination analyzed whether standards for HID lamps would be technologically feasible, economically justified, and would result in significant energy savings. (42 U.S.C. 6317(a)(1)) Each of these criteria is discussed below.

[11] OMB Circular A–4, section E (Sept. 17, 2003). Available at: *www.whitehouse.gov/omb/circulars_a004_a-4.*

1. Technological Feasibility

EPCA mandates that DOE determine whether energy conservation standards for HID lamps would be ''technologically feasible.'' (42 U.S.C. 6317(a)(1)) DOE determines that standards for HPS lamps would not be technologically feasible due to the lack of technology options discussed in section V.A.3. DOE determines that standards for MV lamps for specialty applications are not technologically feasible because MH lamps do not provide adequate ultraviolet light output to act as a direct substitute for specialty application MV lamp (see chapter 2 of the final determination TSD for additional detail). DOE determines that energy conservation standards for certain other HID lamps (MV and MH lamps) would be technologically feasible because they can be satisfied with HID lighting systems currently available on the market. However, DOE has some concern regarding the limited market availability of MH lamps that meet EL 3 at 250 W. Currently, only one manufacturer produces a lamp subject to standards that meets EL 3 at 250 W, though some lamps not subject to standards (*i.e.,* lamps operated by electronic ballasts only) may also be available as an energy saving replacement.

2. Significance of Energy Savings

EPCA also mandates that DOE determine whether energy conservation standards for HID lamps would result in ''significant energy savings.'' (42 U.S.C. 6317(a)(1)) DOE determines that standards for certain categories of HID lamps (MH and MV lamps less than 50 W, MH lamps greater than 2000 W, MV lamps greater than 1000 W, directional lamps, self-ballasted lamps, lamps designed to operate exclusively on electronic ballasts, high-CRI MH lamps, colored MH lamps, and electrodeless lamps) would not result in significant energy savings due to low shipment market share (see chapter 2 of the final determination TSD for additional detail). However, DOE estimates that a standard for all other HID lamps would result in maximum energy savings of up to 1.4 quads over a 30-year analysis period (2018–2047). Therefore, DOE determines that potential energy conservation standards for certain HID lamps would result in significant energy savings.

3. Economic Justification

EPCA requires DOE to determine whether energy conservation standards for HID lamps would be economically justified. (42 U.S.C. 6317(a)(1)) Using the methods and data described in section V.G, DOE conducted an LCC analysis to estimate the net costs/benefits to users from increased efficacy in the considered HID lamps. DOE then aggregated the results from the LCC analysis to estimate national energy savings and national economic impacts in section VI.A. DOE also conducted an MIA to estimate the financial impact of potential energy conservation standards on manufacturers.

DOE first considered the most efficacious level, EL 3, which is applicable only to the 50 W–400 W equipment class. Regarding economic impacts to commercial consumers, DOE notes that regulation of the 400 W MH representative lamp type (a subset of the 50–400 W equipment class) does not allow commercial consumers to purchase only a new lamp at EL 3. In this case, all commercial consumers would need to purchase a new ballast and fixture in addition to a new lamp in order to achieve energy and cost savings. Purchasing a new lamp, ballast, and fixture rather than only a lamp represents a large first cost difference (about a 400 percent increase). All other lamp types and equipment classes offer a direct lamp replacement (a more efficacious, but equal wattage replacement). The 50–400 W equipment class at EL 3 has an estimated negative NPV of commercial consumer benefit of −$1.69 billion using a 7-percent discount rate, and a negative NPV of commercial consumer benefit of −$1.14-billion using a 3-percent discount rate.

Regarding economic impacts to manufacturers, at EL 3 for the 50–400 W equipment class, DOE estimates industry will need to invest approximately $109.5 million in conversion costs. New investment would be necessary to produce EL 3 CMH lamps at a mass market scale for the 50–400 W equipment class. As a result, EL 3 has large conversion costs. At EL 3 for the 50–400 W equipment class, the projected change in INPV ranges from a decrease of $75.9 million to an increase of $21.8 million, which equates to a decrease of 26.2 percent and an increase of 7.5 percent, respectively, in INPV for manufacturers of HID lamps.

On the basis of the negative NPV, large differences in first costs for some commercial consumers, and potential decrease in industry net present value for HID lamp manufacturers (including large conversion costs), DOE determined that the EL 3 standard was not economically justified.

DOE then considered the next most efficacious level, EL 2, which applies to the 50–400 W and 401–1000 W equipment classes. Regarding economic impacts to commercial consumers, the 50–400 W equipment class at EL 2 has an estimated negative NPV of commercial consumer benefit of –$1.21 billion using a 7-percent discount rate, and a negative NPV of commercial consumer benefit of −$2.20 billion using a 3-percent discount rate. The 401–1000 W equipment class at EL 2 has an estimated negative NPV of commercial consumer benefit of –$0.25 billion using a 7-percent discount rate, and a negative NPV of commercial consumer benefit of −$0.49 billion using a 3-percent discount rate.

Regarding economic impacts to manufacturers, at EL 2 for the 50–400 W equipment class, DOE estimates industry will need to invest approximately $37.4 million in conversion costs. At EL 2 for the 401–1000 W equipment class, DOE estimates industry will need to invest approximately $5.7 million in conversion costs. Conversion costs are small because minimal capital expenditures are necessary to produce EL 2 compliant lamps at a mass market scale. At EL 2 for the 50–400 W equipment class, the projected change in INPV ranges from a decrease of $50.1 million to a decrease of $33.3 million, which equates to a decrease of 17.3 percent and a decrease of 11.5 percent, respectively, in INPV for manufacturers of HID lamps. At EL 2 for the 401–1000 W equipment class, the projected change in INPV ranges from a decrease of $3.9 million to an increase of $0.2 million, which equates to a decrease of 8.7 percent and an increase of 0.6 percent, respectively, in INPV for manufacturers of HID lamps.

On the basis of the negative NPV and potential decrease in industry net present value for HID lamp manufacturers, DOE determined that an EL 2 standard was not economically justified.

Finally, DOE considered EL 1, which applies to the 50–400 W, 401–1000 W, and 1001–2000 W equipment classes. Regarding economic impacts to commercial consumers, the 50–400 W equipment class at EL 1 has an estimated negative NPV of commercial consumer benefit of –$0.03 billion using a 7-percent discount rate, and a negative NPV of commercial consumer benefit of −$0.01 billion using a 3-percent discount rate. The 401–1000 W equipment class at EL 1 has an NPV of commercial consumer benefit of $0.0 using a 7-percent discount rate, and $0.0 using a 3-percent discount rate. The 1001–2000 W equipment class at EL 1 has an estimated negative NPV of

commercial consumer benefit of −$0.012 billion using a 7-percent discount rate, and an estimated negative NPV of −$0.02 billion using a 3-percent discount rate. The NPV for 400–1000 W equipment class because of no shipments for this baseline.

Regarding economic impacts to manufacturers, at EL 1 for the 50–400 W equipment class, DOE estimates industry will need to invest approximately $7.4 million in conversion costs. At EL 1 for the 401–1000 W equipment class, DOE estimates industry will need to invest approximately $0.5 million in conversion costs. At EL 1 for the 1001–2000 W equipment class, DOE estimates industry will need to invest approximately $0.9 million in conversion costs. Conversion costs are small because minimal capital expenditures are necessary to produce EL 1 compliant lamps at a mass market scale. At EL 1 for the 50–400 W equipment class, the projected change in INPV ranges from a decrease of $5.1 million to a decrease of $4.7 million, which equates to a decrease of 1.7 percent and a decrease of 1.6 percent, respectively, in INPV for manufacturers of HID lamps. At EL 1 for the 401–1000 W equipment class, the projected change in INPV is a decrease of $0.3 million, which equates to a decrease of 0.8 percent, in INPV for manufacturers of HID lamps. At EL 1 for the 1001–2000 W equipment class, the projected change in INPV ranges from a decrease of $0.8 million to a decrease of $0.7 million, which equates to a decrease of 25.2 percent and a decrease of 24.4 percent, respectively, in INPV for manufacturers of HID lamps.

On the basis of the negative NPV and potential decrease in industry net present value for HID lamp manufacturers, DOE determined that an EL 1 standard was not economically justified.

4. Conclusions

DOE determines that standards for HID lamps are either not technologically feasible, would not result in significant energy savings, or are not economically justified (see Table VI.17). Therefore, DOE is not establishing energy conservation standards for HID lamps.

TABLE VI.17—RATIONALE FOR NOT ESTABLISHING ENERGY CONSERVATION STANDARDS

Lamp category			Rationale
Directional HID lamps			Would not result in significant energy savings.
Self-ballasted HID lamps			Would not result in significant energy savings.
HID lamps designed to operate exclusively on electronic ballasts			Would not result in significant energy savings.
HID lamps that have a CCT of 5000–6999 K, have a non-screw base, and have a non-T-shaped bulb			Not technologically feasible.
Electrodeless HID lamps			Would not result in significant energy savings.
Other HID Lamps	HPS Lamps		Not technologically feasible.
	MV Lamps	MV lamps less than 50 W or greater than 1000 W.	Would not result in significant energy savings.
		MV lamps that are double-ended, have a non-screw base, and have no outer bulb.	Not technologically feasible.
		MV lamps greater than or equal to 50 W and less than or equal to 1000 W.	Not economically justified.
	MH Lamps	MH lamps less than 50 W or greater than 2000 W.	Would not result in significant energy savings.
		MH lamps with CCT less than 2800 K and greater than or equal to 7000 K.	Would not result in significant energy savings.
		High-CRI MH lamps	Would not result in significant energy savings.
		Colored MH lamps	Would not result in significant energy savings.
		MH lamps greater than or equal to 50 W and less than or equal to 2000 W.	Not economically justified.

VII. Procedural Issues and Regulatory Review

A. Review Under Executive Orders 12866 and 13563

This final determination is not subject to review under Executive Order (E.O.) 12866, ''Regulatory Planning and Review.'' 58 FR 51735 (October 4, 1993).

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis (IRFA) for any rule that by law must be proposed for public comment, and a final regulatory flexibility analysis (FRFA) for any such rule that an agency adopts as a final rule, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the rulemaking process. 68 FR 7990 DOE has made its procedures and policies available on the Office of the

General Counsel's Web site (*http://energy.gov/gc/office-general-counsel*).

DOE reviewed this final determination under the provisions of the Regulatory Flexibility Act and the policies and procedures published on February 19, 2003. In the final determination, DOE finds that standards for HID lamps would not meet all of the required criteria of technologically feasibility, economic justification, and significant energy savings. The final determination does not establish any energy conservation standards for HID lamps, and DOE is not prescribing standards for HID lamps at this time. On the basis of the foregoing, DOE certifies that the final determination has no significant economic impact on a substantial number of small entities. Accordingly, DOE has not prepared an FRFA for this final determination. DOE will transmit this certification and supporting statement of factual basis to the Chief Counsel for Advocacy of the Small Business Administration for review under 5 U.S.C. 605(b).

C. Review Under the Paperwork Reduction Act

This final determination does not impose new information or record keeping requirements since it does not impose any standards. Accordingly, the Office of Management and Budget (OMB) clearance is not required under the Paperwork Reduction Act. (44 U.S.C. 3501 *et seq.*)

D. Review Under the National Environmental Policy Act of 1969

In this final determination, DOE determines that energy conservation standards for HID lamps do not meet all of the required criteria of technologically feasibility, economic justification, and significant energy savings. DOE has determined that review under the National Environmental Policy Act of 1969 (NEPA), Public Law 91–190, codified at 42 U.S.C. 4321 *et seq.* is not required at this time because standards are not being imposed. NEPA review can only be initiated ''as soon as environmental impacts can be meaningfully evaluated.'' Because this final determination concludes only that future standards are not warranted, and does not propose or set any standard, DOE has determined that there are no environmental impacts to be evaluated at this time. Accordingly, neither an environmental assessment not an environmental impact statement is required.

E. Review Under Executive Order 13132

Executive Order 13132, ''Federalism.'' 64 FR 43255 (Aug. 10, 1999) imposes certain requirements on Federal agencies formulating and implementing policies or regulations that preempt State law or that have Federalism implications. The Executive Order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of states and to carefully assess the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have Federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. 65 FR 13735. As this final determination finds that standards are not warranted for HID lamps, there is no impact on the policymaking discretion of the states. Therefore, no action is required by Executive Order 13132.

F. Review Under Executive Order 12988

With respect to the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, ''Civil Justice Reform,'' imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity; (2) write regulations to minimize litigation; and (3) provide a clear legal standard for affected conduct rather than a general standard and promote simplification and burden reduction. 61 FR 4729 (Feb. 7, 1996). Section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation: (1) Clearly specifies the preemptive effect, if any; (2) clearly specifies any effect on existing Federal law or regulation; (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction; (4) specifies the retroactive effect, if any; (5) adequately defines key terms; and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in section 3(a) and section 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, this final determination meets the relevant standards of Executive Order 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a proposed regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed ''significant intergovernmental mandate,'' and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820. DOE's policy statement is also available at *http://energy.gov/gc/office-general-counsel.* This final determination contains neither an intergovernmental mandate nor a mandate that may result in the expenditure of $100 million or more in any year, so these UMRA requirements do not apply.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This final determination does not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

DOE has determined, under Executive Order 12630, ''Governmental Actions

and Interference with Constitutionally Protected Property Rights'' 53 FR 8859 (Mar. 18, 1988) that this final determination does not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under the Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516, note) provides for Federal agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (Feb. 22, 2002), and DOE's guidelines were published at 67 FR 62446 (Oct. 7, 2002). DOE has reviewed this final determination under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

Executive Order 13211, ''Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use'' 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OIRA at OMB, a Statement of Energy Effects for any proposed significant energy action. A ''significant energy action'' is defined as any action by an agency that promulgates or is expected to lead to promulgation of a final rule, and that: (1) Is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy, or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

Because the final determination finds that standards for HID lamps are not warranted, it is not a significant energy action, nor has it been designated as such by the Administrator at OIRA. Accordingly, DOE has not prepared a Statement of Energy Effects.

L. Review Under the Information Quality Bulletin for Peer Review

On December 16, 2004, OMB, in consultation with the Office of Science and Technology Policy (OSTP), issued its Final Information Quality Bulletin for Peer Review (the Bulletin). 70 FR 2664 (Jan. 14, 2005). The Bulletin establishes that certain scientific information shall be peer reviewed by qualified specialists before it is disseminated by the Federal Government, including influential scientific information related to agency regulatory actions. The purpose of the Bulletin is to enhance the quality and credibility of the Government's scientific information. Under the Bulletin, the energy conservation standards rulemaking analyses are ''influential scientific information,'' which the Bulletin defines as scientific information the agency reasonably can determine will have, or does have, a clear and substantial impact on important public policies or private sector decisions. 70 FR 2667.

In response to OMB's Bulletin, DOE conducted formal in-progress peer reviews of the energy conservation standards development process and analyses and has prepared a Peer Review Report pertaining to the energy conservation standards rulemaking analyses. Generation of this report involved a rigorous, formal, and documented evaluation using objective criteria and qualified and independent reviewers to make a judgment as to the technical/scientific/business merit, the actual or anticipated results, and the productivity and management effectiveness of programs and/or projects. The ''Energy Conservation Standards Rulemaking Peer Review Report'' dated February 2007 has been disseminated and is available at the following Web site: *www1.eere.energy.gov/buildings/appliance_standards/peer_review.html.*

VIII. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this final determination.

Issued in Washington, DC, on December 2, 2015.

David Danielson,

Assistant Secretary, Energy Efficiency and Renewable Energy.

[FR Doc. 2015–30992 Filed 12–8–15; 8:45 am]

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FEDERAL RESERVE SYSTEM

12 CFR Part 217

[Docket No. R–1506]

RIN 7100–AE 27

Regulatory Capital Rules: Regulatory Capital, Final Rule Demonstrating Application of Common Equity Tier 1 Capital Eligibility Criteria and Excluding Certain Holding Companies From Regulation Q

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Final rule.

SUMMARY: The Board of Governors of the Federal Reserve System (Board) is adopting amendments to the Board's regulatory capital framework (Regulation Q) to clarify how the definition of common equity tier 1 capital, a key capital component, applies to ownership interests issued by depository institution holding companies that are structured as partnerships or limited liability companies. In addition, the final rule amends Regulation Q to exclude temporarily from Regulation Q savings and loan holding companies that are trusts and depository institution holding companies that are employee stock ownership plans.

DATES: The final rule is effective January 1, 2016. Any company subject to the final rule may elect to adopt it before this date.

FOR FURTHER INFORMATION CONTACT: Juan Climent, Manager, (202) 872–7526, Page Conkling, Senior Supervisory Financial Analyst, (202) 912–4647, Noah Cuttler, Senior Financial Analyst, (202) 912–4678, Division of Banking Supervision and Regulation, Board of Governors of the Federal Reserve System; or Benjamin McDonough, Special Counsel, (202) 452–2036, or Mark Buresh, Senior Attorney, (202) 452–5270, Legal Division, 20th Street and Constitution Avenue NW., Washington, DC 20551. Users of Telecommunication Device for Deaf (TDD) only, call (202) 263–4869.

SUPPLEMENTARY INFORMATION:

I. Background

In July 2013, the Board adopted Regulation Q, a revised capital framework that strengthened the capital requirements applicable to state member banks and bank holding companies (BHCs) and implemented capital requirements for certain savings and loan holding companies (SLHCs).[1]

[1] *See* 12 CFR part 217. Savings and loan holding companies that are substantially engaged in

Among other changes, Regulation Q introduced a common equity tier 1 capital (CET1) requirement.

Following issuance of Regulation Q, several depository institution holding companies sought clarification as to how the CET1 requirement would apply in light of their capital structures. These holding companies included BHCs and SLHCs organized in non-stock form (non-stock holding companies) (such as partnerships or limited liability corporations (LLCs)), estate trusts that are SLHCs (estate trust SLHCs), and employee stock ownership plans that are BHCs or SLHCs (ESOP holding companies).

On December 12, 2014, the Board invited comment on a proposed rule that described how the CET1 requirement would apply to holding companies organized as partnerships or LLCs and that would have temporarily excluded estate trust SLHCs and ESOP holding companies from Regulation Q.[2]

The Board received two comments on the proposal—one from a financial services trade association and another from a savings and loan holding company—both of which expressed support for the proposal. After reviewing these comments, the Board is adopting the proposal largely as proposed, with certain clarifying edits and non-substantive changes to order and formatting.

II. Description of the Proposed and Final Rules

1. Application of the Eligibility Criteria for Common Equity Tier 1 Instruments to LLC and Partnership Interests

Regulation Q includes a CET1 requirement of 4.5 percent of risk-weighted assets. The purpose of the requirement is to ensure that banking organizations subject to Regulation Q hold sufficient high-quality regulatory capital that is available to absorb losses on a going concern basis.[3] In particular, CET1 must be the most subordinated form of capital in an institution's capital structure and thus available to absorb losses first.[4] CET1 is composed of common stock and instruments issued by mutual banking organizations that meet certain eligibility criteria.[5]

In a stock company, common stock generally is the most subordinated element of its capital structure. While a non-stock holding company does not issue common stock, it generally should also have the ability to issue capital instruments that have loss absorbency features similar to those of common stock.

In addition, a stock company may issue capital instruments that are not the most subordinated elements of its capital structure, such as preferred stock with a liquidation preference and cumulative dividend rights. Similarly, non-stock holding companies may issue capital instruments that are not the most subordinated elements of their capital structure. Regardless of whether the issuer is a stock company or a non-stock company, a capital instrument that is not the most subordinated element of a company's capital structure would not qualify as CET1 under Regulation Q.[6]

Features that cast doubt on whether a particular class of capital instruments is the most subordinated and therefore available to absorb losses first include unlimited liability for the general partner in a partnership, allocation of losses among classes that is disproportionate to amounts invested, mandatory distributions, minimum rates of return, and/or reallocations of earlier distributions. If such features limit or could limit the ability of capital instruments to bear first losses or effectively absorb losses then such features are inconsistent with Regulation Q's eligibility criteria for CET1 instruments and therefore may not qualify as such under Regulation Q.[7]

The proposed rule would have clarified, through examples, how the definition of CET1 would apply to ownership interests issued by non-stock holding companies.[8] In general, the examples showed that an LLC or partnership could issue capital that would qualify as CET1 provided that all ownership classes shared equally in losses, even if all ownership classes do not share equally in profits. The examples also showed that other features of capital instruments, such as a mandatory capital distribution upon the occurrence of an event or a date, different liquidation preferences among ownership classes, or unequal sharing of losses, could prevent a capital instrument from qualifying as CET1.

As noted, the Board received two comments on the proposal. One comment related to the application of the eligibility criteria for CET1 instruments to LLC and partnership interests. The commenter expressed concern that Regulation Q did not adequately address the special characteristics of non-stock holding companies and observed that the proposal facilitated the application of Regulation Q to such holding companies.

The final rule follows the same basic structure of the proposal, and adds some clarifications. The Board reordered the examples in the final rule to group together those examples discussing similar structures. In addition, the Board revised examples related to loss sharing to clarify that each distribution must be reviewed separately and to clarify that losses must be borne equally by all holders of CET1 instruments when investment proceeds are distributed.

In particular, Example (3) in the proposal related to an LLC with two classes of membership interests that share proportionately in losses, return of contributed capital, and profits up to a set rate of return. However, the classes of membership interests share disproportionately in profits above a particular level. This example provided that both classes of membership interest could qualify as CET1 so long as the classes always share any losses proportionately among the classes or among the instruments in each class, even if there is disproportionate allocation of profits. In the final rule, this example, renumbered as Example (4), clarifies that disproportionate sharing of profits does not prevent qualification as CET1, so long as the classes bear the losses pro rata. Despite the potential for disproportionate allocations of profits from a distribution, the classes of capital instruments would bear losses pro rata, placing them at the same level of seniority in bankruptcy or liquidation.

In the proposal, Example (7) related to an LLC with two classes of membership interests where one class could be required, under certain circumstances, to return previously received distributions that would then be allocated to the other class. The example provided that a class of capital instruments advantaged by an arrangement such that the advantaged

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insurance underwriting or commercial activities are exempt temporarily from the revised capital framework. *See* 12 CFR 217.2, ''Covered savings and loan holding company.'' In addition, earlier this year, the Board issued a final rule that raised the asset threshold for applicability of the Board's Small Bank Holding Company Policy Statement (12 CFR part 225, Appendix C) from less than $500 million to less than $1 billion and made corresponding revisions to the applicability provisions of Regulation Q to exempt small SLHCs from Regulation Q to the same extent as small BHCs. *See* 12 CFR 217.1(c)(1)(ii) and (iii); 80 FR 20153 (April 15, 2015).

[2] 79 FR 75759 (December 19, 2014).

[3] 12 CFR 217.20(b); 78 FR 62018, 62029.

[4] 78 FR 62018, 62044.

[5] The qualifying criteria under Regulation Q for a CET1 instrument are at 12 CFR 217.20(b)(1).

[6] *See* 12 CFR 217.20(b)(1)(i).

[7] To the extent that the economic rights of one class of ownership interests differ from those of another class, each class should be evaluated separately to determine qualification as common equity tier 1 capital.

[8] *See* 79 FR 75759, 75761–2.

class might not bear losses pro rata with the other class, would not qualify as CET1. The example also offered general suggestions for revising such arrangements so that such class of capital instrument could count as CET1. In the final rule, the Board revised Example (7) to emphasize the concern that a reallocation of distributions may affect the analysis of whether a class of capital instruments is in a first-loss position. In addition, the Board revised Example (7) to state that reallocations that were limited to reversing prior disproportionate allocations of profits would not raise this concern. Finally, the Board removed general suggestions in Example (7) regarding potential alternative structures to avoid confusion for the reader.

Section 217.501 of the final rule does not differ fundamentally from the existing CET1 eligibility criteria in Regulation Q. Instead, it expands on and clarifies the application of these criteria in particular circumstances in substantially the same manner as the proposal.

In addition, the proposed rule would have allowed an LLC or partnership with outstanding capital instruments that would not have qualified under the proposed rule as CET1 to continue to treat these instruments as CET1 until January 1, 2016. The Board proposed this extension to provide time for depository institution holding companies organized as LLCs or partnership to assess whether their capital instruments comply with the Regulation Q eligibility criteria and to make any needed modifications. The final rule extends this compliance date to July 1, 2016.

The Board expects that all holding companies that are subject to Regulation Q and that have issued capital instruments that do not qualify as CET1 under sections 217.20 and 217.501 to be in full compliance with Regulation Q by July 1, 2016. A non-stock holding company subject to Regulation Q, such as a company organized as an LLC or partnership, that has capital instruments that do not meet the applicable eligibility criteria under Regulation Q may need to take steps to ensure compliance with Regulation Q, including modifying its capital structure or the governing documents of specific capital instruments or issuing additional qualifying capital.

The Board may consider the appropriate treatment under Regulation Q for specific capital instruments on a case-by-case basis. Further, the Board reserves the authority to determine that a particular capital instrument may or may not qualify as any form of regulatory capital based on its ability to absorb losses or other considerations, or whether the capital instrument qualifies as an element of a particular regulatory capital component under Regulation Q.[9]

2. Estate Trust SLHCs

Estate trust SLHCs with total consolidated assets of more than $1 billion became subject to Regulation Q on January 1, 2015.[10] Many estate trusts, however, do not issue capital instruments that would qualify as regulatory capital under Regulation Q or prepare financial statements under U.S. Generally Applicable Accounting Principles (GAAP). Such estate trust SLHCs, therefore, may not be able to meet the minimum regulatory capital ratios under Regulation Q, and requiring these institutions to develop and implement the management information systems necessary to prepare financial statements to demonstrate compliance with Regulation Q could impose significant burden and expense. In addition, a temporary exemption from Regulation Q for estate trust SLHCs does not appear to raise significant supervisory concerns because the estate planning purpose of these entities generally results in limited operations and leverage.[11] To address these issues, the proposed rule would have excluded estate trust SLHCs from Regulation Q, pending development by the Board of an alternative capital regime for these institutions.

The Board received one comment on this aspect of the proposal. This commenter noted that it was a closely held SLHC with an ownership structure that included estate trusts and a limited partnership. This commenter expressed concern over the application of Regulation Q and other prudential regulations to family estate planning vehicles and expressed support for the Board's proposed temporary exclusion of estate trust SLHCs from Regulation Q.

The final rule adopts the exclusion for SLHCs that are estate trusts without modification. For these entities, the Board intends to develop alternative capital adequacy standards.[12]

3. ESOPs

ESOPs are entities created as part of employee benefits arrangements that hold shares of the sponsoring entities' stock. An ESOP may be a holding company due to its ownership interest in the banking organization that sponsors the ESOP. Under U.S. GAAP, the assets and liabilities of ESOP holding companies are consolidated onto the balance sheet of the banking organization that sponsors the ESOP (either a depository institution or a holding company that may be subject to Regulation Q). Thus, an ESOP holding company may be considered the top-tier holding company in a banking organization for ownership purposes but not considered the top-tier holding company for accounting purposes. This distinction has created confusion regarding the application of Regulation Q to ESOP holding companies, which generally do not issue capital instruments.

The proposed rule would have excluded ESOPs from Regulation Q until the Board clarifies the regulatory capital treatment for these entities. The Board did not receive any comments on the aspects of the proposal related to ESOPs and is adopting the proposed temporary exclusion for ESOPs without modification.

For a banking organization that has an ESOP holding company within its structure, the Board will evaluate compliance with Regulation Q by assessing the regulatory capital of an ESOP holding company's sponsor banking organization.

4. Early Compliance

The final rule will be effective January 1, 2016. As noted above, the final rule includes an extended compliance date of July 1, 2016, to allow time for non-stock holding companies to assess whether their capital instruments comply with Regulation Q and to make any necessary modifications. However, any banking organization subject to Regulation Q may elect to treat the final rule as effective before the effective date. Accordingly, the Board will not

[9] 12 CFR 217.1(d)(2).

[10] While the Home Owners' Loan Act contains a narrow exemption for testamentary trusts from the definition of savings and loan holding company, there are approximately 107 family and personal trusts that do not qualify for this exemption and thus, are savings and loan holding companies. As of January 1, 2015, some of these entities became subject to Regulation Q. The Bank Holding Company Act exempts certain testamentary and inter vivos trusts from the definition of ''company.''

[11] A review of estate trust SLHCs found that these institutions generally hold high levels of capital, with an estimated median leverage ratio of approximately 99 percent and an estimated mean leverage ratio of approximately 94 percent. Leverage was measured as the ratio of assets minus liabilities over assets. However, estate trust SLHCs do not file regular financial reports with the Board, and estimated median and mean leverage ratios are based on data collected from a significant number of estate trust SLHCs in 2014.

[12] Any alternative capital standard must be consistent section 171 of the Dodd-Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act). Section 171 of the Dodd-Frank Act generally requires that the Board impose minimum leverage and risk-based capital requirements on depository institution holding companies, including estate trust SLHCs.

object if an institution wishes to apply the provisions of the final rule beginning with the date it is published in the **Federal Register**.

III. Regulatory Analysis

A. Paperwork Reduction Act (PRA)

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506; 5 CFR 1320, Appendix A.1), the Board reviewed the final rule under the authority delegated to the Board by the Office of Management and Budget. The final rule contains no requirements subject to the PRA.

B. Regulatory Flexibility Act Analysis

The Board is providing a final regulatory flexibility analysis with respect to this final rule. As discussed previously, the final rule provides examples of how the Board will apply the eligibility criteria for CET1 under Regulation Q to instruments issued by non-stock holding companies and provides certain exclusions from Regulation Q. The Regulatory Flexibility Act, 5 U.S.C. 601 *et seq.* (RFA), generally requires that an agency provide a final regulatory flexibility analysis in connection with a final rule. Under regulations issued by the Small Business Administration, a small entity includes a BHC, bank, or SLHC with assets of $550 million or less (small banking organization).[13] As of December 31, 2014, there were approximately 3,833 small BHCs and 271 small SLHCs.

The Board received no comments from the public or from the Chief Counsel for Advocacy of the Small Business Administration in response to the initial regulatory flexibility analysis. Thus, no issues were raised in public comments related to the Board's initial Regulatory Flexibility Act analysis and no changes are being made in response to such comments.

The final rule would apply to top-tier depository institution holding companies that are subject to Regulation Q. A substantial number of small depository institution holding companies are exempt from Regulation Q through the application of the Board's Small Bank Holding Company Policy Statement.[14] In addition, the Board does not believe that the final rule would have a significant impact on small banking organizations because the Board considers the final rule as clarifying the CET1 eligibility criteria and providing specific guidance on the application of the eligibility criteria to entities subject to Regulation Q, rather than imposing significant new requirements. The temporary exemptions from Regulation Q provided for estate trust SLHCs and ESOP holding companies relieve burden on covered small banking organizations, rather than imposing burden.

The Board is not aware of any other Federal rules that duplicate, overlap, or conflict with the final rule. The Board believes that the final rule will not have a significant economic impact on small banking organizations supervised by the Board and therefore believes that there are no significant alternatives to the final rule that would reduce the economic impact on small banking organizations supervised by the Board.

C. Plain Language

Section 722 of the Gramm-Leach-Bliley Act requires the Federal banking agencies to use plain language in all proposed and final rules published after January 1, 2000. The Board has sought to present the final rule in a simple and straightforward manner. The Board did not receive any comments on its use of plain language in the proposed rule.

List of Subjects in 12 CFR Part 217

Administrative practice and procedure, Banks, Banking, Capital, Federal Reserve System, Holding companies, Reporting and recordkeeping requirements, Securities.

Board of Governors of the Federal Reserve System

12 CFR CHAPTER II

Authority and Issuance

For the reasons set forth in the preamble, part 217 of chapter II of title 12 of the Code of Federal Regulations is amended as follows:

PART 217—CAPITAL ADEQUACY OF BANK HOLDING COMPANIES, SAVINGS AND LOAN HOLDING COMPANIES AND STATE MEMBER BANKS (REGULATION Q)

■ 1. The authority citation for part 217 continues to read as follows:

Authority: 12 U.S.C. 248(a), 321–338a, 481–486, 1462a, 1467a, 1818, 1828, 1831n, 1831o, 1831p–l, 1831w, 1835, 1844(b), 1851, 3904, 3906–3909, 4808, 5365, 5368, 5371.

■ 2. Add subpart I to read as follows:

Subpart I—Application of Capital Rules

Sec.

§ 217.501 The Board's Regulatory Capital Framework for Depository Institution Holding Companies Organized as Non-Stock Companies.

(a) *Applicability.* (1) This section applies to all depository institution holding companies that are organized as legal entities other than stock corporations and that are subject to this part (Regulation Q, 12 CFR part 217).[1]

(2) Notwithstanding §§ 217.2 and 217.10, a bank holding company or covered savings and loan holding company that is organized as a legal entity other than a stock corporation and has issued capital instruments that do not qualify as common equity tier 1 capital under § 217.20 by virtue of the requirements set forth in this section may treat those capital instruments as common equity tier 1 capital until July 1, 2016.

(b) *Common equity tier 1 capital criteria applied to capital instruments issued by non-stock companies.* (1) Subpart C of this part provides criteria for capital instruments to qualify as common equity tier 1 capital. This section describes how certain criteria apply to capital instruments issued by bank holding companies and covered savings and loan holding companies that are organized as legal entities other than stock corporations, such as limited liability companies (LLCs) and partnerships.

(2) Holding companies are organized using a variety of legal structures, including corporate forms, LLCs, partnerships, and similar structures.[2] In the Board's experience, some depository institution holding companies that are organized in non-stock form issue multiple classes of capital instruments that allocate profit and loss from a distribution differently among classes, which may affect the ability of those classes to qualify as common equity tier 1 capital.[3]

(3) Common equity tier 1 capital is defined in § 217.20(b). To qualify as

[13] *See* 13 CFR 121.201. Effective July 14, 2014, the Small Business Administration revised the size standards for banking organizations to $550 million in assets from $500 million in assets. 79 FR 33647 (June 12, 2014).

[14] *See* 12 CFR 217.1; 12 CFR part 225, Appendix C; 80 *FR* 5666 (February 3, 2015).

[1] *See* 12 CFR 217.1(c)(1) through (3).

[2] A stock corporation's common stock should satisfy the CET1 criteria so long as the common stock does not have unusual features, such as a limited duration.

[3] Notably, voting powers or other means of exercising control are not relevant for purposes of satisfying the CET1 eligibility criteria. Thus, the fact that a particular partner or member controls a holding company, for instance, due to serving as general partner or managing member, is not material to qualification of particular interests as CET1.

common equity tier 1 capital, capital instruments must satisfy a number of criteria. This section provides examples of the application of certain common equity tier 1 capital criteria that relate to the economic interests in the company represented by particular capital instruments.

(c) *Examples.* The following examples show how the criteria for common equity tier 1 capital apply to particular partnership or LLC structures.[4]

(1) *LLC with one class of membership interests.* (i) An LLC issues one class of membership interests that provides that all holders of the interests bear losses and receive dividends proportionate to their levels of ownership.

(ii) Provided that the other criteria in § 217.20(b) are met, the membership interests would qualify as common equity tier 1 capital.

(2) *Partnership with limited and general partners.* (i) A partnership has two classes of interests: General partnership interests and limited partnership interests. The general partners and the limited partners bear losses and receive distributions allocated proportionately to their capital contributions. In addition, the general partner has unlimited liability for the debts of the partnership.

(ii) Provided that the other criteria in § 217.20(b) are met, the general and limited partnership interests would qualify as common equity tier 1 capital. The fact of unlimited liability of the general partner is not relevant in the context of the eligibility criteria of common equity tier 1 capital instruments, provided that the general partner and limited partners share losses equally to the extent of the assets of the partnership, and the general partner is liable after the assets of the partnership are exhausted. In this regard, the general partner's unlimited liability is similar to a guarantee provided by the general partner, rather than a feature of the general partnership interest.

(3) *Senior and junior classes of capital instruments.* (i) An LLC issues two types of membership interests, Class A and Class B. Holders of Class A and Class B interests participate equally in operating distributions and have equal voting rights. However, in liquidation, holders of Class B interests must receive the entire amount of their contributed capital in order for any distributions to be made to holders of Class A interests.

(ii) Class B interests have a preference over Class A interests in liquidation and, therefore, would not qualify as common equity tier 1 capital as the Class B interests are not the most subordinated claim (criterion (i)) and do not share losses proportionately (criterion (viii) (§ 217.20(b)(1)(i) and (viii), respectively).

(A) If all other criteria are satisfied, Class A interests would qualify as common equity tier 1 capital.

(B) Class B interests may qualify as additional tier 1 capital, or tier 2 capital, if the Class B interests meet the applicable criteria (§ 217.20(c) and (d)).

(4) *LLC with two classes of membership interests.* (i) An LLC issues two types of membership interests, Class A and Class B. To the extent that the LLC makes a distribution, holders of Class A and Class B interests share proportionately in any losses and receive proportionate shares of contributed capital. To the extent that a capital distribution includes an allocation of profits, holders of Class A and Class B interests share proportionately up to the point where all holders receive a specific annual rate of return on capital contributions, and, if the distribution exceeds that point, holders of Class B interests receive double their proportional share and holders of Class A interests receive the remainder of the distribution.

(ii) Class A and Class B interests would both qualify as common equity tier 1 capital, provided that under all circumstances they share losses proportionately, as measured with respect to each distribution, and that they satisfy the common equity tier 1 capital criteria. The holders of Class A and Class B interests may receive different allocations of profits with respect to a distribution, provided that the distribution is made simultaneously to all members of Class A and Class B interests. Despite the potential for disproportionate profits, Class A and Class B interests have the same level of seniority with regard to potential losses and therefore they both satisfy all the criteria in § 217.20(b), including criterion (ii) (§ 217.20(b)(1)(ii)).

(5) *Alternative LLC with two classes of membership interests.* (i) An LLC issues two types of membership interests, Class A and Class B. In the event that the LLC makes a distribution, holders of Class A interests bear a disproportionately low level of any losses, such that the Class B interests bear a disproportionately high level of losses at the distribution. In contrast to the example in paragraph (c)(4) of this section, the different participation rights apply to distributions in situations where losses are allocated, including losses at liquidation.

(ii) Because holders of the Class A interests do not bear a proportional interest in the losses (criterion (ii) (§ 217.20(b)(1)(ii)), the Class A interests would not qualify as common equity tier 1 capital.

(A) Companies with such structures may revise their capital structures in order to provide for a sufficiently large class of capital instruments that proportionally bear first losses in liquidation (that is, the Class B interests in this example).

(B) Alternatively, companies with such structures could revise their capital structure to ensure that all classes of capital instruments that are intended to qualify as common equity tier 1 capital share equally in losses in liquidation consistent with criteria (i), (ii), (vii), and (viii) in § 217.20(b)(1)(i), (ii), (vii), respectively, even if each class of capital instruments has different rights to allocations of profits, as in paragraph (c)(4) of this section.

(6) *Mandatory distributions.* (i) A partnership agreement contains provisions that require distributions to holders of one or more classes of capital instruments on the occurrence of particular events, such as upon specific dates or following a significant sale of assets, but not including any final distributions in liquidation.

(ii) Any class of capital instruments that provides holders with rights to mandatory distributions would not qualify as common equity tier 1 capital because a holding company must have full discretion at all times to refrain from paying any dividends and making any other distributions on the instrument without triggering an event of default, a requirement to make a payment-in-kind, or an imposition of any other restriction on the holding company (criterion (vi) in § 217.20(b)(1)(vi)). Companies must ensure that they have a sufficient amount of capital instruments that do not have such rights and that meet the other criteria of common equity tier 1 capital, in order to meet the requirements of Regulation Q.

(7) *Features that Reallocate Prior Distributions.* (i) An LLC issues two types of membership interests, Class A and Class B. The terms of the LLC's membership interests provide that, under certain circumstances, holders of Class A interests must return a portion of earlier distributions, which are then distributed to holders of Class B interests (sometimes called a ''clawback'').

(ii) If the reallocation of prior distributions described in paragraph (c)(7)(i) of this section could result in holders of the Class B interests bearing

[4] Although the examples refer to specific types of legal entities for purposes of illustration, the substance of the Regulation Q criteria reflected in the examples applies to all types of legal entities.

fewer losses on an aggregate basis than Class A interests, the Class B interests would not qualify as common equity tier 1 capital. However, where the membership interests provide for disproportionate allocation of profits, such as described in the example in paragraph (c)(4) of this section, and the reallocation of prior distributions would be limited to reversing the disproportionate portions of prior distributions, both the Class A and Class B interests could qualify as common equity tier 1 capital provided that they met all the other criteria in § 217.20(b).

§ 217.502 Application of the Board's Regulatory Capital Framework to Employee Stock Ownership Plans that are Depository Institution Holding Companies and Certain Trusts that are Savings and Loan Holding Companies.

(a) *Employee Stock Ownership Plans.* Notwithstanding § 217.1(c), a bank holding company or covered savings and loan holding company that is an employee stock ownership plan is exempt from this part until the Board adopts regulations that directly relate to the application of capital regulations to employee stock ownership plans.

(b) *Personal or Family Trusts.* Notwithstanding § 217.1(c), a covered savings and loan holding company is exempt from this part if it is a personal or family trust and not a business trust until the Board adopts regulations that apply capital regulations to such a covered savings and loan holding company.

By order of the Board of Governors of the Federal Reserve System, December 4, 2015.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2015–31013 Filed 12–8–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 23

[Docket No. FAA–2015–3464; Special Conditions No. 23–272–SC]

Special Conditions: Cirrus Aircraft Corporation, SF50; Auto Throttle

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final special conditions.

SUMMARY: These special conditions are issued for the Cirrus Aircraft Corporation Model SF50 airplane. This airplane will have a novel or unusual design feature(s) associated with installation of an Auto Throttle System. The applicable airworthiness regulations do not contain adequate or appropriate safety standards for this design feature. These special conditions contain the additional safety standards that the Administrator considers necessary to establish a level of safety equivalent to that established by the existing airworthiness standards.

DATES: The effective date of these special conditions is December 9, 2015 and are applicable on December 2, 2015.

FOR FURTHER INFORMATION CONTACT: Jeff Pretz, Regulations and Policy Branch, ACE–111, Federal Aviation Administration, Small Airplane Directorate, Aircraft Certification Service, ACE–111, 901 Locust, Room 301, Kansas City, MO 64106; telephone (816) 329–3239, facsimile (816) 329–4090.

SUPPLEMENTARY INFORMATION:

Background

On September 9, 2008, Cirrus Aircraft Corporation applied for a type certificate for their new Model SF50. On December 11, 2012 Cirrus elected to adjust the certification basis of the SF50 to include 14 CFR part 23 through amendment 62. The SF50 is a low-wing, 7-seat (5 adults and 2 children), pressurized, retractable gear, carbon composite airplane with one turbofan engine mounted partially in the upper aft fuselage. It is constructed largely of carbon and fiberglass composite materials. Like other Cirrus products, the SF50 includes a ballistically deployed airframe parachute. The SF50 has a maximum operating altitude of 28,000 feet and the maximum takeoff weight will be at or below 6,000 pounds with a range at economy cruise of roughly 1,000 nautical miles.

Current part 23 airworthiness regulations do not contain appropriate safety standards for an Auto Throttle System (ATS) installation; therefore, special conditions are required to establish an acceptable level of safety. Part 25 regulations contain appropriate safety standards for these systems, making the intent for this project to apply the language in § 25.1329 for the auto throttle, while substituting § 23.1309 and § 23.143 in place of the similar part 25 regulations referenced in § 25.1329. In addition, malfunction of the ATS to perform its intended function shall be evaluated per the Loss of Thrust Control (LOTC) criteria established under part 33 for electronic engine controls. An analysis must show that no single failure or malfunction or probable combinations of failures of the ATS will permit the LOTC probability to exceed those established under part 33 for an electronic engine control.

Type Certification Basis

Under the provisions of 14 CFR 21.17, Cirrus must show that the Model SF50 meets the applicable provisions of part 23, as amended by amendments 23–1 through 23–62 thereto.

If the Administrator finds that the applicable airworthiness regulations (*i.e.,* 14 CFR part 23) do not contain adequate or appropriate safety standards for the SF50 because of a novel or unusual design feature, special conditions are prescribed under the provisions of § 21.16.

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

In addition to the applicable airworthiness regulations and special conditions, the SF50 must comply with the fuel vent and exhaust emission requirements of 14 CFR part 34 and the noise certification requirements of 14 CFR part 36 and the FAA must issue a finding of regulatory adequacy under section 611 of Public Law 92–574, the Noise Control Act of 1972.

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

Novel or Unusual Design Features

The SF50 will incorporate the following novel or unusual design features: An ATS as part of the automatic flight control system. The ATS utilizes a Garmin ''smart'' autopilot servo with a physical connection to the throttle quadrant control linkage. The auto throttle may be controlled by the pilot with an optional auto throttle control panel adjacent to the throttle lever. The auto throttle also provides an envelope protection function which does not require installation of the optional control panel.

Discussion

Part 23 currently does not sufficiently address auto throttle (also referred to as auto thrust) technology and safety concerns. Therefore, special conditions must be developed and applied to this project to ensure an acceptable level of safety has been obtained. For approval to use the ATS during flight, the SF50 must demonstrate compliance to the intent of the requirements of § 25.1329,

applying the appropriate part 23 references to § 23.1309 (to include performing a functional hazard assessment or system safety assessment to determine the applicable Software and Airborne Electronic Hardware assurance levels, and compliance to DO–178C & DO–254, as required) and § 23.143.

In addition, a malfunction of the ATS to perform its intended function is an LOTC event, and may result in a total loss of thrust control, transients, or uncommanded thrust changes. The classification of the failure condition for an LOTC event on a Class II single-engine aircraft is hazardous for aircraft that stall at or below 61 knots. From publication AC 23.1309–1E, based upon failure probability values shown in Figure 2, an LOTC event would have to meet a probability of failure value not to exceed 1×10^{-6}. In-service data for LOTC in single-engine turbine aircraft shows LOTC events exceed this probability; therefore, part 33 requirements for engine control probabilities will be accepted for the part 23 LOTC requirement.

The probabilities of failure for an LOTC event on a turbine engine shall not exceed the following (see AC33.28–1 and ANE–1993–33.28TLD–R1 for further guidance):

1. Average Events per Million Hours: 10 (1×10^{-05} per hour)
2. Maximum Events per Million Hours: 100 (1×10^{-04} per hour)

Note: The maximum events per flight hour are intended for Time Limited Dispatch (TLD) operation where the risk exposure is mitigated by limiting the time in which the aircraft is operated in the degraded condition.

Discussion of Comments

Notice of proposed special conditions No. 23–15–04–SC for the Cirrus Aircraft Corporation Model SF50 airplanes was published in the **Federal Register** on August 21, 2015 (80 FR 50808). No comments were received, and the special conditions are adopted as proposed.

Applicability

As discussed above, these special conditions are applicable to the Model SF50. Should Cirrus apply at a later date for a change to the type certificate to include another model incorporating the same novel or unusual design feature, the special conditions would apply to that model as well.

Under standard practice, the effective date of final special conditions would be 30 days after the date of publication in the **Federal Register**; however, as the certification date for the Cirrus Aircraft Corporation Model SF50 airplane is imminent, the FAA finds that good cause exists to make these special conditions effective upon issuance.

Conclusion

This action affects only certain novel or unusual design features on one model of airplanes. It is not a rule of general applicability and it affects only the applicant who applied to the FAA for approval of these features on the airplane.

List of Subjects in 14 CFR Part 23

Aircraft, Aviation safety, Signs and symbols.

Citation

The authority citation for these special conditions is as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701, 44702, 44704, 14 CFR 21.16 and 14 CFR 11.38 and 11.19.

The Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the following special conditions are issued as part of the type certification basis for Cirrus Aircraft Corporation Model SF50 airplanes.

1. Certification of Auto Throttle System Under Part 23

a. Quick disengagement controls for the auto thrust functions must be provided for each pilot. The auto thrust quick disengagement controls must be located on the thrust control levers. Quick disengagement controls must be readily accessible to each pilot while operating the thrust control levers.

b. The effects of a failure of the system to disengage the auto thrust functions when manually commanded by the pilot must be assessed in accordance with the requirements of § 23.1309.

c. Engagement or switching of the flight guidance system, a mode, or a sensor may not cause the auto thrust system to affect a transient response that alters the airplane's flight path any greater than a minor transient, as defined in paragraph (l)(1) of this section.

d. Under normal conditions, the disengagement of any automatic control function of a flight guidance system may not cause a transient response of the airplane's flight path any greater than a minor transient.

e. Under rare normal and non-normal conditions, disengagement of any automatic control function of a flight guidance system may not result in a transient any greater than a significant transient, as defined in paragraph (l)(2) of this section.

f. The function and direction of motion of each command reference control, such as heading select or vertical speed, must be plainly indicated on, or adjacent to, each control if necessary to prevent inappropriate use or confusion.

g. Under any condition of flight appropriate to its use, the flight guidance system may not produce hazardous loads on the airplane, nor create hazardous deviations in the flight path. This applies to both fault-free operation and in the event of a malfunction, and assumes that the pilot begins corrective action within a reasonable period of time.

h. When the flight guidance system is in use, a means must be provided to avoid excursions beyond an acceptable margin from the speed range of the normal flight envelope. If the airplane experiences an excursion outside this range, a means must be provided to prevent the flight guidance system from providing guidance or control to an unsafe speed.

i. The flight guidance system functions, controls, indications, and alerts must be designed to minimize flight crew errors and confusion concerning the behavior and operation of the flight guidance system. Means must be provided to indicate the current mode of operation, including any armed modes, transitions, and reversions. Selector switch position is not an acceptable means of indication. The controls and indications must be grouped and presented in a logical and consistent manner. The indications must be visible to each pilot under all expected lighting conditions.

j. Following disengagement of the auto thrust function, a caution (visual and auditory) must be provided to each pilot.

k. During auto thrust operation, it must be possible for the flight crew to move the thrust levers without requiring excessive force. The auto thrust may not create a potential hazard when the flight crew applies an override force to the thrust levers.

l. For purposes of this section, a transient is a disturbance in the control or flight path of the airplane that is not consistent with response to flight crew inputs or environmental conditions.

(1) A minor transient would not significantly reduce safety margins and would involve flight crew actions that are well within their capabilities. A minor transient may involve a slight increase in flight crew workload or some physical discomfort to passengers or cabin crew.

(2) A significant transient may lead to a significant reduction in safety

margins, an increase in flight crew workload, discomfort to the flight crew, or physical distress to the passengers or cabin crew, possibly including non-fatal injuries. Significant transients do not require, in order to remain within or recover to the normal flight envelope, any of the following:

i. Exceptional piloting skill, alertness, or strength.

ii. Forces applied by the pilot which are greater than those specified in § 23.143(c).

iii. Accelerations or attitudes in the airplane that might result in further hazard to secured or non-secured occupants.

It must also be demonstrated, through tests and analysis, that no single failure or malfunction or probable combinations of failures of the auto thrust system components results in the probability for LOTC, or un-commanded thrust changes and transients that result in an LOTC event, to exceed the following:

(1) Average Events per Million Hours: 10 (1×10^{-05} per hour)

(2) Maximum Events per Million Hours: 100 (1×10^{-04} per hour)

Note: The term ''probable'' in the context of ''probable combination of failures'' does not have the same meaning as used for a safety assessment process. The term ''probable'' in ''probable combination of failures'' means ''foreseeable,'' or those failure conditions anticipated to occur one or more times during the operational life of each airplane.

Issued in Kansas City, Missouri, on December 2, 2015.

Patrick Mullen,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–31058 Filed 12–8–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–3783; Directorate Identifier 2015–SW–027–AD; Amendment 39–18342; AD 2015–25–04]

RIN 2120–AA64

Airworthiness Directives; Agusta S.p.A. Helicopters

AGENCY: Federal Aviation Administration (FAA), Department of Transportation (DOT).

ACTION: Final rule; request for comments.

SUMMARY: We are adopting a new airworthiness directive (AD) for Agusta S.p.A. (Agusta) Model A109A and A109A II helicopters. This AD requires inspecting the slider assembly pitch control (slider) for play and replacing the slider if the play exceeds certain limits. This AD is prompted by a report of excessive slider play and wear that was detected during a scheduled inspection of a Model A109A II helicopter. These actions are intended to detect and prevent excessive wear and play on a slider, which could lead to loss of tail rotor pitch control and consequently loss of helicopter control.

DATES: This AD becomes effective December 24, 2015.

We must receive comments on this AD by February 8, 2016.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Docket:* Go to *http://www.regulations.gov.* Follow the online instructions for sending your comments electronically.
- *Fax:* 202–493–2251.
- *Mail:* Send comments to the U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590–0001.
- *Hand Delivery:* Deliver to the ''Mail'' address between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–3783; or in person at the Docket Operations Office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the European Aviation Safety Agency (EASA) AD, the economic evaluation, any comments received, and other information. The street address for the Docket Operations Office (telephone 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

For service information identified in this AD, contact AgustaWestland, Product Support Engineering, Via del Gregge, 100, 21015 Lonate Pozzolo (VA) Italy, ATTN: Maurizio D'Angelo; telephone 39–0331–664757; fax 39–0331–664680; or at *http://www.agustawestland.com/technical-bulletins.* You may review the referenced service information at the FAA, Office of the Regional Counsel, Southwest Region, Room 6N–321, 10101 Hillwood Pkwy, Fort Worth, TX 76177.

FOR FURTHER INFORMATION CONTACT: Martin R. Crane, Aviation Safety Engineer, Safety Management Group, Rotorcraft Directorate, FAA, 10101 Hillwood Pkwy, Fort Worth, TX 76177; telephone (817) 222–5110; email *martin.r.crane@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

This AD is a final rule that involves requirements affecting flight safety, and we did not provide you with notice and an opportunity to provide your comments prior to it becoming effective. However, we invite you to participate in this rulemaking by submitting written comments, data, or views. We also invite comments relating to the economic, environmental, energy, or federalism impacts that resulted from adopting this AD. The most helpful comments reference a specific portion of the AD, explain the reason for any recommended change, and include supporting data. To ensure the docket does not contain duplicate comments, commenters should send only one copy of written comments, or if comments are filed electronically, commenters should submit them only one time. We will file in the docket all comments that we receive, as well as a report summarizing each substantive public contact with FAA personnel concerning this rulemaking during the comment period. We will consider all the comments we receive and may conduct additional rulemaking based on those comments.

Discussion

EASA, which is the Technical Agent for the Member States of the European Union, has issued EASA AD No. 2015–0097, dated June 1, 2015, to correct an unsafe condition for Agusta Model A109A and A109A II helicopters. EASA advises that during a scheduled 100-flight-hour inspection on a Model A109A II helicopter, unusual play was detected on a part number (P/N) 109–0130–11–7 slider. Further investigation revealed excessive wear of the slider broaching at the point of contact with the tail rotor shaft. However, the cause of the excessive play and wear has not been determined.

This condition, if not detected and corrected, could lead to reduced control of the helicopter, EASA advises. EASA consequently requires repetitive inspections of slider P/N 109–0130–11–7 more frequently than those performed at the 100-flight-hour inspection and corrective actions depending on the findings. EASA advises that its AD is an interim measure and further AD action may follow.

FAA's Determination

These helicopters have been approved by the aviation authority of Italy and are approved for operation in the United States. Pursuant to our bilateral agreement with Italy, EASA, its technical representative, has notified us of the unsafe condition described in the EASA AD. We are issuing this AD because we evaluated all information provided by EASA and determined the unsafe condition exists and is likely to exist or develop on other helicopters of these same type designs.

Related Service Information

We reviewed AgustaWestland Bollettino Tecnico No. 109–149, dated May 29, 2015, for Model A109A and A109A II helicopters. The bulletin states that during a 100-flight-hour inspection of a Model A109A II helicopter, ''anomalous'' play was found on a P/N 109–0130–11–7 slider. After the slider was removed and inspected, extended, unusual wear of the broaching in the point of contact with the tail rotor shaft was found. Agusta states that the investigation is ongoing, but as a precautionary measure it is reducing the slider inspection intervals from 100 flight hours to 25 flight hours.

AD Requirements

This AD requires, within 25 hours time-in-service (TIS) and thereafter at intervals not to exceed 25 hours TIS, inspecting the slider for play. If there is any play that exceeds 2.3 millimeters (0.09 inch), this AD requires replacing the slider with an airworthy slider before further flight.

Interim Action

We consider this AD to be an interim action. The design approval holder has not determined the cause of the unsafe condition identified in this AD. If a cause is determined and actions developed to address the cause, we might consider additional rulemaking.

Costs of Compliance

We estimate that this AD will affect 36 helicopters of U.S. Registry and that labor costs average $85 a work-hour. Based on these estimates, we expect the following costs:

- Inspecting the slider for play requires 1 work-hour for a labor cost of $85 per helicopter and $3060 for the U.S. fleet.
- Replacing the slider requires 10 work-hours and $4068 in parts for a total cost of $4918 per helicopter.

According to Agusta's service information, some of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage by Agusta. Accordingly, we have included all costs in our cost estimate.

FAA's Justification and Determination of the Effective Date

Providing an opportunity for public comments prior to adopting these AD requirements would delay implementing the safety actions needed to correct this known unsafe condition. Therefore, we find that the risk to the flying public justifies waiving notice and comment prior to the adoption of this rule because the unsafe condition can adversely affect control of the helicopter and the required corrective actions must be accomplished within 25 hours TIS. These helicopters have a variety of uses, including search-and-rescue and medical flights, and are expected to accumulate 25 hours TIS within a few weeks.

Since an unsafe condition exists that requires the immediate adoption of this AD, we determined that notice and opportunity for public comment before issuing this AD are impracticable and contrary to the public interest and that good cause exists for making this amendment effective in less than 30 days.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed, I certify that this AD:

1. Is not a ''significant regulatory action'' under Executive Order 12866;

2. Is not a ''significant rule'' under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);

3. Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction; and

4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

We prepared an economic evaluation of the estimated costs to comply with this AD and placed it in the AD docket.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

2015–25–04 Agusta S.p.A.: Amendment 39–18342; Docket No. FAA–2015–3783; Directorate Identifier 2015–SW–027–AD.

(a) Applicability

This AD applies to Agusta S.p.A. (Agusta) Model A109A and A109A II helicopters with a slider assembly pitch control (slider) part number 109–0130–11–7 installed, certificated in any category.

(b) Unsafe Condition

This AD defines the unsafe condition as excessive wear and play on a slider. This condition could result in loss of tail rotor pitch control and consequently loss of helicopter control.

(c) Effective Date

This AD becomes effective December 24, 2015.

(d) Compliance

You are responsible for performing each action required by this AD within the specified compliance time unless it has already been accomplished prior to that time.

(e) Required Actions

Within 25 hours time-in-service (TIS) and thereafter at intervals not to exceed 25 hours

TIS, inspect the slider for play. If there is play greater than 2.3 millimeters (0.09 inch), replace the slider with an airworthy slider before further flight.

(f) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Safety Management Group, FAA, may approve AMOCs for this AD. Send your proposal to: Martin R. Crane, Aviation Safety Engineer, Safety Management Group, Rotorcraft Directorate, FAA, 10101 Hillwood Pkwy, Fort Worth, TX 76177; telephone (817) 222–5110; email *9-ASW-FTW-AMOC-Requests@faa.gov.*

(2) For operations conducted under a 14 CFR part 119 operating certificate or under 14 CFR part 91, subpart K, we suggest that you notify your principal inspector, or lacking a principal inspector, the manager of the local flight standards district office or certificate holding district office, before operating any aircraft complying with this AD through an AMOC.

(g) Additional Information

(1) AgustaWestland Bollettino Tecnico No. 109–149, dated May 29, 2015, which is not incorporated by reference, contains additional information about the subject of this AD. For service information identified in this AD, contact AgustaWestland, Product Support Engineering, Via del Gregge, 100, 21015 Lonate Pozzolo (VA) Italy, ATTN: Maurizio D'Angelo; telephone 39–0331–664757; fax 39–0331–664680; or at *http://www.agustawestland.com/technical-bulletins.* You may review a copy of the service information at the FAA, Office of the Regional Counsel, Southwest Region, Room 6N–321, 10101 Hillwood Pkwy, Fort Worth, TX 76177.

(2) The subject of this AD is addressed in European Aviation Safety Agency (EASA) AD No. 2015–0097, dated June 1, 2015. You may view the EASA AD on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2015–3783.

(h) Subject

Joint Aircraft Service Component (JASC) Code: 6720, Tail Rotor Control System.

Issued in Fort Worth, Texas, on December 2, 2015.

James A. Grigg,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 2015–30973 Filed 12–8–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Parts 730, 734, 736, 742, 744, and 745

[Docket No. 151123999–5999–01]

RIN 0694–AG78

Updated Statements of Legal Authority for the Export Administration Regulations

AGENCY: Bureau of Industry and Security, Commerce.

ACTION: Final rule.

SUMMARY: This rule updates the Code of Federal Regulations (CFR) legal authority citations in the Export Administration Regulations (EAR) to cite the most recent Presidential notice continuing an emergency declared pursuant to the International Emergency Economic Powers Act. This is a non-substantive rule that only updates authority paragraphs of the EAR. It does not alter any right, obligation or prohibition that applies to any person under the EAR.

DATES: The rule is effective December 9, 2015.

FOR FURTHER INFORMATION CONTACT: William Arvin, Regulatory Policy Division, Bureau of Industry and Security, email *william.arvin@bis.doc.gov* or telephone: (202) 482–2440.

SUPPLEMENTARY INFORMATION:

Background

The authority for parts 730, 734, 736, 742, 744, and 745 of the EAR rests, in part, on Executive Order 12938 of November 14, 1994—Proliferation of Weapons of Mass Destruction, 59 FR 59099, 3 CFR, 1994 Comp., p. 950 and on annual notices continuing the emergency declared in that executive order. This rule revises the authority citations for the affected parts to cite the most recent such notice, which the President signed on November 12, 2015.

This rule is purely non-substantive, and makes no changes other than to revise CFR authority citations for the purpose of making the authority citations current. It does not change the text of any section of the EAR, nor does it alter any right, obligation or prohibition that applies to any person under the EAR.

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). This rule does not impose any regulatory burden on the public and is consistent with the goals of Executive Order 13563. This rule has been determined to be not significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor 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 does not involve any collection of information.

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

4. The Department finds that there is good cause under 5 U.S.C. 553(b)(B) to waive the provisions of the Administrative Procedure Act requiring prior notice and the opportunity for public comment because they are unnecessary. This rule only updates legal authority citations. It clarifies information and is non-discretionary. This rule does not alter any right, obligation or prohibition that applies to any person under the EAR. Because these revisions are not substantive changes, it is unnecessary to provide notice and opportunity for public comment. In addition, the 30-day delay in effectiveness otherwise required by 5 U.S.C. 553(d) is not applicable because this rule is not a substantive rule. Because neither the Administrative Procedure Act nor any other law requires that notice of proposed rulemaking and an opportunity for public comment be given for this rule, the analytical requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) are not applicable. Accordingly, no Regulatory Flexibility Analysis is required and none has been prepared.

List of Subjects

15 CFR Part 730

Administrative practice and procedure, Advisory committees, Exports, Reporting and recordkeeping requirements, Strategic and critical materials.

15 CFR Part 734

Administrative practice and procedure, Exports, Inventions and patents, Research, Science and technology.

15 CFR Part 736

Exports.

15 CFR Part 742

Exports, Terrorism.

15 CFR Part 744

Exports, Reporting and recordkeeping requirements, Terrorism.

15 CFR Part 745

Administrative practice and procedure, Chemicals, Exports, Foreign trade, Reporting and recordkeeping requirements.

Accordingly, parts 730, 734, 736, 742, 744, and 745 of the EAR (15 CFR parts 730–774) are amended as follows:

PART 730—[AMENDED]

■ 1. The authority citation for 15 CFR part 730 is revised 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. 2151 note; 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. 11912, 41 FR 15825, 3 CFR, 1976 Comp., p. 114; E.O. 12002, 42 FR 35623, 3 CFR, 1977 Comp., p. 133; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12214, 45 FR 29783, 3 CFR, 1980 Comp., p. 256; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12854, 58 FR 36587, 3 CFR, 1993 Comp., p. 179; E.O. 12918, 59 FR 28205, 3 CFR, 1994 Comp., p. 899; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 12981, 60 FR 62981, 3 CFR, 1995 Comp., p. 419; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; E.O. 13338, 69 FR 26751, 3 CFR, 2004 Comp., p 168; E.O. 13637, 78 FR 16129, 3 CFR, 2014 Comp., p. 223; Notice of January 21, 2015, 80 FR 3461 (January 22, 2015); Notice of May 6, 2015, 80 FR 26815 (May 8, 2015); Notice of August 7, 2015, 80 FR 48233 (August 11, 2015); Notice of September 18, 2015, 80 FR 57281 (September 22, 2015); Notice of November 12, 2015, 80 FR 70667 (November 13, 2015).

PART 734—[AMENDED]

■ 2. The authority citation for 15 CFR part 734 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13637, 78 FR 16129, 3 CFR, 2014 Comp., p. 223; Notice of August 7, 2015, 80 FR 48233 (August 11, 2015); Notice of November 12, 2015, 80 FR 70667 (November 13, 2015).

PART 736—[AMENDED]

■ 3. The authority citation for 15 CFR part 736 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 2151 note; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 13020, 61 FR 54079, 3 CFR, 1996 Comp., p. 219; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13338, 69 FR 26751, 3 CFR, 2004 Comp., p. 168; Notice of May 6, 2015, 80 FR 26815 (May 8, 2015); Notice of August 7, 2015, 80 FR 48233 (August 11, 2015); Notice of November 12, 2015, 80 FR 70667 (November 13, 2015).

PART 742—[AMENDED]

■ 4. The authority citation for 15 CFR part 742 is revised 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, 68 FR 26459, 3 CFR, 2004 Comp., p. 320; Notice of August 7, 2015, 80 FR 48233 (August 11, 2015); Notice of November 12, 2015, 80 FR 70667 (November 13, 2015).

PART 744—[AMENDED]

■ 5. The authority citation for 15 CFR part 744 is revised to read as follows:

Authority: 50 U.S.C. app. 2401 *et seq.;* 50 U.S.C. 1701 *et seq.;* 22 U.S.C. 3201 *et seq.;* 42 U.S.C. 2139a; 22 U.S.C. 7201 *et seq.;* 22 U.S.C. 7210; E.O. 12058, 43 FR 20947, 3 CFR, 1978 Comp., p. 179; E.O. 12851, 58 FR 33181, 3 CFR, 1993 Comp., p. 608; E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; E.O. 12947, 60 FR 5079, 3 CFR, 1995 Comp., p. 356; E.O. 13026, 61 FR 58767, 3 CFR, 1996 Comp., p. 228; E.O. 13099, 63 FR 45167, 3 CFR, 1998 Comp., p. 208; E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; E.O. 13224, 66 FR 49079, 3 CFR, 2001 Comp., p. 786; Notice of January 21, 2015, 80 FR 3461 (January 22, 2015); Notice of August 7, 2015, 80 FR 48233 (August 11, 2015); Notice of September 18, 2015, 80 FR 57281 (September 22, 2015); Notice of November 12, 2015, 80 FR 70667 (November 13, 2015).

PART 745—[AMENDED]

■ 6. The authority citation for 15 CFR part 745 is revised to read as follows:

Authority: 50 U.S.C. 1701 *et seq.;* E.O. 12938, 59 FR 59099, 3 CFR, 1994 Comp., p. 950; Notice of November 12, 2015, 80 FR 70667 (November 13, 2015).

Dated: November 30, 2015.

Kevin J. Wolf,

Assistant Secretary for Export Administration.

[FR Doc. 2015–30753 Filed 12–8–15; 8:45 am]

BILLING CODE 3510–33–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510, 520, 522, 524, and 558

[Docket No. FDA–2015–N–0002]

New Animal Drugs; Approval of New Animal Drug Applications; Withdrawals of Approval of New Animal Drug Applications; Changes of Sponsorship

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect application-related actions for new animal drug applications (NADAs) and abbreviated new animal drug applications (ANADAs) during September and October 2015. FDA is also informing the public of the availability of summaries of the basis of approval and of environmental review documents, where applicable. The animal drug regulations are also being amended to reflect changes of sponsorship of applications and the voluntary withdrawals of approval of applications that occurred in September and October 2015.

DATES: This rule is effective December 9, 2015, except for the amendments to 21 CFR 520.446, 520.2043, 558.625, and 558.630, which are effective December 21, 2015.

FOR FURTHER INFORMATION CONTACT: George K. Haibel, Center for Veterinary Medicine (HFV–6), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5689, *george.haibel@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Approval Actions

FDA is amending the animal drug regulations to reflect approval actions for NADAs and ANADAs during September and October 2015, as listed in table 1. In addition, FDA is informing the public of the availability, where applicable, of documentation of environmental review required under the National Environmental Policy Act (NEPA) and, for actions requiring review of safety or effectiveness data, summaries of the basis of approval (FOI Summaries) under the Freedom of Information Act (FOIA). These public documents may be seen in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday. Persons with access to the Internet may obtain these documents at the Center for Veterinary Medicine FOIA Electronic Reading Room: *http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/CVMFOIAElectronicReadingRoom/default.htm.* Marketing exclusivity and patent information may be accessed in FDA's publication, Approved Animal Drug Products Online (Green Book) at: *http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm.*

TABLE 1—ORIGINAL AND SUPPLEMENTAL NADAS AND ANADAS APPROVED DURING SEPTEMBER AND OCTOBER 2015

File No.	Sponsor	Product name	Action	21 CFR section	FOIA summary	NEPA review
141–440	Piedmont Animal Health, 204 Muirs Chapel Rd., suite 200, Greensboro, NC 27410.	CLARO (florfenicol, terbinafine, mometasone furoate) Otic Solution.	Original approval for the treatment of otitis externa in dogs.	524.957	yes	CE.[1] [2]
141–449	Intervet, Inc., 2 Giralda Farms, Madison, NJ 07940.	SAFE–GUARD AquaSol (fenbendazole oral suspension) Suspension Concentrate.	Original approval for the treatment and control of certain nematode worms in broiler chickens, replacement chickens intended to become breeding chickens, and breeding chickens.	520.905a	yes	EA/FONSI.[3]
141–442	Zoetis Inc., 333 Portage St., Kalamazoo, MI 49007.	LUTALYSE HighCon (dinoprost tromethamine injection) Injection.	Supplemental approval of subcutaneous route of administration.	522.690	yes	CE.[1] [4]
108–901	Zoetis Inc. 333 Portage St., Kalamazoo, MI 49007.	LUTALYSE (dinoprost tromethamine injection) Injection.	Supplemental approval of revised indications for uses in cattle.	522.690	no	CE.[1] [4]

[1] The Agency has determined that this action is categorically excluded (CE) from the requirement to submit an environmental assessment or an environmental impact statement because it is of a type that does not have a significant effect on the human environment.
[2] CE granted under 21 CFR 25.33(d)(1).
[3] The Agency has carefully considered an environmental assessment (EA) of the potential environmental impact of this action and has made a finding of no significant impact (FONSI).
[4] CE granted under 21 CFR 25.33(a)(1).

II. Changes of Sponsorship

During September and October 2015, ownership of, and all rights and interest in, the following approved applications have been transferred as follows:

File No.	Previous sponsor	Product name	New sponsor	21 CFR section
141–440	Piedmont Animal Health, 204 Muirs Chapel Rd., suite 200, Greensboro, NC 27410.	CLARO (florfenicol, terbinafine, mometasone furoate) Otic Solution.	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201.	524.957
200–582	Orkeo USA, Inc., 77 Water St., New York, NY 10005.	LONCOR 300 (florfenicol) Injectable Solution.	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201.	522.955

As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these changes of sponsorship. Following the change of sponsorship of ANADA 200–582, Orkeo USA, Inc., is no longer the sponsor of an approved application.

III. Withdrawals of Approval

In addition, during September and October 2015, the following three sponsors have requested that FDA withdraw approval of the NADAs and ANADAs listed in the following table because the products are no longer manufactured or marketed:

File No.	Sponsor	Product name	21 CFR section
140–680 [1]	Pharmgate LLC, 1015 Ashes Dr., suite 102, Wilmington, NC 28405.	TYLAN (tylosin phosphate) Premix	558.625

File No.	Sponsor	Product name	21 CFR section
140–681 [1]	Pharmgate LLC, 1015 Ashes Dr., suite 102, Wilmington, NC 28405.	TYLAN SULFA G (tylosin phosphate and sulfamethazine) Premix.	558.630
200–028	Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514.	EVICT 300 (pyrantel pamoate) Suspension	520.2043
200–383	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201.	CLINDAROBE (clindamycin) Capsules	520.446

[1] These NADAs were identified as being affected by guidance for industry #213, ''New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209,'' December 2013.

Elsewhere in this issue of the **Federal Register**, FDA gave notice that approval of NADA 140–680, NADA 140–681, ANADA 200–028, and ANADA 200–383, and all supplements and amendments thereto, is withdrawn, effective December 21, 2015. As provided in the regulatory text of this document, the animal drug regulations are amended to reflect these voluntary withdrawals of approval.

IV. Technical Amendments

FDA has noticed that a previous sponsor of ANADA 200–383, Teva Canada Ltd., was no longer the sponsor of an approved application following a prior change of sponsorship. At this time, FDA is amending the regulation to remove the firm from the listings of sponsors of approved applications in 21 CFR 510.600. This action is being taken to improve the accuracy of the regulations.

FDA is also revising the special considerations for medicated feeds containing veterinary feed directive drugs to align with 21 CFR 558.6(a)(6), which was recently amended (80 FR 31708, June 3, 2015). This action is being taken to improve the consistency of the regulations.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability''. Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Parts 520, 522, and 524

Animal drugs.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR parts 510, 520, 522, 524, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e.

§ 510.600 [Amended]

■ 2. In § 510.600:

■ a. In the table in paragraph (c)(1), remove the entries for ''Orkeo USA, Inc.'' and ''Teva Canada Ltd.''; and

■ b. In the table in paragraph (c)(2), remove the entries for ''043806'' and ''086050''.

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 3. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 520.446 [Amended]

■ 4. Effective December 21, 2015, in § 520.446, in paragraph (b)(1), remove ''Nos. 000859 and 054771'' and in its place add ''No. 054771''.

■ 5. In § 520.905a:

■ a. Revise paragraphs (a) and (e)(4)(i);

■ b. In paragraph (e)(4)(iii), remove the first sentence; and

■ c. Add paragraph (e)(5).

The revisions and addition read as follows:

§ 520.905a Fenbendazole suspension.

(a) *Specifications.* Each milliliter of suspension contains 100 milligrams (mg) fenbendazole for use as in paragraphs (e)(1), (2), (3), and (4) of this section; or 200 mg fenbendazole for use as in paragraph (e)(5) of this section.

* * * * *

(e) * * *

(4) * * *

(i) *Amount.* Administer orally 5 mg/kg of body weight (2.3 mg/lb). Retreatment may be needed after 4 to 6 weeks.

* * * * *

(5) *Chickens*—(i) *Amount.* Administer orally via drinking water at a daily dose of 1 mg/kg body weight (0.454 mg/lb) for 5 consecutive days.

(ii) *Indications for use.* For the treatment and control of adult *Ascaridia galli* in broiler chickens and replacement chickens intended to become breeding chickens, and for the treatment and control of adult *A. galli* and *Heterakis gallinarum* in breeding chickens.

(iii) *Limitations.* Not for use in laying hens and replacement chickens intended to become laying hens.

§ 520.2043 [Amended]

■ 6. Effective December 21, 2015, in § 520.2043, in paragraph (b)(2), remove ''Nos. 054771, 055246, 058829, and 059130'' and in its place add ''Nos. 000859, 054771, and 058829''.

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

■ 7. The authority citation for 21 CFR part 522 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 8. In § 522.690, revise paragraphs (b)(2) and (d)(1)(i) and add paragraph (b)(3) to read as follows:

§ 522.690 Dinoprost.

* * * * *

(b) * * *

(2) No. 054771 for use of the 5 mg/mL product as in paragraphs (d)(1), (2), and (3) of this section.

(3) No. 000859 for use of the 5 mg/mL product as in paragraphs (d)(2), (3), and (4) of this section.

* * * * *

(d) * * *

(1) * * *

(i) *Amount.* 25 mg as a single intramuscular or subcutaneous injection.

* * * * *

§ 522.955 [Amended]

■ 9. In § 522.955(b)(2), remove ''086050'' and in its place add ''000859''.

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

■ 10. The authority citation for 21 CFR part 524 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 11. Add § 524.957 to read as follows:

§ 524.957 Florfenicol, terbinafine, and mometasone otic solution.

(a) *Specifications.* Each single-dose, prefilled dropperette contains 1 milliliter (mL) of a solution containing 15 milligrams (mg) florfenicol, 13.3 mg terbinafine, and 2 mg mometasone furoate.

(b) *Sponsor.* See No. 000859 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs*—(1) *Amount.* Administer one dropperette (1 mL) per affected ear(s).

(2) *Indications for use.* For the treatment of otitis externa in dogs associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Staphylococcus pseudintermedius*).

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

■ 12. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: (P≤21 U.S.C. 354, 360b, 360ccc, 360ccc–1, 371.

■ 13. In § 558.68, revise paragraph (c)(1) to read as follows:

§ 558.68 Avilamycin.

* * * * *

(c) * * *

(1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

* * * * *

■ 14. In § 558.261, revise paragraphs (c)(1) and (2) introductory text to read as follows:

§ 558.261 Florfenicol.

* * * * *

(c) * * *

(1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

(2) The expiration date of VFDs for florfenicol medicated feeds:

* * * * *

■ 15. In § 558.618, revise paragraph (c)(1) to read as follows:

§ 558.618 Tilmicosin.

* * * * *

(c) * * *

(1) Federal law restricts medicated feed containing this veterinary feed directive (VFD) drug to use by or on the order of a licensed veterinarian. See § 558.6 for additional requirements.

* * * * *

§ 558.625 [Amended]

■ 16. Effective December 21, 2015, in § 558.625, remove paragraph (b)(5) and redesignate paragraph (b)(6) as paragraph (b)(5).

§ 558.630 [Amended]

■ 17. Effective December 21, 2015, in § 558.630, in paragraph (b)(2), remove ''Nos. 054771 and 069254'' and in its place add ''No. 054771''.

Dated: December 4, 2015.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2015–31042 Filed 12–8–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 520 and 558

[Docket No. FDA–2015–N–0002]

New Animal Drugs; Withdrawal of Approval of New Animal Drug Applications

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification of withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing approval of two new animal drug applications (NADAs) and two abbreviated new animal drug applications (ANADAs). This action is being taken at the sponsors' requests because these products are no longer manufactured or marketed.

DATES: Withdrawal of approval is effective December 21, 2015.

FOR FURTHER INFORMATION CONTACT: Sujaya Dessai, Center for Veterinary Medicine (HFV–212), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5761, *sujaya.dessai@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: The following three sponsors have requested that FDA withdraw approval of the NADAs and ANADAs listed in the following table because the products are no longer manufactured or marketed:

File No.	Sponsor	Product name	21 CFR section
140–680 [1]	Pharmgate LLC, 1015 Ashes Dr., suite 102, Wilmington, NC 28405.	TYLAN (tylosin phosphate) Premix	558.625
140–681 [1]	Pharmgate LLC, 1015 Ashes Dr., suite 102, Wilmington, NC 28405.	TYLAN SULFA G (tylosin phosphate and sulfamethazine) Premix.	558.630
200–028	Pegasus Laboratories, Inc., 8809 Ely Rd., Pensacola, FL 32514.	EVICT 300 (pyrantel pamoate) Suspension	520.2043
200–383	Bayer HealthCare LLC, Animal Health Division, P.O. Box 390, Shawnee Mission, KS 66201.	CLINDAROBE (clindamycin) Capsules	520.446

[1] These NADAs were identified as being affected by guidance for industry #213, ''New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209,'' December 2013.

Therefore, under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, and in accordance with 21 CFR 514.116 *Notice of withdrawal of approval of application,* notice is given that approval of NADA 140–680, NADA 140–681, ANADA 200–028, and ANADA 200–383, and all supplements and amendments thereto, is hereby withdrawn, effective December 21, 2015.

Elsewhere in this issue of the **Federal Register**, FDA is amending the animal drug regulations to reflect the voluntary

withdrawal of approval of these applications.

Dated: December 4, 2015.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2015–31040 Filed 12–8–15; 8:45 am]

BILLING CODE 4164–01–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA–HQ–OPP–2014–0822; FRL–9939–52]

Azoxystrobin; Pesticide Tolerances

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes tolerances for residues of azoxystrobin in or on quinoa grain, ti leaves, ti roots, and modifies the existing tolerances for the stone fruit group 12 and tree nut group 14 to read ''stone fruit group 12–12'' and ''tree nut group 14–12, except pistachio'' respectively. Interregional Research Project Number 4 (IR–4) requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

DATES: This regulation is effective December 9, 2015. Objections and requests for hearings must be received on or before February 8, 2016, 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–2014–0822, 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 Printing 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–2014–0822 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 February 8, 2016. 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–2014–0822, 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 March 4, 2015 (80 FR 11611) (FRL–9922–68), 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 4E8319) by IR–4, 500 College Road East, Suite 201 W, Princeton, NJ 08540. The petition requested that 40 CFR part 180 be amended by establishing tolerances for residues of azoxystrobin (methyl (E)-2-{2-[6-(2-cyanophenoxy) pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate) and the Z isomer of azoxystrobin (methyl (Z)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate) in or on the raw agricultural commodities ti palm, leaves at 50 parts per million (ppm); ti palm, roots at 0.5 ppm; fruit, stone, group 12–12 at 2.0 ppm; and nut, tree, group 14–12 at 0.02 ppm. Upon the approval of the aforementioned tolerances, the petitioner requested to remove the established tolerances for azoxystrobin in or on the raw agricultural commodities fruit, stone, group 12 at 1.5 ppm; and nut, tree, group 14 at 0.02 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, the registrant, which is available in the docket, *http://www.regulations.gov.* EPA received two comments in response to the March 4, 2015 Notice of Filing that simply said ''Good.''

In the **Federal Register** of October 21, 2015 (80 FR 63731) (FRL–9935–29), EPA amended the initial notice of filing for pesticide petition (PP 4E8319), including the commodity quinoa grain at 3.0 ppm in addition to the commodities originally requested and listed above. Comments were received

to the notice of filing. EPA's response to these comments is discussed in Unit IV.C.

EPA has modified the tolerance for the tree nut group 14–12 to exclude pistachio. The reason for this change is explained in Unit IV.D.

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), 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, consistent with FFDCA section 408(b)(2), for tolerances for residues of azoxystrobin in or on quinoa grain, ti palm leaves, ti palm roots, the stone fruit group 12–12, and the tree nut group 14–12. As discussed below, EPA is relying upon the findings in the preamble to the rule published in the **Federal Register** May 1, 2015 (80 FR 24824) (FRL–9926–24) establishing tolerances for azoxystrobin and supporting risk assessments to establish and modify these tolerances.

On May 1, 2015, EPA published a final rule establishing tolerances for residues of azoxystrobin in or on coffee, green bean; pear, Asian; and tea, dried based on the Agency's conclusion that aggregate exposure to azoxystrobin is safe for the general population, including infants and children. In addition to the tolerances listed above, EPA also considered the following uses in the risk assessments that supported the May 1, 2015 final rule: Ti palm leaves, ti palm roots, the stone fruit group 12–12, and the tree nut group 14–12 and also separately evaluated the request to establish a tolerance in or on quinoa grain.

Since the publication of the May 1, 2015 final rule, the toxicity profile of azoxystrobin has not changed, and the risk assessments that supported the establishment of those azoxystrobin tolerances published in the May 1, 2015 **Federal Register** remain valid. Those risk assessments also support the establishment of the tolerances that are the subject of this action. The Agency also evaluated the request to establish a tolerance in or on quinoa grain at 3.0 ppm and concluded that the aggregate exposure and risks would not increase as a result of the proposed use on quinoa and are the same as those estimated in the May 1 final rule. Therefore, EPA is relying on those risk assessments in order to establish the new tolerances. For a detailed discussion of the aggregate risk assessments and determination of safety for the proposed tolerances, please refer to the May 1, 2015 **Federal Register** document and its supporting documents, available at *http://www.regulations.gov.* EPA relies upon those supporting risk assessments and the findings made in the **Federal Register** document in support of this rule.

Based on the risk assessments and information described above, 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 azoxystrobin residues. Further information about EPA's risk assessment and determination of safety supporting the tolerances established in the May 1, 2015 **Federal Register** action, as well as the new azoxystrobin tolerances can be found at *http://www.regulations.gov* in the documents entitled: ''Azoxystrobin. Human Health Aggregate Risk Assessment for Permanent Tolerances on Imported Asian Pear, Imported Tea, and Imported Coffee; Establishment of Permanent Tolerances on Ti Palm and for Crop Group Conversions for Stone Fruits Group 12–12 and Tree Nut Group 14–12 Crop Groups'' and ''Azoxystrobin. Addendum to Human Health Aggregate Risk Assessment D423691 and D418374, Dated 4/7/2015, to Support a New Use on Quinoa.'' The documents may be found in docket ID number EPA–HQ–OPP–2014–0822.

IV. Other Considerations

A. Analytical Enforcement Methodology

Adequate enforcement methodology (gas chromatography with a nitrogenphosphorus detector (GC/NPD) method, RAM 243/04) is available to enforce the tolerance expression for residues of azoxystrobin and its *Z*-isomer in crop commodities. This method (designated RAM 243, dated 5/15/98) has been submitted to FDA for inclusion in the Pesticide Analytical Manual (PAM), Volume II.

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 quinoa grain or ti palm leaves or roots.

The Codex has established an MRL for stone fruit at 2 milligram/kilogram (mg/kg), which is harmonized with the U.S. tolerance of 2 ppm.

The Codex has established an MRL of 0.01 mg/kg for tree nuts. The US crop group tolerance is based on a residue definition of azoxystrobin plus the *Z*-isomer (R230310). Residues were < 0.01 ppm for each component in the almond and pecan trials. Therefore, the tolerance estimate is 0.02 ppm, the sum of the components. The Codex residue definition is parent only, which support the 0.01 mg/kg MRL. The US tolerance cannot be harmonized with Codex at this time.

C. Response to Comments

Four comments were received in response to the October 21, 2015 notice of filing. The first comment asserted that no residues should be allowed and that the pesticide should not be approved for sale or use. The second stated that pesticides are ''causing normally

healthy people to have serious life treating (sic) health issues and is making many Americans overweight'' and the commenter did not want their food to have pesticide residues. The third commenter stated that they were very allergic to any chemical and demanded that all chemical treatments must be rejected and stopped. The Agency understands the commenters' concerns and recognizes that some individuals believe that pesticides should be banned on agricultural crops. However, the existing legal framework provided by section 408 of the FFDCA states that tolerances may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. The comments appear to be directed at the underlying statute and not EPA's implementation of it; the citizens have made no contention that EPA has acted in violation of the statutory framework.

The fourth comment was from the Center for Biological Diversity and concerned endangered species; specifically stating that EPA cannot approve this new use prior to completion of consultations with the U.S. Fish and Wildlife Service and the National Marine Fisheries Service (''the Services''). This comment is not relevant to the Agency's evaluation of safety of the azoxystrobin tolerances; section 408 of the FFDCA focuses on potential harms to human health and does not permit consideration of effects on the environment.

D. Revisions to Petitioned-For Tolerances

The petitioned-for tolerance for ''Nut, tree, group 14–12'' is being modified to read ''Nut, tree, group 14–12, except pistachio'' because an existing tolerance for pistachio exists at a higher level (0.50 ppm). In addition, although the petition requested tolerances for ti palm leaves and roots, EPA is establishing tolerances for ''ti, leaves'' and ''ti, roots'' to be consistent with its food and feed commodity vocabulary.

V. Conclusion

Therefore, tolerances are established for residues of azoxystrobin (methyl (E)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate) and the Z isomer of azoxystrobin (methyl (Z)-2-{2-[6-(2-cyanophenoxy)pyrimidin-4-yloxy]phenyl}-3-methoxyacrylate) in or on the raw agricultural commodities quinoa, grain at 3.0 ppm; ti, leaves at 50 ppm; and ti, roots at 0.5 ppm. Additionally, the existing tolerance for ''fruit, stone, group 12'' is modified to read ''fruit, stone, group 12–12'' and to increase the tolerance level from 1.5 ppm to 2.0 ppm. Finally, the existing tolerance for ''nut, tree, group 14'' is modified to read ''nut, tree, group 14–12, except pistachio.''

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 FFDCA section 408(d), such as the tolerances 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 FFDCA 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: December 2, 2015.

Susan Lewis,

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 § 180.507:

■ a. Add alphabetically the commodities to the table in paragraph (a)(1).

■ b. Revise the commodities ''fruit, stone, group 12'' and ''nut, tree, group 14'' in paragraph (a)(1).

The additions and revisions read as follows:

§ 180.507 Azoxystrobin; tolerances for residues.

(a)(1) * * *

Commodity	Parts per million
* * * * *	
Fruit, stone, group 12–12	2.0
* * * * *	
Nut, tree, group 14–12, except pistachio	0.02

Commodity	Parts per million
* * * * *	
Quinoa, grain	3.0
* * * * *	
Ti, leaves	50.0
Ti, roots	0.5
* * * * *	

* * * * *

[FR Doc. 2015–31053 Filed 12–8–15; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 64

[Docket ID FEMA–2015–0001; Internal Agency Docket No. FEMA–8413]

Suspension of Community Eligibility

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final rule.

SUMMARY: This rule identifies communities where the sale of flood insurance has been authorized under the National Flood Insurance Program (NFIP) that are scheduled for suspension on the effective dates listed within this rule because of noncompliance with the floodplain management requirements of the program. If the Federal Emergency Management Agency (FEMA) receives documentation that the community has adopted the required floodplain management measures prior to the effective suspension date given in this rule, the suspension will not occur and a notice of this will be provided by publication in the **Federal Register** on a subsequent date. Also, information identifying the current participation status of a community can be obtained from FEMA's Community Status Book (CSB). The CSB is available at *http://www.fema.gov/fema/csb.shtm.*

DATES: The effective date of each community's scheduled suspension is the third date (''Susp.'') listed in the third column of the following tables.

FOR FURTHER INFORMATION CONTACT: If you want to determine whether a particular community was suspended on the suspension date or for further information, contact Patricia Suber, Federal Insurance and Mitigation Administration, Federal Emergency Management Agency, 500 C Street SW., Washington, DC 20472, (202) 646–4149.

SUPPLEMENTARY INFORMATION: The NFIP enables property owners to purchase Federal flood insurance that is not otherwise generally available from private insurers. In return, communities agree to adopt and administer local floodplain management measures aimed at protecting lives and new construction from future flooding. Section 1315 of the National Flood Insurance Act of 1968, as amended, 42 U.S.C. 4022, prohibits the sale of NFIP flood insurance unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed in this document no longer meet that statutory requirement for compliance with program regulations, 44 CFR part 59. Accordingly, the communities will be suspended on the effective date in the third column. As of that date, flood insurance will no longer be available in the community. We recognize that some of these communities may adopt and submit the required documentation of legally enforceable floodplain management measures after this rule is published but prior to the actual suspension date. These communities will not be suspended and will continue to be eligible for the sale of NFIP flood insurance. A notice withdrawing the suspension of such communities will be published in the **Federal Register**.

In addition, FEMA publishes a Flood Insurance Rate Map (FIRM) that identifies the Special Flood Hazard Areas (SFHAs) in these communities. The date of the FIRM, if one has been published, is indicated in the fourth column of the table. No direct Federal financial assistance (except assistance pursuant to the Robert T. Stafford Disaster Relief and Emergency Assistance Act not in connection with a flood) may be provided for construction or acquisition of buildings in identified SFHAs for communities not participating in the NFIP and identified for more than a year on FEMA's initial FIRM for the community as having flood-prone areas (section 202(a) of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4106(a), as amended). This prohibition against certain types of Federal assistance becomes effective for the communities listed on the date shown in the last column. The Administrator finds that notice and public comment procedures under 5 U.S.C. 553(b), are impracticable and unnecessary because communities listed in this final rule have been adequately notified.

Each community receives 6-month, 90-day, and 30-day notification letters addressed to the Chief Executive Officer stating that the community will be suspended unless the required floodplain management measures are met prior to the effective suspension date. Since these notifications were made, this final rule may take effect within less than 30 days.

National Environmental Policy Act. This rule is categorically excluded from the requirements of 44 CFR part 10, Environmental Considerations. No environmental impact assessment has been prepared.

Regulatory Flexibility Act. The Administrator has determined that this rule is exempt from the requirements of the Regulatory Flexibility Act because the National Flood Insurance Act of 1968, as amended, Section 1315, 42 U.S.C. 4022, prohibits flood insurance coverage unless an appropriate public body adopts adequate floodplain management measures with effective enforcement measures. The communities listed no longer comply with the statutory requirements, and after the effective date, flood insurance will no longer be available in the communities unless remedial action takes place.

Regulatory Classification. This final rule is not a significant regulatory action under the criteria of section 3(f) of Executive Order 12866 of September 30, 1993, Regulatory Planning and Review, 58 FR 51735.

Executive Order 13132, Federalism. This rule involves no policies that have federalism implications under Executive Order 13132.

Executive Order 12988, Civil Justice Reform. This rule meets the applicable standards of Executive Order 12988.

Paperwork Reduction Act. This rule does not involve any collection of information for purposes of the Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.*

List of Subjects in 44 CFR Part 64

Flood insurance, Floodplains.

Accordingly, 44 CFR part 64 is amended as follows:

PART 64—[AMENDED]

■ 1. The authority citation for part 64 continues to read as follows:

Authority: 42 U.S.C. 4001 *et seq.*; Reorganization Plan No. 3 of 1978, 3 CFR, 1978 Comp.; p. 329; E.O. 12127, 44 FR 19367, 3 CFR, 1979 Comp.; p. 376.

§ 64.6 [Amended]

■ 2. The tables published under the authority of § 64.6 are amended as follows:

State and Location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Region V				
Wisconsin:				
Appleton, City of, Calumet and Outagamie Counties.	555542	April 23, 1971, Emerg; April 6, 1973, Reg; January 20, 2016, Susp.	January 20, 2016.	January 20, 2016
Outagamie County, Unincorporated Areas.	550302	January 14, 1972, Emerg; September 30, 1977, Reg; January 20, 2016, Susp.	.....do	Do.
Region VI				
Louisiana:				
Monroe, City of, Ouachita Parish	220136	September 6, 1974, Emerg; December 18, 1979, Reg; January 20, 2016, Susp.	.....do	Do
Ouachita Parish, Unincorporated Areas	220135	January 29, 1974, Emerg; July 2, 1980, Reg; January 20, 2016, Susp.	.....do	Do
Richwood, Town of, Ouachita Parish	220378	February 9, 1978, Emerg; September 30, 1987, Reg; January 20, 2016, Susp.	.....do	Do
Sterlington, Town of, Ouachita Parish ..	220400	N/A, Emerg; June 14, 1994, Reg; January 20, 2016, Susp.	.....do	Do
West Monroe, City of, Ouachita Parish	220138	April 6, 1973, Emerg; December 1, 1978, Reg; January 20, 2016, Susp.	.....do	Do
Region VII				
Missouri:				
Augusta, Town of, Saint Charles County.	290461	N/A, Emerg; January 31, 2001, Reg; January 20, 2016, Susp.	.....do	Do
Cottleville, City of, Saint Charles County.	290898	N/A, Emerg; February 1, 1990, Reg; January 20, 2016, Susp.	.....do	Do
Dardenne Prairie, City of, Saint Charles County.	290899	N/A, Emerg; March 13, 1995, Reg; January 20, 2016, Susp.	.....do	Do
Flint Hill, City of, Saint Charles County	290883	July 9, 1980, Emerg; November 19, 1986, Reg; January 20, 2016, Susp.	.....do	Do
Foristell, City of, Saint Charles and Warren Counties.	290902	N/A, Emerg; February 24, 1993, Reg; January 20, 2016, Susp.	.....do	Do
Lake Saint Louis, City of, Saint Charles County.	290868	March 20, 1978, Emerg; September 18, 1987, Reg; January 20, 2016, Susp.	.....do	Do
O'Fallon, City of, Saint Charles County	290316	April 17, 1975, Emerg; March 16, 1981, Reg; January 20, 2016, Susp.	.....do	Do
Portage Des Sioux, City of, Saint Charles County.	290317	August 29, 1973, Emerg; April 1, 1977, Reg; January 20, 2016, Susp.	.....do	Do
Saint Charles, City of, Saint Charles County.	290318	June 27, 1973, Emerg; March 22, 1974, Reg; January 20, 2016, Susp.	.....do	Do
Saint Paul, City of, Saint Charles County.	290900	N/A, Emerg; February 13, 1998, Reg; January 20, 2016, Susp.	.....do	Do
Weldon Spring, City of, Saint Charles County.	290901	N/A, Emerg; July 2, 1993, Reg; January 20, 2016, Susp.	.....do	Do
Wentzville, City of, Saint Charles County.	290320	April 18, 1975, Emerg; July 28, 1978, Reg; January 20, 2016, Susp.	.....do	Do
West Alton, City of, Saint Charles County.	290924	N/A, Emerg; July 9, 1997, Reg; January 20, 2016, Susp.	.....do	Do
Region VIII				
Colorado:				
Adams County, Unincorporated Areas ..	080001	January 14, 1972, Emerg; February 1, 1979, Reg; January 20, 2016, Susp.	.....do	Do
Arvada, City of, Adams and Jefferson Counties.	085072	April 30, 1971, Emerg; June 23, 1972, Reg; January 20, 2016, Susp.	.....do	Do
Ault, Town of, Weld County	080179	May 28, 1975, Emerg; June 10, 1980, Reg; January 20, 2016, Susp.	.....do	Do
Broomfield, City and County of, Broomfield County.	085073	February 18, 1972, Emerg; September 7, 1973, Reg; January 20, 2016, Susp.	.....do	Do
Eaton, Town of, Weld County	080180	March 3, 1975, Emerg; June 4, 1980, Reg; January 20, 2016, Susp.	.....do	Do
Evans, City of, Weld County	080182	July 25, 1974, Emerg; April 2, 1979, Reg; January 20, 2016, Susp.	.....do	Do
Firestone, Town of, Weld County	080241	October 26, 1976, Emerg; December 18, 1979, Reg; January 20, 2016, Susp.	.....do	Do
Fort Lupton, City of, Weld County	080183	July 23, 1974, Emerg; April 2, 1979, Reg; January 20, 2016, Susp.	.....do	Do

State and Location	Community No.	Effective date authorization/cancellation of sale of flood insurance in community	Current effective map date	Date certain Federal assistance no longer available in SFHAs
Frederick, Town of, Weld County	080244	October 18, 1976, Emerg; July 16, 1979, Reg; January 20, 2016, Susp.	.....do	Do
Gilcrest, Town of, Weld County	080213	September 21, 1976, Emerg; June 10, 1980, Reg; January 20, 2016, Susp.	.....do	Do
Greeley, City of, Weld County	080184	October 15, 1974, Emerg; July 16, 1979, Reg; January 20, 2016, Susp.	.....do	Do
Hudson, Town of, Weld County	080249	August 20, 1997, Emerg; N/A, Reg; January 20, 2016, Susp.	.....do	Do
Jefferson County, Unincorporated Areas.	080087	July 5, 1973, Emerg; August 5, 1986, Reg; January 20, 2016, Susp.	.....do	Do
Keenesburg, Town of, Weld County	080251	September 21, 1976, Emerg; August 24, 1981, Reg; January 20, 2016, Susp.	.....do	Do
La Salle, Town of, Weld County	080186	July 19, 1974, Emerg; May 25, 1978, Reg; January 20, 2016, Susp.	.....do	Do
Milliken, Town of, Weld County	080187	July 23, 1975, Emerg; August 1, 1979, Reg; January 20, 2016, Susp.	.....do	Do
Northglenn, City of, Adams County	080257	January 22, 1975, Emerg; September 15, 1978, Reg; January 20, 2016, Susp.	.....do	Do
Nunn, Town of, Weld County	080188	August 7, 1975, Emerg; February 1, 1979, Reg; January 20, 2016, Susp.	.....do	Do
Pierce, Town of, Weld County	080189	July 17, 1975, Emerg; November 15, 1979, Reg; January 20, 2016, Susp.	.....do	Do
Platteville, Town of, Weld County	080190	May 5, 1975, Emerg; February 29, 1980, Reg; January 20, 2016, Susp.	.....do	Do
Severance, Town of, Weld County	080317	N/A, Emerg; March 28, 1995, Reg; January 20, 2016, Susp.	.....do	Do
Thornton, City of, Adams County	080007	July 31, 1975, Emerg; June 15, 1978, Reg; January 20, 2016, Susp.	.....do	Do
Weld County, Unincorporated Areas	080266	September 16, 1974, Emerg; March 18, 1980, Reg; January 20, 2016, Susp.	.....do	Do
Westminster, City of, Adams and Jefferson Counties.	080008	July 13, 1973, Emerg; September 30, 1988, Reg; January 20, 2016, Susp.	.....do	Do
Windsor, Town of, Larimer and Weld Counties.	080264	N/A, Emerg; September 27, 1991, Reg; January 20, 2016, Susp.	.....do	Do

* - do - = Ditto.
Code for reading third column: Emerg.—Emergency; Reg.—Regular; Susp.—Suspension.

Dated: November 20, 2015.

Roy E. Wright,

Deputy Associate Administrator, Federal Insurance and Mitigation Administration, Department of Homeland Security, Federal Emergency Management Agency.

[FR Doc. 2015–31016 Filed 12–8–15; 8:45 am]

BILLING CODE 9110–12–P

Proposed Rules

Federal Register
Vol. 80, No. 236
Wednesday, December 9, 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.

NUCLEAR REGULATORY COMMISSION

10 CFR Part 26

[NRC–2009–0090]

RIN 3150–AF12

Fitness-for-Duty Programs

AGENCY: Nuclear Regulatory Commission.

ACTION: Rulemaking activity; discontinuation.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is discontinuing a rulemaking activity that would have amended its regulations governing fatigue management programs for nuclear power plant workers. The purpose of this action is to inform members of the public that this rulemaking activity is being discontinued and to provide a discussion of the NRC's decision to discontinue it.

DATES: As of December 9, 2015, the rulemaking activity is discontinued.

ADDRESSES: Please refer to Docket ID NRC–2009–0090 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

• Federal Rulemaking Web site: Go to *http://www.regulations.gov* and search for Docket ID NRC–2009–0090. 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 Document 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.* For the convenience of the reader, instructions about obtaining materials referenced in this document are provided in the ''Availability of Documents'' section.

• NRC's PDR: You may examine and purchase copies of public documents at the NRC's PDR Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

FOR FURTHER INFORMATION CONTACT: Stewart Schneider, Office of Nuclear Reactor Regulation, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, telephone: 301–415–4123, email: *Stewart.Schneider@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On March 31, 2008, the NRC issued a final rule that substantially revised its regulations for fitness-for-duty programs in part 26 of Title 10 of the *Code of Federal Regulations* (10 CFR), ''Fitness for Duty Programs.'' The 2008 final rule established 10 CFR part 26, subpart I, ''Managing Fatigue,'' to require that nuclear power plant licensees provide reasonable assurance that the effects of worker fatigue are managed commensurate with maintaining public health and safety. The regulations in 10 CFR part 26 require licensees to manage worker fatigue at reactors that are operating or under construction (no later than the receipt of special nuclear material in the form of fuel assemblies), for all individuals who are granted unescorted access to protected areas of the plant. The regulations also require licensees to control the work hours of those individuals whose work activities have the greatest potential to adversely affect public health and safety or the common defense and security if their performance is degraded by fatigue (*e.g.,* licensed operators, maintenance technicians, security officers).

The Commission's staff requirements memorandum (SRM), SRM–SECY–06–0244, ''Final Rulemaking–10 CFR part 26–Fitness-for-Duty Programs,'' approving the 2008 final rule directed the NRC staff to ensure that personnel who actually perform independent quality control/quality verification (QC/QV) checks under the licensee's NRC-approved Quality Assurance Program are subject to the same 10 CFR part 26, subpart I, provisions as operating personnel defined in § 26.4(a)(1). The SRM also directed the NRC staff to publish the final rule without the QC/QV provision, if the staff determined that its inclusion would require re-notice and comment under the Administrative Procedure Act of 1946.

Because the NRC staff determined that including the QC/QV provision would require re-noticing of the rule to provide a new opportunity for public comment, the NRC issued the final rule without imposing work hour controls on individuals performing QC/QV activities.[1] As directed in the SRM, the NRC staff initiated a new proposed rulemaking to apply the work hour controls for operating personnel to the QC/QV-dedicated personnel who perform QC/QV checks.[2]

On September 10, 2012, the NRC published the regulatory basis and preliminary proposed rule language in support of the QC/QV proposed rulemaking. Because the documents were made publicly available to provide preparatory material for discussion in future public meetings, a public comment period was not initiated.

The NRC staff held multiple public meetings between December 2011 and February 2014 to discuss the QC/QV rulemaking and other potential changes to 10 CFR part 26, subpart I. The meetings were attended by members of the nuclear power reactor community, organized labor, contractors, and the media. Summaries of these meetings are publicly available at *http://www.regulations.gov* under Docket ID NRC–2009–0090.

II. Petitions for Rulemaking

The NRC received petitions for rulemaking (PRMs) regarding 10 CFR part 26, subpart I, from the Professional Reactor Operator Society (PROS), the Nuclear Energy Institute (NEI), and Mr. Erik Erb following issuance of the 2008 final rule.

[1] The QC/QV activities are a part of the planned and systematic actions under a licensee's quality assurance program that are necessary to provide adequate assurance that a safety-related structure, system, and component will perform satisfactorily in service. The QC/QV inspections are a subset of the QC/QV activities.

[2] ''QC/QV-dedicated personnel'' means individuals who perform QC/QV activities and are not otherwise subject to the work hour controls in 10 CFR part 26, subpart I.

In the SRM to SECY–11–0003/0028, ''Status of Enforcement Discretion Request and Rulemaking Activities Related to 10 CFR part 26, subpart I, 'Managing Fatigue' and Options for Implementing an Alternative Interim Regulatory Approach to the Minimum Days Off Provisions of 10 CFR part 26, subpart I, 'Managing Fatigue,' '' the Commission directed the NRC staff to address these PRMs in a rulemaking effort separate from the alternative to the minimum days off (MDO) rulemaking. The scope of the alternative MDO rulemaking was limited solely to providing an alternative to the then-current requirements for minimum days off in 10 CFR part 26, subpart I. This rulemaking provided a new requirement for working a 54-hour per week average over a rolling period of up to 6 weeks.

On May 16, 2011, the NRC published three documents in the **Federal Register** (one for each PRM) informing the public that the issues raised in each PRM would be considered in the planned QC/QV rulemaking. The three PRMs are discussed below.

(1) PRM–26–3 Submitted by Robert N. Meyer on Behalf of PROS

Robert N. Meyer on behalf of PROS, an organization of operations personnel employed at nuclear power plants throughout the United States, submitted a PRM dated October 16, 2009. The petitioner requested that the NRC change the term ''unit outage'' to ''site outage'' in 10 CFR part 26 and that the definition of ''site outage'' read ''up to 1 week prior to disconnecting the reactor unit from the grid and up to 75-percent turbine power following reconnection to the grid.'' The NRC published a notice of receipt of, and request for public comment on, the PRM on November 27, 2009. The public comment period ended on February 10, 2010, and the NRC received 4 comment letters from NEI, nuclear power plant operators and managers, and a private citizen. The comments generally supported the petition.

(2) PRM–26–5 Submitted by Anthony R. Pietrangelo on Behalf of NEI

Anthony R. Pietrangelo on behalf of NEI, a nuclear power industry trade association, submitted a PRM dated September 3, 2010. The petitioner requested that the NRC amend its regulations regarding fitness-for-duty programs to refine existing requirements based on experience gained since the regulations were last amended in 2008. The NRC published a notice of receipt of, and request for public comment on, the PRM on October 22, 2010. The public comment period ended on January 5, 2011, and the NRC received 39 comment letters from corporations, professional organizations, and private citizens. Of these 39 comment letters, 11 specifically voiced support for the petition, while 13 voiced opposition. Those comment letters that voiced neither support for nor opposition to the petition itself discussed a diverse range of perspectives on the fatigue management provisions contained in 10 CFR part 26, subpart I.

(3) PRM–26–6 Submitted by Erik Erb and 91-Co-Signers

Erik Erb and 91 co-signers submitted a PRM dated August 17, 2010. The NRC published a notice of receipt of, and request for public comment on, the PRM on November 23, 2010. The petitioner requested that the NRC amend its fitness-for-duty regulations to decrease the minimum days off requirement from an average of 3 days per week to 2.5 or 2 days per week for security officers working 12-hour shifts. The public comment period ended on February 7, 2011, and the NRC received 5 comment letters from coroporations, professional organizations, and private citizens. The comments generally supported the petition.

III. Rulemaking Discontinuation

In SECY–15–0074, ''Discontinuation of Rulemaking Activity—Title 10 of the *Code of Federal Regulations* Part 26, Subpart I, Quality Control and Quality Verification Personnel in Fitness for Duty Program,'' the NRC staff requested Commission approval to discontinue the QC/QV rulemaking. This request was based on the following factors: (1) QC/QV inspections are most often performed by maintenance personnel who are already covered by the work hour controls in 10 CFR part 26, subpart I; (2) the few remaining inspections are performed by a small number of QC/QV-dedicated personnel; and (3) backfitting [3] the 10 CFR part 26, subpart I, work hour controls to the QC/QV-dedicated personnel would not result in a substantial increase in the overall protection of the public health and safety or common defense and security.

In the SRM to SECY–15–0074, the Commission approved the NRC staff's request to discontinue the QC/QV rulemaking activity. The Commission directed the NRC staff to inform the public that the NRC is no longer pursuing rulemaking in this area and that the three PRMs will be addressed in a separate action.

[3] 10 CFR 50.109, ''Backfitting.''

IV. Public Comments Outside the Scope of the Alternative to the Minimum Days Off Proposed Rule

On April 26, 2011, the NRC published a proposed rule to provide licensees with an option for managing cumulative fatigue that differed from the minimum days off requirements in § 26.205(d)(3) (76 FR 23208). The NRC received two comment submissions from private citizens on the proposed rule that were determined to be outside of the scope of that limited rulemaking activity. The Commission had previously directed the NRC staff in SRM–SECY–11–0003/0028 to consider in a separate rulemaking activity any comments on the alternative MDO proposed rule that were determined to be outside the limited scope of the rulemaking. Therefore, the **Federal Register** notice for the final rule stated that public comments outside of the scope of the proposed rule would be considered in the QC/QV rulemaking (76 FR 43534, 43540; July 21, 2011). Because the QC/QV rulemaking is being discontinued, the NRC's responses will be provided here.

Comment: One commenter remarked that some duties do not require constant surveillance, so the individuals performing these duties should not be subject to the fatigue management requirements. The commenter also stated that it is more important to have a qualified person performing a task than it is to ensure that the person performing the task complies with the work hour controls. According to the commenter, the fatigue management requirements are too complex and do not guarantee that an individual subject to the work hour requirements will diligently perform his or her duties.

NRC Response: The NRC agrees in part and disagrees in part with the comment. The NRC has consistently held that work conducted within the protected area of a nuclear power plant is of such safety significance that individuals granted unescorted access to those protected areas must be fit for duty, including management of the effects of cumulative and acute fatigue. However, the NRC recognizes the functions that individuals within different job categories perform differ in their potential impact on plant safety and security. Therefore, the NRC has identified specific categories of individuals in § 26.4 who require additional work hour controls due to their job function. This graded approach provides the maximum flexibility for nuclear power plant licensees and individuals while providing reasonable assurance that those individuals granted

unescorted access to the protected areas of nuclear power plants are fit to safely and competently perform their duties free from the adverse effects of cumulative and acute fatigue.

Further, the NRC has neither proposed nor finalized fatigue management regulations that require nuclear power plant licensees to choose between having a qualified individual perform a task or having a well-rested individual perform a task. For circumstances outside the licensee's reasonable control in which the potential for such a choice exists, § 26.207, ''Waivers and exceptions,'' establishes specific conditions in which licensees may waive or exclude personnel from the work hour controls. In addition, licensees have the option to provide an escort to individuals who may be needed for a short period in unusual situations without subjecting them to the work hour controls. On a day-to-day basis, however, licensees need to ensure that personnel meet the applicable qualification requirements for the tasks they are assigned to perform and are fit for duty.

The NRC also disagrees that the fatigue management requirements of 10 CFR part 26, subpart I, including the voluntary alternative to the MDO provisions in § 26.205(d)(3), are too complex. The NRC acknowledges that there are significant administrative requirements that are part of the fatigue management regulations. However, the NRC has sought out opportunities to relieve administrative burden where possible while still maintaining the performance objectives of the rule. For example, the voluntary alternative to the MDO provisions in § 26.205(d)(3) provides a significant reduction in administrative burden as it permits nuclear power plant licensees to manage cumulative fatigue by limiting an individual's work hours to an average of not more than 54-hours per week over a 6-week rolling period.

The NRC agrees, however, that compliance with the fatigue management provisions of 10 CFR part 26, subpart I, does not guarantee that an individual subject to the work hour requirements will diligently perform his or her duties. As stated in the statement of considerations for the 2008 part 26 final rule, compliance with the work hour requirements alone will not ensure proper fatigue management. It remains the responsibility of licensees and individuals granted unescorted access to nuclear power plants to ensure that individuals subject to the fatigue management provisions of 10 CFR part 26, subpart I, are properly rested to safely and competently perform their duties.

Comment: One commenter claimed that the 10 CFR part 26, subpart I, work hour controls do not reduce worker fatigue during outages but can increase fatigue during outages. Specifically, the commenter noted that when an individual works a backshift (*i.e.,* night shift) schedule during outages, taking a 1-day break disrupts that person's sleep pattern. Recovery from this disruption takes several days, therefore inducing fatigue. The commenter concluded that once a person adjusts to the unnatural sleep pattern of the night shift, it is far better to continue that pattern for the duration of the outage. The commenter also stated that the rule has caused a drop in his earnings.

NRC Response: The NRC agrees in part with the comment. Under circumstances postulated by the commenter (*i.e.,* a 1-day break during consecutive night shifts), the adjustment of an individual's sleep-wake cycle to night shift can be affected by cues that influence the sleep-wake cycle, such as exposure to bright sunlight. However, the break and day off requirements of 10 CFR Part 26, subpart I, are minimum requirements (*i.e.,* they do not require a schedule that provides only 1-day off during consecutive night shifts, as described by the commenter), and they are not limited to serve as a means for establishing shift schedules. As stated in Section 2.3.5 of NUREG–1912, ''Summary and Analysis of Public Comments Received on Proposed Revisions to 10 CFR part 26—Fitness for Duty Program,'' the NRC intends that the maximum work hour and minimum break and day off requirements that are specified in § 26.205(d) be applied to infrequent, temporary circumstances. They should not be used as guidelines or limits for routine work scheduling. In addition, the § 26.205(d) work hour controls do not address several elements of routine schedules that can significantly affect worker fatigue. These include shift length, the number of consecutive shifts, the duration of breaks between blocks of shifts, and the direction of shift rotation. Therefore, § 26.205(c) requires licensees to schedule personnel consistent with preventing impairment from fatigue from these scheduling factors, including periods of high workload during outages.

The rule requires licensees to address scheduling factors, because human alertness and the propensity to sleep vary markedly through the course of a 24-hour period. These circadian variations are the result of changes in physiology outside the control of the individual. Work, with the consequent timing of periods of sleep and wakefulness, may be scheduled in a manner that either facilitates an individual's adaptation to the work schedule or challenges the individual's ability to get adequate rest. Therefore, the duration, frequency, and sequencing of shifts, particularly for personnel who work rotating shifts, are critical elements of fatigue management. The importance of these elements for fatigue management is reflected in guidelines for work scheduling, such as the Electric Power Research Institute's report, EPRI–NP–6748, ''Control-Room Operator Alertness and Performance in Nuclear Power Plants,'' and in technical reports, such as the NRC's NUREG/CR–4248, ''Recommendations for NRC Policy on Shift Scheduling and Overtime at Nuclear Power Plants,'' and the Office of Technology Assessment's report, OTA–BA–463, ''Biological Rhythms: Implications for the Worker.'' Although research provides clear evidence of the importance of these factors in developing schedules that support effective fatigue management, the NRC also recognizes that the complexity of effectively addressing and integrating each of these factors in work scheduling decisions precludes a prescriptive requirement. Therefore, § 26.205(c) establishes a non-prescriptive, performance-based requirement that also applies to shift scheduling during outages.

Further, the NRC disagrees that the requirements of 10 CFR part 26, subpart I, have resulted in a pay cut for the commenter and notes that the work hour requirements require licensees to manage fatigue, in part, by limiting work hours, not compensation. Furthermore, the work hour controls provide licensees with a significant amount of flexibility when establishing schedules, and those work hour controls continue to allow for overtime. One objective of the NRC's fitness-for-duty program is to ''provide reasonable assurance that the effects of fatigue and degraded alertness on individuals' abilities to safely and competently perform their duties are managed commensurate with maintaining public health and safety.'' Therefore, the NRC's focus and mission is on safety, not compensation and wages.

V. Availability of Documents

The documents identified in the following table are available to interested persons as indicated.

Document	Adams accession No./**Federal Register** Notice/Web link
U.S. Nuclear Regulatory Commission, NUREG/CR–4248 (PNL–5435), ''Recommendations for NRC Policy on Shift Scheduling and Overtime at Nuclear Power Plants'' (July 1985).	ML102520362.
Electric Power Research Institute, EPRI–NP–6748, ''Control-Room Operator Alertness and Performance in Nuclear Power Plants'' (March 1, 1990).	*http://www.epri.com/abstracts/Pages/ProductAbstract.aspx?ProductId=NP–6748.*
U.S. Congress, Office of Technology Assessment, OTA–BA–463, ''Biological Rhythms: Implications for the Worker'' (September 1991).	*https://www.princeton.edu/~ota/disk1/1991/9108/9108.PDF.*
Staff Requirements—SECY–06–0244—Final Rulemaking—10 CFR Part 26—Fitness-for-Duty Programs (April 17, 2007).	ML071070361.
Fitness for Duty Programs; Final rule (March 31, 2008)	73 FR 16966.
PRM–26–3, Petition to Amend 10 CFR part 26, ''Fitness–for–Duty Programs,'' filed by the Professional Reactor Operator Society, Docket ID NRC–2009–0482 (October 16, 2009).	ML092960440.
Professional Reactor Operator Society; Notice of Receipt of Petition for Rulemaking [Docket No. PRM–26–3; NRC–2009–0482] (November 27, 2009).	74 FR 62257.
PRM–26–6, Petition to Amend 10 CFR part 26, ''Fitness–for–Duty Programs,'' filed by Erik Erb, Docket ID NRC–2010–0310 (August 17, 2010).	ML102630127.
PRM–26–5, Petition to Amend 10 CFR part 26, ''Fitness–for–Duty Programs,'' filed by the Nuclear Energy Institute, Docket ID NRC–2010–0304 (September 3, 2010).	ML102590440.
Anthony R. Pietrangelo on Behalf of the Nuclear Energy Institute; Notice of Receipt of Petition for Rulemaking [Docket No. PRM–26–5; NRC–2010–0304] (October 22, 2010).	75 FR 65249.
Erik Erb; Notice of Receipt of Petition for Rulemaking [Docket No. PRM–26–6; NRC–2010–0310] (November 23, 2010).	75 FR 71368.
U.S. Nuclear Regulatory Commission, NUREG–1912, ''Summary and Analysis of Public Comments Received on Proposed Revisions to 10 CFR Part 26—Fitness for Duty Programs'' (Comments received between August 26, 2005 and May 10, 2007) (December 2010).	ML110310431.
Staff Requirements—SECY–11–0003—Status of Enforcement Discretion Request and Rulemaking Activities Related to 10 CFR Part 26, Subpart I, ''Managing Fatigue'' and SECY–11–0028—Options for Implementing an Alternative Interim Regulatory Approach to the Minimum Days Off Provisions of 10 CFR Part 26, Subpart I, ''Managing Fatigue'' (March 24, 2011).	ML110830971.
Petition for Rulemaking Submitted by the Professional Reactor Operator Society; Petition for rulemaking consideration in the rulemaking process [Docket No. PRM–26–3; NRC–2009–0482] (May 16, 2011).	76 FR 28192.
Petition for Rulemaking Submitted by the Nuclear Energy Institute; Petition for rulemaking consideration in the rulemaking process [Docket No. PRM–26–5; NRC–2010–0304] (May 16, 2011).	76 FR 28192.
Petition for Rulemaking Submitted by Erik Erb and 91 Cosigners; Petition for rulemaking consideration in the rulemaking process [Docket No. PRM–26–6; NRC–2010–0310] (May 16, 2011).	76 FR 28191.
Comments of Mr. Harry Sloan [Docket ID NRC–2011–0058] (May 22, 2011).	ML11144A157.
Comments of Mr. Mark Callahan [Docket ID NRC–2011–0058] (May 25, 2011).	ML11146A110.
SECY–15–0074, Discontinuation of Rulemaking Activity—Title 10 of the Code of Federal Regulations Part 26, Subpart I, Quality Control and Quality Verification Personnel in Fitness for Duty Program (May 19, 2015).	ML15084A092.
Staff Requirements—SECY–15–0074—Discontinuation of Rulemaking Activity–Title 10 of the Code of Federal Regulations Part 26, Subpart I, Quality Control and Quality Verification Personnel in Fitness for Duty Program (July 14, 2015).	ML15195A577.

The NRC may post materials related to this document on the Federal rulemaking Web site at *http://www.regulations.gov* under Docket ID NRC–2009–0090. The Federal rulemaking Web site allows you to receive alerts when changes or additions occur in a docket folder. To subscribe: (1) Navigate to the docket folder (NRC–2009–0090); (2) click the ''Sign up for Emails Alerts'' link; and (3) enter your email address and select how frequently you would like to receive emails (daily, weekly, or monthly).

VI. Conclusion

The NRC is discontinuing the QC/QV rulemaking activity for the reasons previously stated. This rulemaking will no longer be reported in the NRC's portion of the Unified Agenda of Regulatory and Deregulatory Actions. Should the NRC determine to pursue rulemaking in this area in the future, NRC will inform the public through a new rulemaking entry in the Unified Agenda. While the three notices in the **Federal Register** published on May 16, 2011, stated that the PRM dockets are closed, the NRC will issue a subsequent action on the determination of these PRMs.

Dated at Rockville, Maryland, this 19th day of November, 2015.

For the Nuclear Regulatory Commission.

Victor M. McCree,

Executive Director for Operations.

[FR Doc. 2015–30578 Filed 12–8–15; 8:45 am]

BILLING CODE 7590–01–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–7205; Directorate Identifier 2015–CE–025–AD]

RIN 2120–AA64

Airworthiness Directives; Piper Aircraft, Inc. Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to supersede Airworthiness Directive (AD) 96–12–12, which applies to certain Piper Aircraft, Inc. Models PA–31, PA–31–300, PA–31–325, and PA–31–350 airplanes. AD 96–12–12 currently requires a one-time inspection of the bulkhead assembly at fuselage station (FS) 317.75 for cracks and the installation of one of two reinforcement kits determined by whether cracks were found during the inspection. Since we issued AD 96–12–12, bulkhead cracks were found on airplanes that had complied with AD 96–12–12 and on additional airplanes not affected by AD 96–12–12. This proposed AD would require repetitive inspections of the bulkhead assembly at FS 317.75 for cracks, repair of cracks as necessary, and the installation of a reinforcement modification. We are proposing this AD to correct the unsafe condition on these products.

DATES: We must receive comments on this proposed AD by January 25, 2016.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Piper Aircraft, Inc., 2926 Piper Drive, Vero Beach, FL 32960; telephone: (415) 330–9500; email: *sales@atp.com;* and Internet: *http://www.piper.com/technical-publications/.* You may view this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–7205; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Gregory ''Keith'' Noles, Aerospace Engineer, FAA, Atlanta Aircraft Certification Office (ACO), 1701 Columbia Avenue, College Park, Georgia 30337; phone: (404) 474–5551; fax: (404) 474–5606; email: *gregory.noles@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2015–7205; Directorate Identifier 2015–CE–025–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

On May 30, 1996, we issued AD 96–12–12, Amendment 39–9654 (61 FR 28732, June 6, 1996) (''AD 96–12–12''), for certain Piper Aircraft, Inc. Models PA–31, PA–31–300, PA–31–325, and PA–31–350 airplanes. AD 96–12–12 requires a one-time inspection of the bulkhead assembly at fuselage station (FS) 317.75 for cracks and the installation of one of two reinforcement kits, determined by whether cracks were found during the inspection. AD 96–12–12 resulted from cracks found in the FS 317.75 upper bulkhead. We issued AD 96–12–12 to prevent structural failure of the vertical fin forward spar caused by cracks in the FS 317.75 upper bulkhead, which could lead to loss of control.

Actions Since AD 96–12–12 Was Issued

Since we issued AD 96–12–12, cracks were found on the bulkhead assembly of airplanes in compliance with AD 96–12–12 and on additional airplanes not affected by AD 96–12–12 but of a similar type design. Piper Aircraft, Inc. has issued new service information that gives instructions for repair of the cracks and instructions for the installation of a reinforcement modification to prevent cracks from developing.

Related Service Information Under 1 CFR Part 51

We reviewed Piper Aircraft, Inc. Service Bulletin No. 1273A, dated October 22, 2015. The service bulletin describes procedures for inspecting the bulkhead assembly at FS 317.75, repairing any cracks found, and installation of a reinforcement modification to prevent cracks from developing. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this NPRM.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would retain none of the requirements of AD 96–12–12. This NPRM would add airplanes to the Applicability, paragraph (c) of this proposed AD. This proposed AD would also require accomplishing the actions specified in the service information described previously. Airplanes in compliance with AD 96–12–12 must be re-inspected, repaired if necessary, and modified following the new service information.

Costs of Compliance

We estimate that this proposed AD affects 977 airplanes of U.S. registry.

We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Inspection of the bulkhead assembly.	2 work-hours × $85 per hour = $170	Not applicable.	$170	$166,090
Repair/reinforcement of bulkhead assembly.	8 work-hours × $85 per hour = $680	$500	1,180	1,152,860

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, Section 106, describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701, ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We have determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that the proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 96–12–12, Amendment 39–9654 (61 FR 28732, June 6, 1996), and adding the following new AD:

Piper Aircraft, Inc.: Docket No. FAA–2015–7205; Directorate Identifier 2015–CE–025–AD.

(a) Comments Due Date

The FAA must receive comments on this AD action by January 25, 2016.

(b) Affected ADs

This AD replaces 96–12–12, Amendment 39–9654 (61 FR 28732, June 6, 1996) (''AD 96–12–12'').

(c) Applicability

This AD applies to the following Piper Aircraft, Inc. airplanes listed in paragraphs (c)(1) and (c)(2) of this AD, certificated in any category:

(1) Models PA–31, PA–31–300, and PA–31–325: Serial numbers 31–2 through 31–900 and 31–7300901 through 31–8312019; and

(2) Model PA–31–350: Serial numbers 31–5001 through 31–5004 and 31–7305005 through 31–8553002.

Note 1 to paragraph (c)(1) of this AD: The Model PA–31 may also be identified as a PA–31–310, even though the PA–31–310 is not a model recognized by the Federal Aviation Administration (FAA) on the type certificate data sheet.

(d) Subject

Joint Aircraft System Component (JASC)/Air Transport Association (ATA) of America Code 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by bulkhead cracks found on airplanes that had complied with AD 96–12–12 and on additional airplanes not affected by AD 96–12–12. We are issuing this AD to prevent structural failure of the vertical fin forward spar caused by cracks in the fuselage station (FS) at 317.75 upper bulkhead, which could lead to loss of control.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Inspection/Repair

(1) Before or upon accumulating 2,000 hours time-in-service (TIS) or within the next 100 hours TIS after the effective date of this AD, whichever occurs later, and repetitively thereafter at intervals not to exceed 100 hours TIS, inspect the bulkhead assembly at FS 317.75 for cracks following Part I of the Instructions in Piper Aircraft, Inc. Service Bulletin No. 1273A, dated October 22, 2015.

(2) If any cracks are found during the inspection required in paragraph (g)(1) of this AD, before further flight, repair the cracks and install the reinforcement modification following Part I of the Instructions in Piper Aircraft, Inc. Service Bulletin No. 1273A, dated October 22, 2015. This repair/modification terminates the requirements for the repetitive inspections required in paragraph (g)(1) of this AD.

(3) You may do the modification required in paragraph (h) of this AD to terminate the repetitive inspections required in paragraph (g)(1) of this AD.

(h) Modification

Unless already done as a repair for cracks found in the inspection required in paragraph (g)(1) of this AD, before or upon accumulating 2,500 hours TIS or within the next 500 hours after the effective date of this AD, whichever occurs later, install the reinforcement modification following Part II of the Instructions in Piper Aircraft, Inc. Service Bulletin No. 1273A, dated October 22, 2015. This modification terminates the repetitive inspections required in paragraph (g)(1) of this AD.

(i) Credit for Actions Accomplished in Accordance With Previous Service Information

This AD allows credit for the inspection required in paragraph (g)(1) of this AD and the repair required in paragraph (g)(2) of this AD, if done before the effective date of this AD, following Part I of the Instructions in Piper Aircraft, Inc. Service Bulletin No. 1273, dated June 4, 2015. This AD also allows credit for the modification required in paragraph (h) of this AD, if done before the effective date of this AD, following Part II of the Instructions in Piper Aircraft, Inc. Service Bulletin No. 1273, dated June 4, 2015.

(j) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Atlanta Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in Related Information, paragraph (j)(1) of this AD.

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(k) Related Information

(1) For more information about this AD, contact Gregory ''Keith'' Noles, Aerospace Engineer, FAA, Atlanta ACO, 1701 Columbia Avenue, College Park, Georgia 30337; phone: (404) 474–5551; fax: (404) 474–5606; email: *gregory.noles@faa.gov.*

(2) For service information identified in this AD, contact Piper Aircraft, Inc. 2926 Piper Drive, Vero Beach, FL 32960; telephone: (415) 330–9500; email: *sales@atp.com;* and Internet: *http://www.piper.com/technical-publications/.* You may view this referenced service information at the FAA, Small Airplane Directorate, 901 Locust, Kansas City, Missouri 64106. For information on the availability of this material at the FAA, call (816) 329–4148.

Issued in Kansas City, Missouri, on December 1, 2015.

Pat Mullen,

Acting Manager, Small Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2015–30882 Filed 12–8–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–4474; Directorate Identifier 2015–NE–34–AD]

RIN 2120–AA64

Airworthiness Directives; Pratt & Whitney Division Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Pratt & Whitney Division (PW) PW4000–94 inch and PW4000–100 inch model turbofan engines. This proposed AD was prompted by a report of a crack find in the high-pressure compressor (HPC) disk. This proposed AD would require performing an ultrasonic inspection (USI) or an eddy current inspection (ECI) of the HPC 10th stage disk. We are proposing this AD to prevent failure of the HPC 10th stage disk, an uncontained disk release, damage to the engine, and damage to the airplane.

DATES: We must receive comments on this proposed AD by February 8, 2016.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this proposed AD, contact Pratt & Whitney Division, 400 Main St., East Hartford, CT 06108; phone: (860) 565–8770; fax: (860) 565–4503. You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call (781) 238–7125.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–4474; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Katheryn Malatek, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7747; fax: 781–238–7199; email: *katheryn.malatek@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this NPRM. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2015–4474; Directorate Identifier 2015–NE–34–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this NPRM. We will consider all comments received by the closing date and may amend this NPRM because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov*, including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this NPRM.

Discussion

We propose to adopt a new AD for certain PW PW4000–94 inch turbofan engines with HPC 10th stage disk, part number (P/N) 51H710 or 53H976–06, installed and certain PW4000–100 inch turbofan engines with HPC 10th stage disk, P/N 53H976–06, installed. This proposed AD was prompted by a report of a crack find in the HPC 10th stage disk. The root cause of the crack was a manual polishing procedure, previously used during manufacture, that caused surface scratches on the disk. This proposed AD would require a USI or ECI of the HPC 10th stage disk. We are proposing this AD to prevent failure of the HPC 10th stage disk, which could lead to an uncontained disk release, damage to the engine, and damage to the airplane.

Related Service Information Under 1 CFR Part 51

We reviewed PW Alert Service Bulletin (ASB) No. PW4G–100–A72–255, dated August 31, 2015 and PW ASB No. PW4ENG A72–833, dated August 20, 2015. The ASBs provide lists of affected HPC disks and describe procedures for USI and ECI of the HPC 10th stage disk. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section of this NPRM.

FAA's Determination

We are proposing this NPRM because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This NPRM would require performing a USI or ECI of the HPC 10th stage disk.

Costs of Compliance

We estimate that this proposed AD affects 763 engines installed on airplanes of U.S. registry. We also estimate that it would take about 12 hours per engine to do the inspection. The average labor rate is $85 per hour. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $778,260.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: ''General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Pratt & Whitney Division: Docket No. FAA–2015–4474; Directorate Identifier 2015–NE–34–AD.

(a) Comments Due Date

We must receive comments by February 8, 2016.

(b) Affected ADs

None.

(c) Applicability

(1) This AD applies to all Pratt & Whitney Division (PW) PW4050, PW4052, PW4056, PW4060, PW4060A, PW4060C, PW4062, PW4062A, PW4152, PW4156, PW4156A, PW4158, PW4160, PW4460, PW4462, and PW4650 turbofan engines, including models with a ''–3'' suffix, with one of the following installed:

(i) High-pressure compressor (HPC) 10th stage disk, part number (P/N) 51H710, with a serial number (S/N) listed in Table 1 of PW Alert Service Bulletin (ASB) No. PW4ENG A72–833, dated August 20, 2015; or

(ii) HPC 10th stage disk, P/N 53H976–06, with an S/N listed in Table 2 of PW ASB No. PW4ENG A72–833, dated August 20, 2015.

(2) This AD also applies to all PW PW4164, PW4168, PW4168A, PW4164C, PW4164C/B, PW4170, PW4168A–1D, PW4168–1D, PW4164–1D, PW4164C–1D, and PW4164C/B–1D turbofan engines with an HPC 10th stage disk, P/N 53H976–06, with an S/N listed Table 1 of PW ASB No. PW4G–100–A72–255, dated August 31, 2015, installed.

(d) Unsafe Condition

This AD was prompted by a report of a crack find in the HPC 10th stage disk. We are issuing this AD to prevent failure of the HPC 10th stage disk, an uncontained disk release, damage to the engine, and damage to the airplane.

(e) Compliance

Comply with this AD within the compliance times specified, unless already done.

(1) Whenever the high-pressure turbine (HPT) or low-pressure turbine (LPT) is removed from the engine, perform an ultrasonic inspection (USI) of the HPC 10th stage disk for cracks. Remove from service any HPC 10th stage disk that fails inspection and replace with a part eligible for installation.

(2) Whenever the HPC front drum rotor disk assembly is removed from the engine, perform an eddy current inspection (ECI) of the HPC 10th stage disk for cracks. Remove from service any HPC 10th stage disk that fails inspection and replace with a part eligible for installation. A USI as required by paragraph (e)(1) of this AD is not required if an ECI is performed.

(f) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request. You may email your request to: *ANE-AD-AMOC@faa.gov.*

(g) Related Information

(1) For more information about this AD, contact Katheryn Malatek, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7747; fax: 781–238–7199; email: *katheryn.malatek@faa.gov.*

(2) PW ASB No. PW4G–100–A72–255, dated August 31, 2015 and PW ASB No. PW4ENG A72–833, dated August 20, 2015, can be obtained from PW using the contact information in paragraph (g)(3) of this AD.

(3) For service information identified in this AD, contact Pratt & Whitney Division, 400 Main St., East Hartford, CT 06108; phone: (860) 565–8770; fax: (860) 565–4503.

(4) You may view this service information at the FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA. For information on the availability of this material at the FAA, call (781) 238–7125.

Issued in Burlington, Massachusetts, on December 3, 2015.

Colleen M. D'Alessandro,

Directorate Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2015–30948 Filed 12–8–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2015–4076; Directorate Identifier 2015–NE–30–AD]

RIN 2120–AA64

Airworthiness Directives; Rolls-Royce plc Turbofan Engines

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain Rolls-Royce plc (RR) RB211–22B and RB211–524 turbofan engines with low-pressure turbine (LPT) support roller bearing, part number (P/N) LK30313 or P/N UL29651, installed. This proposed AD was prompted by a report of a breach of the turbine casing and release of engine debris. This proposed AD would require removal of certain LPT support roller bearings installed in RR RB211–22B and RB211–524 engines. We are proposing this AD to prevent failure of the LPT support roller bearing, loss of radial position following LPT blade failure, uncontained part release, damage to the engine, and damage to the airplane.

DATES: We must receive comments on this proposed AD by February 8, 2016.

ADDRESSES: You may send comments by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the 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:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.
- *Fax:* 202–493–2251.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–4076; or in person at the Docket Operations office between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the mandatory continuing airworthiness information (MCAI), the regulatory evaluation, any comments received, and other information. The address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Brian Kierstead, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7772; fax: 781–238–7199; email: *brian.kierstead@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposed AD. Send your comments to an address listed under the **ADDRESSES** section. Include ''Docket No. FAA–2015–4076; Directorate Identifier 2015–NE–30–AD'' at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD based on those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact with FAA personnel concerning this proposed AD.

Discussion

The European Aviation Safety Agency (EASA), which is the Technical Agent for the Member States of the European Community, has issued EASA AD 2015–0187, dated September 9, 2015 (referred to hereinafter as ''the MCAI''), to correct an unsafe condition for the specified products. The MCAI states:

> An RB211–524G2–T engine experienced an in-service event that resulted in breach of a turbine casing and some release of core engine debris through a hole in the engine nacelle. The investigation of the event determined the primary cause to have been fracture and release of a Low Pressure (LP) turbine stage 2 blade. The blade release caused secondary damage to the LP turbine, producing significant out-of-balance forces. The event engine was fitted with an LP turbine support bearing where the roller retention cage is constructed from two halves that are riveted together. The LP turbine imbalance resulted in an overload of the LP turbine support bearing and caused separation of the riveted, two-piece roller retention cage. Radial location of the LP turbine shaft was lost, allowing further progression of the event that resulted in a breach of the IP turbine casing.

RR introduced a modified LPT support roller bearing that can withstand greater loads when an LPT turbine blade release occurs, thereby preventing LPT rotor movement. You may obtain further information by examining the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2015–4076.

FAA's Determination and Requirements of This Proposed AD

This product has been approved by the aviation authority of the United Kingdom, and is approved for operation in the United States. Pursuant to our bilateral agreement with the European Community, EASA has notified us of the unsafe condition described in the MCAI. We are proposing this AD because we evaluated all information provided by EASA and determined the unsafe condition exists and is likely to exist or develop on other products of the same type design. This proposed AD would require removal from service of the affected LPT support bearings.

Costs of Compliance

We estimate that this proposed AD affects 9 engines installed on airplanes of U.S. registry. We also estimate it would take 0 hours to comply with this proposed AD since the proposed actions required by the AD would be performed during a shop visit, when major engine flanges are separated, which requires the removal of the LPT support roller bearing. Therefore, no additional time is needed to remove it. Parts would cost about $8,184 per engine. The average labor rate is $85 per hour. Based on these figures, we estimate the cost of this proposed AD on U.S. operators to be $73,656.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. ''Subtitle VII: Aviation Programs,'' describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in ''Subtitle VII, Part A, Subpart III, Section 44701: General requirements.'' Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations

for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a ''significant regulatory action'' under Executive Order 12866,

(2) Is not a ''significant rule'' under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska to the extent that it justifies making a regulatory distinction, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

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

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

Rolls-Royce plc: Docket No. FAA–2015–4076; Directorate Identifier 2015–NE–30–AD.

(a) Comments Due Date

We must receive comments by February 8, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to Rolls-Royce plc RB211–22B–02, RB211–22B (MOD 72–8700), RB211–524B–02, RB211–524B–B–02, RB211–524B2–19, RB211–524B2–B–19, RB211–524B3–02, RB211–524B4–02, RB211–524B4–D–02, RB211–524C2–19, RB211–524C2–B–19, RB211–524D4–19, RB211–524D4–B–19, RB211–524D4X–19, RB211–524D4X–B–19, RB211–524D4–39, RB211–524D4–B–39, RB211–524G2–19, RB211–524G3–19, RB211–524–G2–T–19, RB211–524G3–T–19, RB211–524H–36, RB211–524H2–19, RB211–524H–T–36, and RB211–524H2–T–19 turbofan engines, all serial numbers, with low-pressure turbine (LPT) support roller bearing, part number (P/N) LK30313 or P/N UL29651, installed.

(d) Reason

This AD was prompted by a report of a breach of the turbine casing and release of engine debris through a hole in the engine nacelle. We are issuing this AD to prevent failure of the LPT support roller bearing, loss of radial position following LPT blade failure, uncontained part release, damage to the engine, and damage to the airplane.

(e) Actions and Compliance

Comply with this AD within the compliance times specified, unless already done. At the next shop visit or within 24 months after the effective date of this AD, whichever occurs first, remove from service LPT support roller bearing, P/N LK30313 or P/N UL29651, and replace with a part eligible for installation.

(f) Installation Prohibition

After the effective date of this AD, do not install an LPT support roller bearing, P/N LK30313 or P/N UL29651, onto any engine.

(g) Definition

For the purpose of this AD, a ''shop visit'' is defined as induction of an engine into the shop for maintenance involving the separation of pairs of major mating engine flanges, except that the separation of engine flanges solely for the purposes of transportation without subsequent engine maintenance does not constitute an engine shop visit.

(h) Alternative Methods of Compliance (AMOCs)

The Manager, Engine Certification Office, FAA, may approve AMOCs for this AD. Use the procedures found in 14 CFR 39.19 to make your request. You may email your request to: *ANE-AD-AMOC@faa.gov.*

(i) Related Information

(1) For more information about this AD, contact Brian Kierstead, Aerospace Engineer, Engine Certification Office, FAA, Engine & Propeller Directorate, 12 New England Executive Park, Burlington, MA 01803; phone: 781–238–7772; fax: 781–238–7199; email: *brian.kierstead@faa.gov.*

(2) Refer to MCAI European Aviation Safety Agency AD 2015–0187, dated September 9, 2015, for more information. You may examine the MCAI in the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating it in Docket No. FAA–2015–4076.

Issued in Burlington, Massachusetts, on December 2, 2015.

Colleen M. D'Alessandro,

Directorate Manager, Engine & Propeller Directorate, Aircraft Certification Service.

[FR Doc. 2015–30947 Filed 12–8–15; 8:45 am]

BILLING CODE 4910–13–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R05–OAR–2014–0362; FRL–9939–76–Region 5]

Air Plan Approval; Ohio; Regional Haze Glatfelter BART SIP Revision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to extend the compliance date for the Best Available Retrofit Technology (BART) emission limits for sulfur dioxide (SO_2) at the P.H. Glatfelter Company (Glatfelter) facility submitted as part of its State Implementation Plan (SIP) Revision on April 14, 2014. Specifically, EPA is proposing to extend the compliance date for the SO_2 emission limits applicable to Boilers No. 7 and No. 8 at Glatfelter by 25 months, from December 31, 2014, to January 31, 2017. We have reviewed this SIP revision and concluded that it meets the requirements of the Clean Air Act and the regional haze rule and because BART requirements continue to be met.

DATES: Comments must be received on or before January 8, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R05–OAR–2014–0362, 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.

Instructions: Direct your comments to Docket ID No. EPA–R05–OAR–2014–0362. 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 Gilberto Alvarez, Environmental Scientist, at (312) 886–6143 before visiting the Region 5 office.

FOR FURTHER INFORMATION CONTACT: Gilberto Alvarez, Environmental Scientist, Attainment Planning and Maintenance Section, Air Programs Branch (AR–18J), Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604, (312) 886–6143, *alvarez.gilberto@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. What is the background for this proposed action?

On July 2, 2012, EPA approved Ohio's Regional Haze SIP (77 FR 39177). Ohio's Regional Haze SIP included the applicability of BART to the State's only non-utility BART source, Glatfelter, in Chillicothe, Ohio. The BART requirement specified that two of the coal fired boilers at this facility, No. 7 and No. 8, install control technology to limit the amount of SO_2 emissions from the boilers. The compliance date for BART emission reductions was scheduled to be December 31, 2014. The compliance date was aligned with Glatfelter's expected compliance date for the Industrial Boiler Maximum Achievable Control Technology (MACT) requirements finalized by EPA in May, 2011 (76 FR 28862).

On February 6, 2014, Ohio EPA received a request from Glatfelter to extend the original compliance date to January 31, 2017. The extension request is based on the litigation, revision and new compliance date associated with the Industrial Boiler MACT. Under EPA regulations (40 CFR 51.308(e)(1)(iv)), BART is to be implemented ''as expeditiously as practicable, but in no event later than 5 years after approval of the implementation plan revision.'' The required compliance date is July 2, 2017.

This rulemaking addresses an April 14, 2014, submission supplemented on July 27, 2015, from the Ohio EPA to extend the compliance date from December 31, 2014, to January 31, 2017. One of the requests within the April 14, 2014, SIP revision includes ''the requirement that P.H. Glatfelter submit an application for modification of the federally enforceable permit (that will include a compliance date outlining, at a minimum, the specific, selected control technologies and methods of compliance) from December 31, 2013, to requiring the submittal provide for sufficient time for Ohio EPA to include these requirements, along with any appropriate monitoring, record keeping and reporting requirements, in the federally enforceable permit by no later than January 31, 2017.''

Ohio EPA supplemented their original submittal on July 27, 2015, with a revised federally enforceable permit for Glatfelter that included the new compliance date. Ohio EPA made the federally enforceable permit available for public comment on June 6, 2015, and comments were accepted through July 7, 2015. The Ohio EPA consulted the Federal Land Managers and included them in the public comment process. Two comments were received and those comments, along with Ohio EPA's responses were included in the July 27, 2015, submittal.

II. What is EPA's analysis of Ohio's April 14, 2014, SIP revision?

The CAA and the Regional Haze Rule require BART controls to be installed as expeditiously as practicable, but in no event later than five years after approval of the Regional Haze implementation plan revision. As discussed in greater detail in section I of this proposed rulemaking, our proposed extension of the compliance date by 25 months, from December 31, 2014, to January 31, 2017, is consistent with the CAA and the Regional Haze Rule. The extension is justified by an expeditious schedule for the installation of multiple control technologies to meet the Boiler MACT.

III. Proposed Action

EPA is proposing to approve a revision to the Ohio SIP submitted by the State of Ohio on April 14, 2014, supplemented on July 27, 2015, related to BART requirements for Glatfelter. Specifically, EPA is proposing to extend the compliance date for the SO_2 emission limits applicable to Boilers No. 7 and No. 8 at Glatfelter by 25 months from December 31, 2014, to January 31, 2017.

IV. Incorporation by Reference

In this rule, 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, EPA is proposing to incorporate by reference Permit Number 0671010028—Final Division of Air Pollution Control Permit to Install for P.H. Glatfelter Company—Chillecothe facility, effective July 20, 2015. 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).

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Intergovernmental relations, Sulfur oxides.

Dated: November 23, 2015.

Susan Hedman,

Regional Administrator, Region 5.

[FR Doc. 2015–30917 Filed 12–8–15; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 150818742–5742–01]

RIN 0648–XE130

Fisheries of the Exclusive Economic Zone Off Alaska; Gulf of Alaska; 2016 and 2017 Harvest Specifications for Groundfish

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes 2016 and 2017 harvest specifications, apportionments, and Pacific halibut prohibited species catch limits for the groundfish fishery of the Gulf of Alaska (GOA). This action is necessary to establish harvest limits for groundfish during the 2016 and 2017 fishing years and to accomplish the goals and objectives of the Fishery Management Plan for Groundfish of the Gulf of Alaska. The intended effect of this action is to conserve and manage the groundfish resources in the GOA in accordance with the Magnuson-Stevens Fishery Conservation and Management Act.

DATES: Comments must be received by January 8, 2016.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2015–0110, by any one of the following methods:

- *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2015-0110,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.
- *Mail:* Submit written comments to Glenn Merrill, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS, Attn: Ellen Sebastian. Mail comments to P.O. Box 21668, Juneau, AK 99802–1668.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Electronic copies of the Alaska Groundfish Harvest Specifications Final Environmental Impact Statement (Final EIS), Record of Decision (ROD) for the Final EIS, Supplementary Information Report (SIR) to the Final EIS, and the Initial Regulatory Flexibility Analysis (IRFA) prepared for this action may be obtained from *http://www.regulations.gov* or from the Alaska Region Web site at *http://alaskafisheries.noaa.gov.* The final 2014 Stock Assessment and Fishery Evaluation (SAFE) report for the groundfish resources of the GOA, dated November 2014, is available from the North Pacific Fishery Management Council (Council) at 605 West 4th Avenue, Suite 306, Anchorage, AK 99501, phone 907–271–2809, or from the Council's Web site at *http://www.npfmc.org.* The draft 2015 SAFE report for the GOA will be available from the same source.

FOR FURTHER INFORMATION CONTACT: Obren Davis, 907–586–7228.

SUPPLEMENTARY INFORMATION: NMFS manages the GOA groundfish fisheries in the exclusive economic zone (EEZ) of the GOA under the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP). The Council prepared the FMP under the authority of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act), 16 U.S.C. 1801, *et seq.* Regulations governing U.S. fisheries and implementing the FMP appear at 50 CFR parts 600, 679, and 680.

The FMP and its implementing regulations require NMFS, after consultation with the Council, to specify the total allowable catch (TAC) for each target species, the sum of which must be within the optimum yield (OY) range of 116,000 to 800,000 metric tons (mt). Section 679.20(c)(1) further requires NMFS to publish and solicit public comment on proposed annual TACs, Pacific halibut prohibited species catch (PSC) limits, and seasonal allowances of pollock and Pacific cod. The proposed harvest specifications in Tables 1 through 19 of this document satisfy these requirements. For 2016 and 2017, the sum of the proposed TAC amounts is 590,161 mt.

Under § 679.20(c)(3), NMFS will publish the final 2016 and 2017 harvest specifications after (1) considering comments received within the comment period (see **DATES**), (2) consulting with the Council at its December 2015 meeting, (3) considering information presented in the 2015 SIR that assesses the need to prepare a Supplemental EIS (see **ADDRESSES**) and, (4) considering information presented in the final 2015 SAFE report prepared for the 2016 and 2017 groundfish fisheries.

Other Actions Potentially Affecting the 2016 and 2017 Harvest Specifications

Removal of Pacific Cod Sideboard Limits for Hook-and-Line Catcher/Processors

At its June 2013 meeting, the Council took final action to establish a temporary process to permanently remove catch limits, known as sideboard limits, for Pacific cod that are applicable to certain hook-and-line catcher/processors (C/Ps) in the Central and Western GOA regulatory areas. This action is known as Amendment 45 to the Fishery Management Plan for Bering Sea/Aleutian Islands King and Tanner Crabs (Amendment 45). The final rule implementing the regulations associated with Amendment 45 was published on May 19, 2015 (80 FR 28539).

If all persons holding a license limitation program license with endorsements that allow directed fishing for Pacific cod as a hook-and-line C/P in the Central or Western GOA sign and submit to NMFS an affidavit affirming that all eligible participants in that regulatory area recommend removal of the Crab Rationalization Program GOA Pacific cod sideboard limit, then NMFS would not establish Crab Rationalization Program GOA Pacific cod sideboard limits for the hook-and-line C/P sector through the annual harvest specification process. All eligible fishery participants submitted affidavits as described above for the Western GOA and Central GOA; therefore NMFS will not establish 2016 and 2017 Pacific cod sideboard limits for hook-and-line C/Ps. These sideboard limits have been removed from Table 15 of this proposed rule.

Revise Maximum Retainable Amounts for Skates

In December 2014, the Council took final action to reduce the maximum retainable amount (MRA) for skates in the Gulf of Alaska (GOA). Per the Council's recommendation, NMFS developed and published a proposed rule to modify regulations that specify the MRA for skates in the GOA (80 FR 39734, July 10, 2015). An MRA is expressed as a percentage and is the maximum amount of a species closed to directed fishing (*i.e.,* skate species) that may be retained on board a vessel relative to the retained amount of other groundfish species or halibut open for directed fishing (basis species). An MRA serves as a management tool to slow the harvest rates of incidental catch species and limit retention up to a maximum percentage of the amount of retained groundfish or halibut on board the vessel. NMFS has established a single MRA percentage for big skate (*Raja binoculata*), longnose skate (*Raja rhina*), and for all remaining skate species (*Bathyraja spp.*). The proposed rule would reduce the MRA for skates in the GOA from 20 percent to 5 percent. The reduced MRA would apply to all vessels directed fishing for groundfish or halibut in the GOA. NMFS anticipates that the proposed regulatory revisions associated with the skate MRA reduction will be effective in 2016.

Proposed Acceptable Biological Catch (ABC) and TAC Specifications

In October 2015, the Council, its Scientific and Statistical Committee (SSC), and its Advisory Panel (AP) reviewed the most recent biological and harvest information about the condition of groundfish stocks in the GOA. This information was compiled by the GOA Groundfish Plan Team (Plan Team) and presented in the final 2014 SAFE report for the GOA groundfish fisheries, dated November 2014 (see **ADDRESSES**). The SAFE report contains a review of the latest scientific analyses and estimates of each species' biomass and other biological parameters, as well as summaries of the available information on the GOA ecosystem and the economic condition of the groundfish fisheries off Alaska. From these data and analyses, the Plan Team estimates and the SSC sets an overfishing level (OFL) and ABC for each species or species group. The amounts proposed for the 2016 and 2017 OFLs and ABCs are based on the 2014 SAFE report. The AP and Council recommended that the proposed 2016 and 2017 TACs be set equal to proposed ABCs for all species and species groups, with the exception of the species categories further discussed below. The proposed OFLs, ABCs, and TACs could be changed in the final harvest specifications depending on the most recent scientific information contained in the final 2015 SAFE report. The draft stock assessments that will comprise, in part, the 2015 SAFE report are available at *http://www.afsc.noaa.gov/REFM/stocks/plan_team/draft_assessments.htm.*

In November 2015, the Plan Team updated the 2014 SAFE report to include new information collected during 2015, such as NMFS stock surveys, revised stock assessments, and catch data. The Plan Team compiled this information and produced the draft 2015 SAFE report for presentation at the December 2015 Council meeting. At that meeting, the Council will consider information in the draft 2015 SAFE report, recommendations from the November 2015 Plan Team meeting and December 2015 SSC and AP meetings, public testimony, and relevant written public comments in making its recommendations for the final 2016 and 2017 harvest specifications. Pursuant to Section 3.2.3.4.1 of the FMP, the Council could recommend adjusting the TACs if ''warranted on the basis of bycatch considerations, management uncertainty, or socioeconomic considerations; or if required in order to cause the sum of the TACs to fall within the OY range.''

In previous years, the OFLs and ABCs that have had the most significant changes (relative to the amount of assessed tonnage of fish) from the proposed to the final harvest specifications have been for OFLs and ABCs that are based on the most recent NMFS stock surveys. These surveys provide updated estimates of stock biomass and spatial distribution, and changes to the models used for producing stock assessments. NMFS scientists presented updated and new survey results, changes to assessment models, and accompanying stock estimates at the September 2015 Plan Team meeting, and the SSC reviewed this information at the October 2015 Council meeting. The species with possible model changes are Pacific cod, rex sole, and rock sole. In November 2015, the Plan Team considered updated stock assessments for groundfish, which are included in the draft 2015 SAFE report.

If the draft 2015 SAFE report indicates that the stock biomass trend is increasing for a species, then the final 2016 and 2017 harvest specifications for that species may reflect an increase from the proposed harvest specifications. Conversely, if the draft 2015 SAFE report indicates that the stock biomass trend is decreasing for a species, then the final 2016 and 2017 harvest specifications may reflect a decrease from the proposed harvest specifications.

The proposed 2016 and 2017 OFLs, ABCs, and TACs are based on the best available biological and socioeconomic information, including projected biomass trends, information on assumed distribution of stock biomass, and revised methods used to calculate stock biomass. The FMP specifies the formulas, or tiers, to be used to compute OFLs and ABCs. The formulas applicable to a particular stock or stock complex are determined by the level of reliable information available to the fisheries scientists. This information is categorized into a successive series of six tiers to define OFL and ABC amounts, with Tier 1 representing the highest level of information quality available and Tier 6 representing the lowest level of information quality available. The Plan Team used the FMP tier structure to calculate OFLs and ABCs for each groundfish species. The SSC adopted the proposed 2016 and 2017 OFLs and ABCs recommended by the Plan Team for all groundfish species. The Council adopted the SSC's OFL and ABC recommendations and the AP's TAC recommendations. These amounts are unchanged from the final 2016 harvest specifications published in the **Federal Register** on February 25, 2015 (80 FR 10250).

Specification and Apportionment of TAC Amounts

The Council recommended proposed 2016 and 2017 TACs that are equal to proposed ABCs for all species and species groups, with the exceptions of shallow-water flatfish in the Western GOA, arrowtooth flounder, flathead sole in the Western and Central GOA, ''other rockfish'' in Southeast Outside (SEO) District, Atka mackerel, and Pacific cod. The shallow-water flatfish, arrowtooth flounder, and flathead sole TACs are set to allow for harvest opportunities while conserving the halibut PSC limit for use in other fisheries. The ''other rockfish'' TAC is set to reduce the potential amount of discards in the SEO District. The Atka mackerel TAC is set to accommodate incidental catch amounts of this species in other directed fisheries.

The proposed 2016 and 2017 Pacific cod TACs are set to accommodate the State's guideline harvest levels (GHLs) for Pacific cod in State waters in the Western and Central Regulatory Areas, as well as in Prince William Sound (PWS). The Plan Team, SSC, AP, and Council recommended that the sum of all State and Federal water Pacific cod removals from the GOA not exceed ABC recommendations. Accordingly, the Council reduced the proposed 2016 and 2017 Pacific cod TACs in the Eastern, Central, and Western Regulatory Areas to account for State GHLs. Therefore, the proposed 2016 and 2017 Pacific cod TACs are less than the proposed ABCs by the following amounts: (1) Eastern GOA, 707 mt; (2) Central GOA, 15,330 mt; and (3) Western GOA, 11,611 mt. These amounts reflect the sum of the State's 2016 and 2017 GHLs in these areas, which are 25 percent of the Eastern and Central and 30 percent of the Western GOA proposed ABCs.

The ABC for the pollock stock in the combined Western, Central, and West Yakutat Regulatory Areas (W/C/WYK) includes the amount for the GHL established by the State for the PWS pollock fishery. The Plan Team, SSC, AP, and Council recommended that the sum of all State and Federal water pollock removals from the GOA not exceed ABC recommendations. Based on genetic studies, fisheries scientists believe that the pollock in PWS is not a separate stock from the combined W/C/WYK population. Since 1996, the Plan Team has had a protocol of recommending that the GHL amount be deducted from the GOA-wide ABC. For 2016 and 2017, the SSC recommended and the Council approved the W/C/WYK pollock ABC including the amount to account for the State's PWS GHL. At the November 2015 Plan Team meeting, State fisheries managers recommended setting the PWS GHL at 2.5 percent of the annual W/C/WYK pollock ABC. Accordingly, the Council recommended adopting a W/C/WYK pollock ABC that has been reduced to account for the State's PWS GHL. For 2016 and 2017, the proposed PWS pollock GHL is 6,271 mt, as recommended by State fisheries managers. The proposed 2016 and 2017 ABC is 263,449 mt, and the proposed TAC is 257,178 mt.

The Council has adopted the SSC's 2014 recommendation to revise the terminology used when apportioning pollock in the W/C/WYK. The SSC recommended describing apportionments of pollock to the W/C/WYK as ''apportionments of annual catch limit (ACLs)'' rather than ''ABCs.'' The SSC noted that describing subarea apportionments as ''apportionments of the ACL'' more accurately reflects that such apportionments address management, rather than biological or conservation, concerns. In addition, apportionments of the ACL in this manner allow NMFS to balance any transfer of TAC from one area to another pursuant to § 679.20(a)(5)(iv)(B) to ensure that the area-wide ACL and ABC are not exceeded. The SSC noted that this terminology change is acceptable for pollock in the W/C/WYK only. Further information about the rationale to adopt this terminology is in the final 2015 and 2016 harvest specifications for GOA groundfish (80 FR 10250, February 25, 2015).

NMFS' proposed apportionments for groundfish species are based on the distribution of biomass among the regulatory areas under which NMFS manages the species. Additional regulations govern the apportionment of Pacific cod, pollock, and sablefish. Additional detail on these apportionments are described below, and briefly summarized here.

NMFS proposes pollock TACs in the W/C/WYK and the SEO District of the GOA (see Table 1). NMFS also proposes seasonal apportionment of the annual pollock TAC in the Western and Central Regulatory Areas of the GOA among Statistical Areas 610, 620, and 630 divided equally among each of the following four seasons: the A season (January 20 through March 10), the B season (March 10 through May 31), the C season (August 25 through October 1), and the D season (October 1 through November 1) (§ 679.23(d)(2)(i) through (iv), and § 679.20(a)(5)(iv)(A) and (B)). Additional detail is provided below; Table 2 lists these amounts.

NMFS proposes Pacific cod TACs in the Western, Central, and Eastern GOA (see Table 1). NMFS also proposes seasonal apportionment of the Pacific cod TACs in the Western and Central Regulatory Areas. Sixty percent of the annual TAC is apportioned to the A season for hook-and-line, pot, or jig gear from January 1 through June 10, and for trawl gear from January 20 through June 10. Forty percent of the annual TAC is apportioned to the B season for jig gear from June 10 through December 31, for hook-and-line or pot gear from September 1 through December 31, and for trawl gear from September 1 through November 1 (§§ 679.23(d)(3) and 679.20(a)(12)). The Western and Central GOA Pacific cod gear and sector apportionments are discussed in detail below; Table 3 lists these amounts.

The Council's recommendation for sablefish area apportionments takes into account the prohibition on the use of

trawl gear in the SEO District of the Eastern Regulatory Area and makes available 5 percent of the combined Eastern Regulatory Area TACs to trawl gear for use as incidental catch in other directed groundfish fisheries in the WYK District (§ 679.20(a)(4)(i)). Additional detail is provided below; Tables 4 and 5 list these amounts.

The sum of the proposed TACs for all GOA groundfish is 590,161 mt for 2016 and 2017, which is within the OY range specified by the FMP. The sums of the proposed 2016 and 2017 TACs are higher than the final 2015 TACs currently specified for the GOA groundfish fisheries (80 FR 10250, February 25, 2015). The proposed 2016 and 2017 TACs for pollock, Pacific ocean perch, and rougheye rockfish are higher than the final 2015 TACs for these species. The proposed 2016 and 2017 TACs for sablefish, shallow-water flatfish, deep-water flatfish, rex sole, flathead sole, northern rockfish, and dusky rockfish are lower than the final 2015 TACs for these species. The proposed 2016 and 2017 TACs for the remaining species are equal to the final 2015 TACs.

For 2016 and 2017, the Council recommends and NMFS proposes the OFLs, ABCs, and TACs listed in Table 1. The proposed ABCs reflect harvest amounts that are less than the specified overfishing levels. Table 1 lists the proposed 2016 and 2017 OFLs, ABCs, TACs, and area apportionments of groundfish in the GOA. These amounts are consistent with the biological condition of groundfish stocks as described in the 2014 SAFE report, and adjusted for other biological and socioeconomic considerations, including maintaining the total TAC within the required OY range. These proposed amounts and apportionments by area, season, and sector are subject to change pending consideration of the draft 2015 SAFE report and the Council's recommendations for the final 2016 and 2017 harvest specifications during its December 2015 meeting.

TABLE 1—PROPOSED 2016 AND 2017 ABCS, TACS, AND OFLS OF GROUNDFISH FOR THE WESTERN/CENTRAL/WEST YAKUTAT, WESTERN, CENTRAL, AND EASTERN REGULATORY AREAS, AND IN THE WEST YAKUTAT, SOUTHEAST OUTSIDE, AND GULFWIDE DISTRICTS OF THE GULF OF ALASKA

[Values are rounded to the nearest metric ton]

Species	Area [1]	OFL	ABC	TAC [2]
Pollock [2]	Shumagin (610)	n/a	41,472	41,472
	Chirikof (620)	n/a	127,936	127,936
	Kodiak (630)	n/a	68,958	68,958
	WYK (640)	n/a	6,187	6,187
	W/C/WYK (subtotal)	321,067	250,824	244,553
	SEO (650)	16,833	12,625	12,625
	Total	337,900	263,449	257,178
Pacific cod [3]	W	n/a	38,702	27,091
	C	n/a	61,320	45,990
	E	n/a	2,828	2,121
	Total	133,100	102,850	75,202
Sablefish [4]	W	n/a	1,338	1,338
	C	n/a	4,232	4,232
	WYK	n/a	1,552	1,552
	SEO	n/a	2,436	2,436
	E (WYK and SEO) (subtotal)	n/a	3,988	3,988
	Total	11,293	9,558	9,558
Shallow-water flatfish [5]	W	n/a	19,577	13,250
	C	n/a	17,114	17,114
	WYK	n/a	1,959	1,959
	SEO	n/a	554	554
	Total	48,407	39,205	32,877
Deep-water flatfish [6]	W	n/a	299	299
	C	n/a	3,645	3,645
	WYK	n/a	5,409	5,409
	SEO	n/a	3,824	3,824
	Total	15,803	13,177	13,177
Rex sole	W	n/a	1,234	1,234
	C	n/a	5,707	5,707
	WYK	n/a	758	758
	SEO	n/a	1,280	1,280
	Total	11,733	8,979	8,979
Arrowtooth flounder	W	n/a	29,545	14,500
	C	n/a	109,692	75,000
	WYK	n/a	35,328	6,900

TABLE 1—PROPOSED 2016 AND 2017 ABCS, TACS, AND OFLS OF GROUNDFISH FOR THE WESTERN/CENTRAL/WEST YAKUTAT, WESTERN, CENTRAL, AND EASTERN REGULATORY AREAS, AND IN THE WEST YAKUTAT, SOUTHEAST OUTSIDE, AND GULFWIDE DISTRICTS OF THE GULF OF ALASKA—Continued

[Values are rounded to the nearest metric ton]

Species	Area [1]	OFL	ABC	TAC [2]
	SEO	n/a	10,787	6,900
	Total	217,522	185,352	103,300
Flathead sole	W	n/a	12,776	8,650
	C	n/a	24,893	15,400
	WYK	n/a	3,538	3,538
	SEO	n/a	171	171
	Total	50,818	41,378	27,759
Pacific ocean perch [7]	W	n/a	2,358	2,358
	C	n/a	16,184	16,184
	WYK	n/a	2,055	2,055
	W/C/WYK	23,876	20,597	20,597
	SEO	2,513	839	839
	Total	24,849	21,436	21,436
Northern rockfish [8]	W	n/a	1,158	1,158
	C	n/a	3,563	3,563
	E	n/a		
	Total	5,631	4,721	4,721
Shortraker rockfish [9]	W	n/a	92	92
	C	n/a	397	397
	E	n/a	834	834
	Total	1,764	1,323	1,323
Dusky rockfish [10]	W	n/a	273	273
	C	n/a	3,077	3,077
	WYK	n/a	1,187	1,187
	SEO	n/a	174	174
	Total	5,759	4,711	4,711
Rougheye and blackspotted rockfish [11]	W	n/a	117	117
	C	n/a	643	643
	E	n/a	382	382
	Total	1,370	1,142	1,142
Demersal shelf rockfish [12]	SEO	361	225	225
Thornyhead rockfish [13]	W	n/a	235	235
	C	n/a	875	875
	E	n/a	731	731
	Total	2,454	1,841	1,841
Other rockfish [14 15]	W/C combined	n/a	1,031	1,031
	WYK	n/a	580	580
	SEO	n/a	2,469	200
	Total	5,347	4,080	1,811
Atka mackerel	GW	6,200	4,700	2,000
Big skates [16]	W	n/a	731	731
	C	n/a	1,257	1,257
	E	n/a	1,267	1,267
	Total	4,340	3,255	3,255
Longnose skates [17]	W	n/a	152	152
	C	n/a	2,090	2,090
	E	n/a	976	976
	Total	4,291	3,218	3,218

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[Values are rounded to the nearest metric ton]

Species	Area [1]	OFL	ABC	TAC [2]
Other skates [18]	GW	2,980	2,235	2,235
Sculpins	GW	7,448	5,569	5,569
Sharks	GW	7,986	5,989	5,989
Squids	GW	1,530	1,148	1,148
Octopuses	GW	2,009	1,507	1,507
Total		910,895	731,049	590,161

[1] Regulatory areas and districts are defined at § 679.2. (W=Western Gulf of Alaska; C=Central Gulf of Alaska; E=Eastern Gulf of Alaska; WYK=West Yakutat District; SEO=Southeast Outside District; GW=Gulf-wide).

[2] The combined pollock ABC for the Western, Central, and West Yakutat areas is apportioned in the Western/Central Regulatory Areas among four statistical areas. These apportionments are considered subarea ACLs, rather than ABCs, for specification and reapportionment purposes. Table 2 lists the proposed 2016 and 2017 seasonal apportionments. In the West Yakutat and Southeast Outside Districts of the Eastern Regulatory Area, pollock is not divided into seasonal allowances.

[3] Section 679.20(a)(12)(i) requires the allocation of the Pacific cod TACs in the Western and Central Regulatory Areas of the GOA among gear and operational sectors. The annual Pacific cod TAC is apportioned among various sectors 60 percent to the A season and 40 percent to the B season in the Western and Central Regulatory Areas of the GOA. In the Eastern Regulatory Area of the GOA, Pacific cod is allocated 90 percent for processing by the inshore component and 10 percent for processing by the offshore component. Table 3 lists the proposed 2016 and 2017 Pacific cod seasonal apportionments.

[4] Sablefish is allocated to hook-and-line and trawl gear in 2016 and trawl gear in 2017. Tables 4 and 5 list the proposed 2016 and 2017 allocations of sablefish TACs.

[5] ''Shallow-water flatfish'' means flatfish not including ''deep-water flatfish,'' flathead sole, rex sole, or arrowtooth flounder.

[6] ''Deep-water flatfish'' means Dover sole, Greenland turbot, Kamchatka flounder, and deep-sea sole.

[7] ''Pacific ocean perch'' means *Sebastes alutus.*

[8] ''Northern rockfish'' means *Sebastes polyspinous.* For management purposes the 3 mt apportionment of ABC to the WYK District of the Eastern Gulf of Alaska has been included in the other rockfish (slope rockfish) species group.

[9] ''Shortraker rockfish'' means *Sebastes borealis.*

[10] ''Dusky rockfish'' means *Sebastes variabilis.*

[11] ''Rougheye rockfish'' means *Sebastes aleutianus* (rougheye) and *Sebastes melanostictus* (blackspotted).

[12] ''Demersal shelf rockfish'' means *Sebastes pinniger* (canary), *S. nebulosus* (china), *S. caurinus* (copper), *S. maliger* (quillback), *S. helvomaculatus* (rosethorn), *S. nigrocinctus* (tiger), and *S. ruberrimus* (yelloweye).

[13] ''Thornyhead rockfish'' means *Sebastes* species.

[14] ''Other rockfish (slope rockfish)'' means *Sebastes aurora* (aurora), *S. melanostomus* (blackgill), *S. paucispinis* (bocaccio), *S. goodei* (chilipepper), *S. crameri* (darkblotch), *S. elongatus* (greenstriped), *S. variegatus* (harlequin), *S. wilsoni* (pygmy), *S. babcocki* (redbanded), *S. proriger* (redstripe), *S. zacentrus* (sharpchin), *S. jordani* (shortbelly), *S. brevispinis* (silvergray), *S. diploproa* (splitnose), *S. saxicola* (stripetail), *S. miniatus* (vermilion), *S. reedi* (yellowmouth), *S. entomelas* (widow), and *S. flavidus* (yellowtail). In the Eastern GOA only, ''other rockfish'' also includes northern rockfish (*S. polyspinous).*

[15] ''Other rockfish'' in the Western and Central Regulatory Areas and in the West Yakutat District means all rockfish species included in the ''other rockfish'' and demersal shelf rockfish categories.

[16] ''Big skates'' means *Raja binoculata.*

[17] ''Longnose skates'' means *Raja rhina.*

[18] ''Other skates'' means *Bathyraja spp.*

Proposed Apportionment of Reserves

Section 679.20(b)(2) requires NMFS to set aside 20 percent of each TAC for pollock, Pacific cod, flatfish, sculpins, sharks, squids, and octopuses in reserves for possible apportionment at a later date during the fishing year. In 2015, NMFS apportioned all of the reserves in the final harvest specifications. For 2016 and 2017, NMFS proposes reapportionment of all the reserves for pollock, Pacific cod, flatfish, sculpins, sharks, squids, and octopuses in anticipation of the projected annual catch of these species. The TACs in Table 1 reflect the apportionment of reserve amounts for these species and species groups. Each proposed TAC for the above mentioned species categories contains the full TAC recommended by the Council, since none of the relevant species and species groups' TACs contributed to a reserve that could be used for future reapportionments.

Proposed Apportionments of Pollock TAC Among Seasons and Regulatory Areas, and Allocations for Processing by Inshore and Offshore Components

In the GOA, pollock is apportioned by season and area, and is further allocated for processing by inshore and offshore components. Pursuant to § 679.20(a)(5)(iv)(B), the annual pollock TAC specified for the Western and Central Regulatory Areas of the GOA is apportioned into four equal seasonal allowances of 25 percent. As established by § 679.23(d)(2)(i) through (iv), the A, B, C, and D season allowances are available from January 20 through March 10, March 10 through May 31, August 25 through October 1, and October 1 through November 1, respectively.

Pollock TACs in the Western and Central Regulatory Areas of the GOA are apportioned among Statistical Areas 610, 620, and 630, pursuant to § 679.20(a)(5)(iv)(A). In the A and B seasons, the apportionments have historically been based on the proportional distribution of pollock biomass based on the four most recent NMFS winter surveys. In the C and D seasons, the apportionments are in proportion to the distribution of pollock biomass based on the four most recent NMFS summer surveys. However, for 2016 and 2017, the Council recommends, and NMFS proposes, averaging the winter and summer distribution of pollock in the Central Regulatory Area for the A season instead of using the distribution based on only the winter surveys. This combination of summer and winter distribution has been used for area apportionments since 2002. The average is intended to reflect the best available information about migration patterns, distribution of pollock, and the performance of the fishery in the area during the A season. For the A season, the apportionment is based on the proposed adjusted estimate

of the relative distribution of pollock biomass of approximately 8 percent, 67 percent, and 25 percent in Statistical Areas 610, 620, and 630, respectively. For the B season, the apportionment is based on the relative distribution of pollock biomass of approximately 8 percent, 83 percent, and 9 percent in Statistical Areas 610, 620, and 630, respectively. For the C and D seasons, the apportionment is based on the relative distribution of pollock biomass of approximately 27 percent, 32 percent, and 41 percent in Statistical Areas 610, 620, and 630, respectively.

Within any fishing year, the amount by which a seasonal allowance is underharvested or overharvested may be added to, or subtracted from, subsequent seasonal allowances in a manner to be determined by the Regional Administrator (§ 679.20(a)(5)(iv)(B)). The rollover amount is limited to 20 percent of the unharvested seasonal apportionment for the statistical area. Any unharvested pollock above the 20-percent limit could be further distributed to the other statistical areas, in proportion to the estimated biomass in the subsequent season in those statistical areas (§ 679.20(a)(5)(iv)(B)). The proposed 2016 and 2017 pollock TACs in the WYK District of 6,187 mt and SEO District of 12,625 mt are not allocated by season.

Section 679.20(a)(6)(i) requires the allocation of 100 percent of the pollock apportionments in all regulatory areas and all seasonal allowances to vessels catching pollock for processing by the inshore component after subtraction of pollock amounts projected by the Regional Administrator to be caught by, or delivered to, the offshore component incidental to directed fishing for other groundfish species. Thus, the amount of pollock available for harvest by vessels harvesting pollock for processing by the offshore component is that amount that will be taken as incidental catch during directed fishing for groundfish species other than pollock, up to the maximum retainable amounts allowed under § 679.20(e) and (f). At this time, these incidental catch amounts of pollock are unknown and will be determined as fishing activity occurs during the fishing year by the offshore component.

Table 2 lists the proposed 2016 and 2017 seasonal biomass distribution of pollock in the Western and Central Regulatory Areas, area apportionments, and seasonal allowances. The amounts of pollock for processing by the inshore and offshore components are not shown.

TABLE 2—PROPOSED 2016 AND 2017 DISTRIBUTION OF POLLOCK IN THE CENTRAL AND WESTERN REGULATORY AREAS OF THE GULF OF ALASKA; SEASONAL BIOMASS DISTRIBUTION, AREA APPORTIONMENTS; AND SEASONAL ALLOWANCES OF ANNUAL TAC [1]

[Values are rounded to the nearest metric ton]

Season [2]	Shumagin (Area 610)		Chirikof (Area 620)		Kodiak (Area 630)		Total
A (Jan 20–Mar 10)	4,760	(7.99%)	39,992	(67.11%)	14,839	(24.90%)	59,592
B (Mar 10–May 31)	4,760	(7.99%)	49,586	(83.21%)	5,245	(8.80%)	59,592
C (Aug 25–Oct 1)	15,975	(26.81%)	19,179	(32.18%)	24,437	(41.01%)	59,592
D (Oct 1–Nov 1)	15,975	(26.81%)	19,179	(32.18%)	24,437	(41.01%)	59,592
Annual Total [3]	41,472		127,936		68,958		238,366

[1] Area apportionments and seasonal allowances may not total precisely due to rounding.

[2] As established by § 679.23(d)(2)(i) through (iv), the A, B, C, and D season allowances are available from January 20 through March 10, March 10 through May 31, August 25 through October 1, and October 1 through November 1, respectively. The amounts of pollock for processing by the inshore and offshore components are not shown in this table.

[3] The West Yakutat and Southeast Outside District pollock TACs are not allocated by season and are not included in the total pollock TACs shown in this table.

Proposed Annual and Seasonal Apportionments of Pacific Cod TAC

Pursuant to § 679.20(a)(12)(i), NMFS proposes allocations for the 2016 and 2017 Pacific cod TACs in the Western and Central Regulatory Areas of the GOA among gear and operational sectors. Pursuant § 679.20(a)(6)(ii) NMFS proposes the allocation of the Pacific cod TAC between the inshore and offshore components in the Eastern Regulatory Area of the GOA. In the Central GOA, the Pacific cod TAC is apportioned seasonally first to vessels using jig gear, and then among catcher vessels (CVs) less than 50 feet in length overall using hook-and-line gear, CVs equal to or greater than 50 feet in length overall using hook-and-line gear, C/Ps using hook-and-line gear, CVs using trawl gear, C/Ps using trawl gear, and vessels using pot gear. In the Western GOA, the Pacific cod TAC is apportioned seasonally first to vessels using jig gear, and then among CVs using hook-and-line gear, C/Ps using hook-and-line gear, CVs using trawl gear, and vessels using pot gear. The overall seasonal apportionments in the Western and Central GOA are 60 percent of the annual TAC to the A season and 40 percent of the annual TAC to the B season.

Under § 679.20(a)(12)(ii), any overage or underage of the Pacific cod allowance from the A season will be subtracted from, or added to, the subsequent B season allowance. In addition, any portion of the hook-and-line, trawl, pot, or jig sector allocations that is determined by NMFS as likely to go unharvested by a sector may be reapportioned to other sectors for harvest during the remainder of the fishery year.

Pursuant to § 679.20(a)(12)(i)(A) and (B), a portion of the annual Pacific cod TACs in the Western and Central GOA will be allocated to vessels with a federal fisheries permit that use jig gear before TAC is apportioned among other non-jig sectors. In accordance with the FMP, the annual jig sector allocations may increase up to 6 percent of the annual Western and Central GOA Pacific cod TACs depending on the annual performance of the jig sector. If such allocation increases are not harvested by the jig sector, then the annual jig sector allocations may subsequently be reduced (See Table 1 of Amendment 83 to the FMP for a detailed discussion of the jig sector allocation process (76 FR 74670, December 1, 2011)). NMFS proposes that the jig sector receive 3.5 percent of the annual Pacific cod TAC in the Western GOA. This includes a base allocation of 1.5 percent and an additional 2.0 percent because this sector harvested greater than 90 percent of its initial 2012 and 2014 allocations in the Western GOA. NMFS also proposes that the jig sector would receive 1.0 percent of the annual Pacific

cod TAC in the Central GOA. This includes a base allocation of 1.0 percent and no additional performance increase. However, allocation increases to the jig sector are established for a minimum of 2 years. NMFS will re-evaluate the annual 2014 and 2015 harvest performance of each jig sector when the 2015 fishing year is complete to determine whether to change the jig sector allocations proposed by this action in conjunction with the final 2016 and 2017 harvest specifications.

Based on the current catch (through November 2015) by the Western GOA jig sector, the Pacific cod allocation percentage to this sector would not change in 2016. Similarly, the current catch by the Central GOA jig sector indicates that this sector's Pacific cod allocation percentage would not change in 2016. The jig sector allocations are further apportioned between the A (60 percent) and B (40 percent) seasons.

Table 3 lists the seasonal apportionments and allocations of the proposed 2016 and 2017 Pacific cod TACs.

TABLE 3—PROPOSED 2016 AND 2017 SEASONAL APPORTIONMENTS AND ALLOCATIONS OF PACIFIC COD TOTAL ALLOWABLE CATCH AMOUNTS IN THE GOA; ALLOCATIONS IN THE WESTERN GOA AND CENTRAL GOA SECTORS, AND THE EASTERN GOA FOR PROCESSING BY THE INSHORE AND OFFSHORE COMPONENTS

[Values are rounded to the nearest metric ton]

Regulatory area and sector	Annual allocation (mt)	A Season		B Season	
		Sector percentage of annual non-jig TAC	Seasonal allowances (mt)	Sector percentage of annual non-jig TAC	Seasonal allowances (mt)
Western GOA:					
Jig (3.5% of TAC)	948	N/A	569	N/A	379
Hook-and-line CV	366	0.70	183	0.70	183
Hook-and-line C/P	5,176	10.90	2,850	8.90	2,327
Trawl CV	10,039	27.70	7,242	10.70	2,797
Trawl C/P	627	0.90	235	1.50	392
Pot CV and Pot C/P	9,934	19.80	5,176	18.20	4,758
Total	27,091	60.00	16,255	40.00	10,837
Central GOA:					
Jig (1.0% of TAC)	460	N/A	276	N/A	184
Hook-and-line <50 CV	6,648	9.32	4,241	5.29	2,407
Hook-and-line ≥50 CV	3,054	5.61	2,554	1.10	500
Hook-and-line C/P	2,324	4.11	1,870	1.00	454
Trawl CV	18,933	21.13	9,623	20.45	9,310
Trawl C/P	1,911	2.00	912	2.19	999
Pot CV and Pot C/P	12,660	17.83	8,118	9.97	4,542
Total	45,990	60.00	27,594	40.00	18,396
		Inshore (90% of Annual TAC)		Offshore (10% of Annual TAC)	
Eastern GOA	2,121		1,909		212

Proposed Allocations of the Sablefish TACs Amounts to Vessels Using Hook-and-Line and Trawl Gear

Sections 679.20(a)(4)(i) and (ii) require allocations of sablefish TACs for each of the regulatory areas and districts to hook-and-line and trawl gear. In the Western and Central Regulatory Areas, 80 percent of each TAC is allocated to hook-and-line gear, and 20 percent of each TAC is allocated to trawl gear. In the Eastern Regulatory Area, 95 percent of the TAC is allocated to hook-and-line gear and 5 percent is allocated to trawl gear. The trawl gear allocation in the Eastern GOA may only be used to support incidental catch of sablefish in directed fisheries for other target species (§ 679.20(a)(4)(i)).

In recognition of the prohibition against trawl gear in the SEO District of the Eastern Regulatory Area, the Council recommended and NMFS proposes the allocation of 5 percent of the combined Eastern Regulatory Area sablefish TAC to trawl gear in the WYK District, making the remainder of the WYK sablefish TAC available to vessels using hook-and-line gear. NMFS proposes to allocate 100 percent of the sablefish TAC in the SEO District to vessels using hook-and-line gear. This action results in a proposed 2016 allocation of 199 mt to trawl gear and 1,353 mt to hook-and-line gear in the WYK District, and 2,436 mt to hook-and-line gear in the SEO District. Table 4 lists the allocations of the proposed 2016 sablefish TACs to hook-and-line and trawl gear. Table 5 lists the allocations of the proposed 2017 sablefish TACs to trawl gear.

The Council recommended that the hook-and-line sablefish TAC be established annually to ensure that the sablefish Individual Fishery Quota (IFQ) fishery is conducted concurrent with the halibut IFQ fishery and is based on recent survey information. The Council also recommended that only the trawl sablefish TAC be established for 2 years so that retention of incidental catch of sablefish by trawl gear could commence in January in the second year of the groundfish harvest specifications. Since there is an annual assessment for sablefish and the final harvest specifications are expected to be published before the IFQ season begins (typically, in early March), the Council recommended that the sablefish TAC be set on an annual basis, rather than for 2 years, so that the best available scientific information could be considered in establishing the ABCs and TACs. With the exception of the trawl allocations that are provided to the Rockfish Program cooperatives (see Table 28c to part 679), directed fishing

for sablefish with trawl gear is closed during the fishing year. Also, fishing for groundfish with trawl gear is prohibited prior to January 20. Therefore, it is not likely that the sablefish allocation to trawl gear would be reached before the effective date of the final 2016 and 2017 harvest specifications.

TABLE 4—PROPOSED 2016 SABLEFISH TOTAL ALLOWABLE CATCH (TAC) IN THE GULF OF ALASKA AND ALLOCATIONS TO HOOK-AND-LINE AND TRAWL GEAR

[Values are rounded to the nearest metric ton]

Area/district	TAC	Hook-and-line allocation	Trawl allocation
Western	1,338	1,070	268
Central	4,232	3,386	846
West Yakutat [1]	1,552	1,353	199
Southeast Outside	2,436	2,436	0
Total	9,558	8,245	1,313

[1] The proposed trawl allocation is based on allocating 5 percent of the combined Eastern Regulatory Area (West Yakutat and Southeast Outside Districts combined) sablefish TAC to trawl gear in the West Yakutat District.

TABLE 5—PROPOSED 2017 SABLEFISH TOTAL ALLOWABLE CATCH (TAC) IN THE GULF OF ALASKA AND ALLOCATION TO TRAWL GEAR [1]

[Values are rounded to the nearest metric ton]

Area/district	TAC	Hook-and-line allocation	Trawl allocation
Western	1,338	n/a	268
Central	4,232	n/a	846
West Yakutat [2]	1,552	n/a	199
Southeast Outside	2,436	n/a	0
Total	9,558	n/a	1,313

[1] The Council recommended that harvest specifications for the hook-and-line gear sablefish Individual Fishing Quota fisheries be limited to 1 year.

[2] The proposed trawl allocation is based on allocating 5 percent of the combined Eastern Regulatory Area (West Yakutat and Southeast Outside Districts combined) sablefish TAC to trawl gear in the West Yakutat District.

Proposed Apportionments to the Rockfish Program

These proposed 2016 and 2017 harvest specifications for the GOA include the fishery cooperative allocations and sideboard limitations established by the Rockfish Program. Program participants are primarily trawl CVs and trawl C/Ps, with limited participation by vessels using longline gear. The Rockfish Program assigns quota share and cooperative quota to participants for primary and secondary species, allows a participant holding a license limitation program (LLP) license with rockfish quota share to form a rockfish cooperative with other persons, and allows holders of C/P LLP licenses to opt out of the fishery. The Rockfish Program also has an entry level fishery for rockfish primary species for vessels using longline gear.

Under the Rockfish Program, rockfish primary species (Pacific ocean perch, northern rockfish, and dusky rockfish) in the Central GOA are allocated to participants after deducting for incidental catch needs in other directed groundfish fisheries. Participants in the Rockfish Program also receive a portion of the Central GOA TAC of specific secondary species (Pacific cod, rougheye rockfish, sablefish, shortraker rockfish, and thornyhead rockfish).

Additionally, the Rockfish Program establishes sideboard limits to restrict the ability of harvesters operating under the Rockfish Program to increase their participation in other, non-Rockfish Program fisheries. Besides groundfish species, the Rockfish Program allocates a portion of the halibut PSC limit (191 mt) from the third season deep-water species fishery allowance for the GOA trawl fisheries to Rockfish Program participants. (Rockfish Program sideboards and halibut PSC limits are discussed below.)

Section 679.81(a)(2)(ii) requires allocations of 5 mt of Pacific ocean perch, 5 mt of northern rockfish, and 30 mt of dusky rockfish to the entry level longline fishery in 2016 and 2017. The allocation for the entry level longline fishery would increase incrementally each year if the catch exceeds 90 percent of the allocation of a species. The incremental increase in the allocation would continue each year until it is the maximum percentage of the TAC for that species. In 2015, the catch did not exceed 90 percent of any allocated rockfish species. Therefore, NMFS is not proposing an increase to the entry level longline fishery 2016 and 2017 allocations in the Central GOA. The remainder of the TACs for the rockfish primary species would be allocated to the CV and C/P cooperatives. Table 6 lists the allocations of the proposed 2016 and 2017 TACs for each rockfish primary species to the entry level longline fishery, the incremental increase for future years, and the maximum percent of the TAC for the entry level longline fishery.

TABLE 6—PROPOSED 2016 AND 2017 ALLOCATIONS OF ROCKFISH PRIMARY SPECIES TO THE ENTRY LEVEL LONGLINE FISHERY IN THE CENTRAL GULF OF ALASKA

Rockfish primary species	2016 and 2017 allocations	Incremental increase in 2017 if ≥90 percent of 2016 allocation is harvested	Up to maximum percent of each TAC of: (%)
Pacific ocean perch	5 metric tons	5 metric tons	1
Northern rockfish	5 metric tons	5 metric tons	2
Dusky rockfish	30 metric tons	20 metric tons	5

Section 679.81(a)(2) requires allocations of rockfish primary species among various components of the Rockfish Program. Table 7 lists the proposed 2016 and 2017 allocations of rockfish in the Central GOA to the entry level longline fishery and other participants in the Rockfish Program, which include CV and C/P cooperatives. NMFS also proposes setting aside incidental catch amounts (ICAs) for other directed fisheries in the Central GOA of 2,000 mt of Pacific ocean perch, 250 mt of northern rockfish, and 250 mt of dusky rockfish. These amounts are based on recent average incidental catches in the Central GOA by other groundfish fisheries.

Allocations between vessels belonging to CV or C/P cooperatives are not included in these proposed harvest specifications. Rockfish Program applications for CV cooperatives and C/P cooperatives are not due to NMFS until March 1 of each calendar year; therefore, NMFS cannot calculate 2016 and 2017 allocations in conjunction with these proposed harvest specifications. NMFS will post these allocations on the Alaska Region Web site at *http://alaskafisheries.noaa.gov/sustainablefisheries/rockfish/* after March 1.

TABLE 7—PROPOSED 2016 AND 2017 ALLOCATIONS OF ROCKFISH PRIMARY SPECIES IN THE CENTRAL GULF OF ALASKA TO THE ENTRY LEVEL LONGLINE FISHERY AND OTHER PARTICIPANTS IN THE ROCKFISH PROGRAM

[Values are rounded to the nearest metric ton]

Rockfish primary species	TAC	Incidental catch allowance (ICA)	TAC minus ICA	Allocation to the entry level longline [1] fishery	Allocation to the Rockfish Cooperatives
Pacific ocean perch	16,184	2,000	14,184	5	14,179
Northern rockfish	3,563	250	3,313	5	3,308
Dusky rockfish	3,077	250	2,827	30	2,797
Total	22,824	2,500	20,324	40	20,284

[1] Longline gear includes hook-and-line, jig, troll, and handline gear.
[2] Rockfish cooperatives include vessels in CV and C/P cooperatives.

Section 679.81(c) requires allocations of rockfish secondary species to CV and C/P cooperatives in the GOA. CV cooperatives receive allocations of Pacific cod, sablefish from the trawl gear allocation, and thornyhead rockfish. C/P cooperatives receive allocations of sablefish from the trawl allocation, rougheye rockfish, shortraker rockfish, and thornyhead rockfish. Table 8 lists the apportionments of the proposed 2016 and 2017 TACs of rockfish secondary species in the Central GOA to CV and C/P cooperatives.

TABLE 8—PROPOSED 2016 AND 2017 APPORTIONMENTS OF ROCKFISH SECONDARY SPECIES IN THE CENTRAL GOA TO CATCHER VESSEL AND CATCHER/PROCESSOR COOPERATIVES

[Values are in metric tons]

Rockfish secondary species	Central GOA annual TAC	Catcher vessel cooperatives		Catcher/processor cooperatives	
		Percentage of TAC	Apportionment (mt)	Percentage of TAC	Apportionment (mt)
Pacific cod	45,990	3.81	1,752	N/A	N/A
Sablefish	4,232	6.78	287	3.51	149
Shortraker rockfish	397	N/A	N/A	40.00	159
Rougheye rockfish	643	N/A	N/A	58.87	379
Thornyhead rockfish	875	7.84	69	26.50	232

Halibut PSC Limits

Section 679.21(d) establishes annual halibut PSC limit apportionments to trawl and hook-and-line gear, and authorizes the establishment of apportionments for pot gear. Amendment 95 to the FMP (79 FR 9625, February 20, 2014) implemented measures establishing GOA halibut PSC limits in Federal regulations and reducing the halibut PSC limits in the GOA trawl and hook-and-line

groundfish fisheries. These reductions are incorporated into the halibut PSC limits that are proposed by this action. For most gear and operational types, the halibut PSC limit reductions are phased-in over 3 years, beginning in 2014 and ending in 2016.

In 2015, the trawl halibut PSC limit was reduced by 12 percent from the 2013 limit. Under Amendment 95 and § 679.21(d)(3)(i), the initial trawl halibut PSC limit is reduced by an additional 3 percent in 2016. This results in a total reduction of 15 percent in 2016 as compared to the 2013 halibut PSC limit. The reduced PSC limit will remain in effect each year thereafter.

In addition, under Amendment 95 and § 679.21(d)(2)(iv), the initial hook-and-line PSC for the other hook and-line CV sector was reduced 7 percent in 2014 and an additional 5-percent in 2015. This action implements an additional 3-percent reduction in 2016 for a total reduction of 15 percent from the 2013 limit. The PSC limit for the hook-and-line C/P sector was reduced by 7 percent in 2014 and thereafter.

In October 2015, the Council recommended halibut PSC limits that reflect the reductions implemented under Amendment 95 of 1,706 mt for trawl gear, 256 mt for hook-and-line gear, and 9 mt for the demersal shelf rockfish (DSR) fishery in the SEO District for the 2016 groundfish fisheries.

The DSR fishery in the SEO District is defined at § 679.21(d)(2)(ii)(A). This fishery is apportioned 9 mt of the halibut PSC limit in recognition of its small-scale harvests of groundfish. NMFS estimates low halibut bycatch in the DSR fishery because (1) the duration of the DSR fisheries and the gear soak times are short, (2) the DSR fishery occurs in the winter when less overlap occurs in the distribution of DSR and halibut, and (3) the directed commercial DSR fishery has a low DSR TAC. The Alaska Department of Fish and Game sets the commercial GHL for the DSR fishery after deducting (1) estimates of DSR incidental catch in all fisheries (including halibut and subsistence) and (2) the allocation to the DSR sport fish fishery. Of the 225 mt TAC for DSR in 2015, 83 mt were available for the DSR commercial directed fishery, of which 36 mt were harvested.

The FMP authorizes the Council to exempt specific gear from the halibut PSC limits. NMFS, after consultation with the Council, proposes to exempt pot gear, jig gear, and the sablefish IFQ hook-and-line gear fishery categories from the non-trawl halibut PSC limit for 2016 and 2017. The Council recommended, and NMFS is proposing, these exemptions because (1) pot gear fisheries have low annual halibut bycatch mortality, (2) IFQ program regulations prohibit discard of halibut if any halibut IFQ permit holder on board a CV holds unused halibut IFQ (§ 679.7(f)(11)), (3) sablefish IFQ fishermen typically hold halibut IFQ permits and are therefore required to retain the halibut they catch while fishing sablefish IFQ, and (4) NMFS estimates negligible halibut mortality for the jig gear fisheries. NMFS estimates halibut mortality is negligible in the jig gear fisheries given the small amount of groundfish harvested by jig gear, the selective nature of jig gear, and the high survival rates of halibut caught and released with jig gear.

The best available information on estimated halibut bycatch consists of data collected by fisheries observers during 2015. The calculated halibut bycatch mortality through October 31, 2015, is 1,324 mt for trawl gear and 185 mt for hook-and-line gear for a total halibut mortality of 1,509 mt. This halibut mortality was calculated using groundfish and halibut catch data from the NMFS Alaska Region's catch accounting system. This account system contains historical and recent catch information compiled from each Alaska groundfish fishery.

Section 679.21(d)(4)(i) and (ii) authorizes NMFS to seasonally apportion the halibut PSC limits after consultation with the Council. The FMP and regulations require that the Council and NMFS consider the following information in seasonally apportioning halibut PSC limits: (1) Seasonal distribution of halibut, (2) seasonal distribution of target groundfish species relative to halibut distribution, (3) expected halibut bycatch needs on a seasonal basis relative to changes in halibut biomass and expected catch of target groundfish species, (4) expected bycatch rates on a seasonal basis, (5) expected changes in directed groundfish fishing seasons, (6) expected actual start of fishing effort, and (7) economic effects of establishing seasonal halibut allocations on segments of the target groundfish industry. Based on public comment and the information presented in the final 2015 SAFE report, the Council may recommend or NMFS may make changes to the seasonal, gear-type, or fishery category apportionments of halibut PSC limits for the final 2016 and 2017 harvest specifications.

The final 2015 and 2016 harvest specifications (80 FR 10250, February 26, 2015) summarized the Council's and NMFS' findings with respect to halibut PSC for each of these FMP considerations. The Council's and NMFS' findings for 2016 are unchanged from 2015. Table 9 lists the proposed 2016 and 2017 Pacific halibut PSC limits, allowances, and apportionments. The halibut PSC limits in these tables reflect the halibut PSC reductions implemented in accordance with Amendment 95 (79 FR 9625, February 20, 2014) and § 679.21(d)(3)(i). Sections 679.21(d)(4)(iii) and (iv) specify that any underages or overages of a seasonal apportionment of a PSC limit will be deducted from or added to the next respective seasonal apportionment within the fishing year.

TABLE 9—PROPOSED 2016 AND 2017 PACIFIC HALIBUT PSC LIMITS, ALLOWANCES, AND APPORTIONMENTS

[Values are in metric tons]

Trawl gear			Hook-and-line gear[1]				
			Other than DSR			DSR	
Season	Percent	Amount	Season	Percent	Amount	Season	Amount
January 20–April 1	27.5	469	January 1–June 10 ..	86	220	January 1–December 31.	9
April 1–July 1	20	341	June 10–September 1.	2	5	.....	.....
July 1–September 1 ..	30	512	September 1–December 31.	12	31	.....	.....
September 1–October 1.	7.5	128	.....	.....	.....	.....	.....

TABLE 9—PROPOSED 2016 AND 2017 PACIFIC HALIBUT PSC LIMITS, ALLOWANCES, AND APPORTIONMENTS—Continued

[Values are in metric tons]

Trawl gear			Hook-and-line gear[1]				
Season	Percent	Amount	Other than DSR			DSR	
			Season	Percent	Amount	Season	Amount
October 1–December 31.	15	256	.....	.....	.....	.....	.....
Total	.....	1,706	.....	.....	256	.....	9

[1] The Pacific halibut PSC limit for hook-and-line gear is allocated to the demersal shelf rockfish (DSR) fishery and fisheries other than DSR. The hook-and-line IFQ sablefish fishery is exempt from halibut PSC limits, as are pot and jig gear for all groundfish fisheries.

Section 679.21(d)(3)(ii) authorizes further apportionment of the trawl halibut PSC limit as bycatch allowances to trawl fishery categories. The annual apportionments are based on each category's proportional share of the anticipated halibut bycatch mortality during a fishing year and optimization of the total amount of groundfish harvest under the halibut PSC limit. The fishery categories for the trawl halibut PSC limits are (1) a deep-water species fishery, composed of sablefish, rockfish, deep-water flatfish, rex sole, and arrowtooth flounder; and (2) a shallow-water species fishery, composed of pollock, Pacific cod, shallow-water flatfish, flathead sole, Atka mackerel, skates and ''other species'' (sculpins, sharks, squids, and octopuses) (§ 679.21(d)(3)(iii)).

Table 10 lists the proposed 2016 and 2017 seasonal apportionments of trawl halibut PSC limits between the trawl gear deep-water and the shallow-water species fisheries. These limits proportionately incorporate the halibut PSC limit reductions implemented in accordance with Amendment 95 (79 FR 9625, February 20, 2014) and § 679.21(d)(3).

Table 28d to 50 CFR part 679 specifies the amount of the trawl halibut PSC limit that is assigned to the CV and C/P sectors that are participating in the Central GOA Rockfish Program. This includes 117 mt of halibut PSC limit to the CV sector and 74 mt of halibut PSC limit to the C/P sector. These amounts are allocated from the trawl deep-water species fishery's halibut PSC third seasonal apportionment.

Section 679.21(d)(4)(iii)(B) limits the amount of the halibut PSC limit allocated to Rockfish Program participants that could be re-apportioned to the general GOA trawl fisheries to no more than 55 percent of the unused annual halibut PSC apportioned to Rockfish Program participants. The remainder of the unused Rockfish Program halibut PSC limit is unavailable for use by vessels directed fishing with trawl gear for the remainder of the fishing year.

TABLE 10—PROPOSED 2016 AND 2017 SEASONAL APPORTIONMENTS OF THE PACIFIC HALIBUT PSC LIMIT APPORTIONED BETWEEN THE TRAWL GEAR SHALLOW-WATER AND DEEP-WATER SPECIES FISHERIES

[Values are in metric tons]

Season	Shallow-water	Deep-water[1]	Total
January 20–April 1	384	85	469
April 1–July 1	85	256	341
July 1–September 1	171	341	512
September 1–October 1	128	Any remainder	128
Subtotal, January 20–October 1	768	682	1,450
October 1–December 31[2]	.....	.....	256
Total	.....	.....	1,706

[1] Vessels participating in cooperatives in the Rockfish Program will receive 191 mt of the third season (July 1 through September 1) deep-water species fishery halibut PSC apportionment.

[2] There is no apportionment between trawl shallow-water and deep-water species fisheries during the fifth season (October 1 through December 31).

Section 679.21(d)(2) requires that the ''other hook-and-line fishery'' halibut PSC apportionment to vessels using hook-and-line gear must be divided between CVs and C/Ps. NMFS must calculate the halibut PSC limit apportionments for the entire GOA to hook-and-line CVs and C/Ps in accordance with § 679.21(d)(2)(iii) in conjunction with these harvest specifications. A comprehensive description and example of the calculations necessary to apportion the ''other hook-and-line fishery'' halibut PSC limit between the hook-and-line CV and C/P sectors were included in the proposed rule to implement Amendment 83 to the FMP (76 FR 44700, July 26, 2011) and is not repeated here.

For 2016 and 2017, NMFS proposes annual halibut PSC limit apportionments of 140 mt and 116 mt to the hook-and-line CV and hook-and-line C/P sectors, respectively. The 2016 and 2017 annual halibut PSC limits are divided into three seasonal apportionments, using seasonal percentages of 86 percent, 2 percent, and 12 percent. Table 11 lists the proposed 2016 and 2017 annual halibut PSC limits and seasonal apportionments between the hook-and-line CV and hook-and-line C/P sectors in the GOA.

No later than November 1 of each year, NMFS calculates the projected

unused amount of halibut PSC limit by either of the hook-and-line sectors for the remainder of the year. The projected unused amount of halibut PSC limit is made available to the other hook-and-line sector for the remainder of that fishing year if NMFS determines that an additional amount of halibut PSC limit is necessary for that sector to continue its directed fishing operations (§ 679.21(d)(2)(iii)(C)).

TABLE 11—PROPOSED 2016 AND 2017 APPORTIONMENTS OF THE "OTHER HOOK-AND-LINE FISHERIES" HALIBUT PSC ALLOWANCE BETWEEN THE HOOK-AND-LINE GEAR CATCHER VESSEL AND CATCHER/PROCESSOR SECTORS

[Values are in metric tons]

"Other than DSR" allowance	Hook-and- line sector	Sector annual amount	Season	Seasonal percentage	Sector seasonal amount
256	Catcher Vessel	140	January 1–June 10	86	120
			June 10–September 1	2	3
			September 1–December 31	12	17
	Catcher/Processor	116	January 1–June 10	86	100
			June 10–September 1	2	2
			September 1–December 31	12	14

Halibut Discard Mortality Rates

To monitor halibut bycatch mortality allowances and apportionments, the Regional Administrator uses observed halibut incidental catch rates, discard mortality rates (DMRs), and estimates of groundfish catch to project when a fishery's halibut bycatch mortality allowance or seasonal apportionment is reached. The DMRs are based on the best information available, including information contained in the annual SAFE report.

NMFS proposes the Council's recommendation that the halibut DMRs developed and recommended by the International Pacific Halibut Commission (IPHC) for the 2016 through 2017 GOA groundfish fisheries be used to monitor the proposed 2016 and 2017 halibut bycatch mortality allowances (see Tables 9 through 11). The IPHC developed the DMRs for the 2016 through 2017 GOA groundfish fisheries using the 10-year mean DMRs for those fisheries. Long-term average DMRs were not available for some fisheries, so rates from the most recent years were used. For the skate, sculpin, shark, squid, and octopus fisheries, where not enough mortality data are available, the mortality rate of halibut caught in the Pacific cod fishery for that gear type was recommended as a default rate. The IPHC will analyze observer data annually and recommend changes to the DMRs when a fishery DMR shows large variation from the mean. A discussion of the DMRs and how the IPHC establishes them is available from the Council (see **ADDRESSES**). Any changes to the current DMRs will be incorporated into the final GOA harvest specifications. Table 12 lists the proposed 2016 and 2017 DMRs.

TABLE 12—PROPOSED 2016 AND 2017 HALIBUT DISCARD MORTALITY RATES FOR VESSELS FISHING IN THE GULF OF ALASKA

[Values are percent of halibut assumed to be dead]

Gear	Target fishery	Mortality rate (%)
Hook-and-line	Other fisheries [1]	10
	Skates	10
	Pacific cod	10
	Rockfish	9
Trawl	Arrowtooth flounder	76
	Deep-water flatfish	43
	Flathead sole	67
	Non-pelagic pollock	58
	Other fisheries	62
	Pacific cod	62
	Pelagic pollock	59
	Rex sole	71
	Rockfish	65
	Sablefish	59
	Shallow-water flatfish	66
Pot	Other fisheries	21
	Pacific cod	21

[1] Other fisheries includes targets for hook-and-line sablefish and all gear types for Atka mackerel, skates, sculpins, sharks, squids, and octopuses.

Chinook Salmon Prohibited Species Catch Limits

Amendment 93 to the FMP (77 FR 42629, July 20, 2012) established separate Chinook salmon PSC limits in the Western and Central GOA in the directed pollock fishery. These limits require NMFS to close the pollock directed fishery in the Western and Central regulatory areas of the GOA if the applicable limit is reached (§ 679.21(h)(6)). The annual Chinook salmon PSC limits in the pollock directed fishery of 6,684 salmon in the Western GOA and 18,316 salmon in the

Central GOA are set in § 679.21(h)(2)(i) and (ii). In addition, all salmon (regardless of species), taken in the pollock directed fisheries in the Western and Central GOA must be retained until an observer at the processing facility that takes delivery of the catch is provided an opportunity to count the number of salmon and to collect any scientific data or biological samples from the salmon (§ 679.21(h)(4)).

Amendment 97 to the FMP (79 FR 71350, December 2, 2014) established an initial annual PSC limit of 7,500 Chinook salmon for the non-pollock groundfish fisheries. This limit is apportioned among three sectors: 3,600 Chinook salmon to trawl C/Ps; 1,200 Chinook salmon to trawl CVs participating in the Rockfish Program; and 2,700 Chinook salmon to trawl CVs not participating in the Rockfish Program that are fishing for groundfish species other than pollock (§ 679.21(i)(3)). NMFS will monitor the Chinook salmon PSC in the non-pollock GOA groundfish fisheries and close an applicable sector if it reaches its Chinook salmon PSC limit.

The Chinook salmon PSC limit for two sectors, trawl C/Ps and trawl CVs not participating in the Rockfish Program, may be increased in subsequent years based on the performance of these two sectors and their ability to minimize their use of their respective Chinook salmon PSC limits. If either or both of these two sectors limits its use of Chinook salmon PSC to a certain threshold amount in 2015, that sector will receive an incremental increase to its 2016 Chinook salmon PSC limit (§ 679.21(i)(3)). NMFS will evaluate the annual Chinook salmon PSC by trawl C/Ps and non-Rockfish Program CVs when the 2015 fishing year is complete to determine whether to increase the Chinook salmon PSC limits for these two sectors. Based on preliminary 2015 Chinook salmon PSC data, the trawl C/P sector will receive an incremental increase of its Chinook salmon PSC limit, whereas the non-Rockfish Program CV sector will not. This evaluation will be completed in conjunction with the final 2016 and 2017 harvest specifications.

American Fisheries Act (AFA) Catcher/Processor and Catcher Vessel Groundfish Sideboard Limits

Section 679.64 establishes groundfish harvesting and processing sideboard limits on AFA C/Ps and CVs in the GOA. These sideboard limits are necessary to protect the interests of fishermen and processors who do not directly benefit from the AFA from those fishermen and processors who receive exclusive harvesting and processing privileges under the AFA. Section 679.7(k)(1)(ii) prohibits listed AFA C/Ps from harvesting any species of fish in the GOA. Additionally, § 679.7(k)(1)(iv) prohibits listed AFA C/Ps from processing any pollock harvested in a directed pollock fishery in the GOA and any groundfish harvested in Statistical Area 630 of the GOA.

AFA CVs that are less than 125 ft (38.1 meters) length overall, have annual landings of pollock in the Bering Sea and Aleutian Islands of less than 5,100 mt, and have made at least 40 landings of GOA groundfish from 1995 through 1997 are exempt from GOA sideboard limits under § 679.64(b)(2)(ii). Sideboard limits for non-exempt AFA CVs operating in the GOA are based on their traditional harvest levels of TAC in groundfish fisheries covered by the FMP. Section 679.64(b)(3)(iii) establishes the groundfish sideboard limitations in the GOA based on the retained catch of non-exempt AFA CVs of each sideboard species from 1995 through 1997 divided by the TAC for that species over the same period.

Table 13 lists the proposed 2016 and 2017 groundfish sideboard limits for non-exempt AFA CVs. NMFS will deduct all targeted or incidental catch of sideboard species made by non-exempt AFA CVs from the sideboard limits listed in Table 16.

TABLE 13—PROPOSED 2016 AND 2017 GOA NON-EXEMPT AMERICAN FISHERIES ACT CATCHER VESSEL (CV) GROUNDFISH HARVEST SIDEBOARD LIMITS

[Values are rounded to the nearest metric ton]

Species	Apportionments by season/gear	Area/component	Ratio of 1995–1997 non-exempt AFA CV catch to 1995–1997 TAC	Proposed 2016 and 2017 TACs [3]	Proposed 2016 and 2017 non-exempt AFA CV sideboard limit
Pollock	A Season, January 20–March 10.	Shumagin (610)	0.6047	4,760	2,879
		Chirikof (620)	0.1167	39,992	4,667
		Kodiak (630)	0.2028	14,839	3,009
	B Season, March 10–May 31	Shumagin (610)	0.6047	4,760	2,879
		Chirikof (620)	0.1167	49,586	5,787
		Kodiak (630)	0.2028	5,245	1,064
	C Season, August 25–October 1.	Shumagin (610)	0.6047	15,975	9,660
		Chirikof (620)	0.1167	19,179	2,238
		Kodiak (630)	0.2028	24,437	4,956
	D Season, October 1–November 1.	Shumagin (610)	0.6047	15,975	9,660
		Chirikof (620)	0.1167	19,179	2,238
		Kodiak (630)	0.2028	24,437	4,956
	Annual	WYK (640)	0.3495	6,187	2,162
		SEO (650)	0.3495	12,625	4,412
Pacific cod	A Season [1], January 1–June 10.	W	0.1331	16,255	2,164
		C	0.0692	27,594	1,910
	B Season [2], September 1–December 31.	W	0.1331	10,837	1,442
		C	0.0692	18,396	1,273
	Annual	E inshore	0.0079	1,909	15
		E offshore	0.0078	212	2
Sablefish	Annual, trawl gear	W	0.0000	268	0
		C	0.0642	846	54
		E	0.0433	199	9

TABLE 13—PROPOSED 2016 AND 2017 GOA NON-EXEMPT AMERICAN FISHERIES ACT CATCHER VESSEL (CV) GROUNDFISH HARVEST SIDEBOARD LIMITS—Continued

[Values are rounded to the nearest metric ton]

Species	Apportionments by season/gear	Area/component	Ratio of 1995–1997 non-exempt AFA CV catch to 1995–1997 TAC	Proposed 2016 and 2017 TACs [3]	Proposed 2016 and 2017 non-exempt AFA CV sideboard limit
Flatfish, shallow-water	Annual	W	0.0156	13,250	207
		C	0.0587	17,114	1,005
		E	0.0126	2,513	32
Flatfish, deep-water	Annual	W	0.0000	299	0
		C	0.0647	3,645	236
		E	0.0128	9,233	118
Rex sole	Annual	W	0.0007	1,234	1
		C	0.0384	5,707	219
		E	0.0029	2,038	6
Arrowtooth flounder	Annual	W	0.0021	14,500	30
		C	0.0280	75,000	2,100
		E	0.0002	13,800	3
Flathead sole	Annual	W	0.0036	8,650	31
		C	0.0213	15,400	328
		E	0.0009	3,709	3
Pacific ocean perch	Annual	W	0.0023	2,358	5
		C	0.0748	16,184	1,211
		E	0.0466	2,894	135
Northern rockfish	Annual	W	0.0003	1,158	0
		C	0.0277	3,563	99
Shortraker rockfish	Annual	W	0.0000	92	0
		C	0.0218	397	9
		E	0.0110	834	9
Dusky Rockfish	Annual	W	0.0001	273	0
		C	0.0000	3,077	0
		E	0.0067	1,361	9
Rougheye rockfish	Annual	W	0.0000	117	0
		C	0.0237	643	15
		E	0.0124	382	5
Demersal shelf rockfish	Annual	SEO	0.0020	225	0
Thornyhead rockfish	Annual	W	0.0280	235	7
		C	0.0280	875	25
		E	0.0280	731	20
Other Rockfish	Annual	W	0.0034	n/a	n/a
		C	0.1699	1,031	175
		E	0.0000	780	0
Atka mackerel	Annual	Gulfwide	0.0309	2,000	62
Big skates	Annual	W	0.0063	731	5
		C	0.0063	1,257	8
		E	0.0063	1,267	8
Longnose skates	Annual	W	0.0063	152	1
		C	0.0063	2,090	13
		E	0.0063	976	6
Other skates	Annual	Gulfwide	0.0063	2,235	14
Squids	Annual	Gulfwide	0.0063	5,569	35
Sharks	Annual	Gulfwide	0.0063	5,989	38
Octopuses	Annual	Gulfwide	0.0063	1,148	7
Sculpins	Annual	Gulfwide	0.0063	1,507	9

[1] The Pacific cod A season for trawl gear does not open until January 20.
[2] The Pacific cod B season for trawl gear closes November 1.
[3] The Western and Central GOA area apportionments of pollock are considered ACLs.

Non-Exempt AFA Catcher Vessel Halibut PSC Limits

The halibut PSC sideboard limits for non-exempt AFA CVs in the GOA are based on the aggregate retained groundfish catch by non-exempt AFA CVs in each PSC target category from 1995 through 1997 divided by the retained catch of all vessels in that fishery from 1995 through 1997 (§ 679.64(b)(4)). Table 14 lists the proposed 2016 and 2017 non-exempt AFA CV halibut PSC limits for vessels using trawl gear in the GOA. The proposed 2016 and 2017 seasonal apportionments of trawl halibut PSC limits between the deep-water and shallow-water species fisheries categories proportionately incorporate reductions made to the annual trawl halibut PSC limits and associated seasonal apportionments (see Table 10).

TABLE 14—PROPOSED 2016 AND 2017 NON-EXEMPT AMERICAN FISHERIES ACT CATCHER VESSEL HALIBUT PROHIBITED SPECIES CATCH (PSC) LIMITS FOR VESSELS USING TRAWL GEAR IN THE GOA

[PSC limits are rounded to the nearest whole metric ton]

Season	Season dates	Target fishery	Ratio of 1995–1997 non-exempt AFA CV retained catch to total retained catch	Proposed 2016 and 2017 PSC limit	Proposed 2016 and 2017 non-exempt AFA CV PSC limit
1	January 20–April 1	shallow-water	0.340	384	131
		deep-water	0.070	85	6
2	April 1–July 1	shallow-water	0.340	85	29
		deep-water	0.070	256	18
3	July 1–September 1	shallow-water	0.340	171	58
		deep-water	0.070	341	24
4	September 1–October 1	shallow-water	0.340	128	44
		deep-water	0.070	0	0
5	October 1–December 31	all targets	0.205	256	52
Total				1,706	361

Non-AFA Crab Vessel Groundfish Sideboard Limits

Section 680.22 establishes groundfish catch limits for vessels with a history of participation in the Bering Sea snow crab fishery to prevent these vessels from using the increased flexibility provided by the Crab Rationalization Program to expand their level of participation in the GOA groundfish fisheries. Sideboard limits restrict these vessels' catch to their collective historical landings in each GOA groundfish fishery (except the fixed-gear sablefish fishery). Sideboard limits also apply to landings made using an LLP license derived from the history of a restricted vessel, even if that LLP license is used on another vessel.

The basis for these sideboard limits is described in detail in the final rules implementing the major provisions of the Crab Rationalization Program, including Amendments 18 and 19 to the Fishery Management Plan for Bering Sea/Aleutian Islands King and Tanner Crabs (Crab FMP) (70 FR 10174, March 2, 2005), Amendment 34 to the Crab FMP (76 FR 35772, June 20, 2011), and Amendment 83 to the GOA FMP (76 FR 74670, December 1, 2011).

Table 15 lists the proposed 2016 and 2017 groundfish sideboard limitations for non-AFA crab vessels. All targeted or incidental catch of sideboard species made by non-AFA crab vessels or associated LLP licenses will be deducted from these sideboard limits.

TABLE 15—PROPOSED 2016 AND 2017 GOA NON-AMERICAN FISHERIES ACT CRAB VESSEL GROUNDFISH HARVEST SIDEBOARD LIMITS

[Values are rounded to the nearest metric ton]

Species	Season/gear	Area/component/gear	Ratio of 1996–2000 non-AFA crab vessel catch to 1996–2000 total harvest	Proposed 2016 and 2017 TACs	Proposed 2016 and 2017 non-AFA crab vessel sideboard limit
Pollock	A Season, January 20–March 10.	Shumagin (610)	0.0098	4,760	47
		Chirikof (620)	0.0031	39,992	124
		Kodiak (630)	0.0002	14,839	3
	B Season, March 10–May 31	Shumagin (610)	0.0098	4,760	47
		Chirikof (620)	0.0031	49,586	154
		Kodiak (630)	0.0002	5,245	1
	C Season, August 25–October 1.	Shumagin (610)	0.0098	15,975	157
		Chirikof (620)	0.0031	19,179	59
		Kodiak (630)	0.0002	24,437	5
	D Season, October 1–November 1.	Shumagin (610)	0.0098	15,975	157
		Chirikof (620)	0.0031	19,179	59
		Kodiak (630)	0.0002	24,437	5
	Annual	WYK (640)	0.0000	6,187	0
		SEO (650)	0.0000	12,625	0
Pacific cod	A Season,[1] January 1–June 10.	W Jig CV	0.0000	16,255	0
		W Hook-and-line CV	0.0004	16,255	7
		W Pot CV	0.0997	16,255	1,621
		W Pot C/P	0.0078	16,255	127
		W Trawl CV	0.0007	16,255	11
		C Jig CV	0.0000	27,594	0
		C Hook-and-line CV	0.0001	27,594	3

TABLE 15—PROPOSED 2016 AND 2017 GOA NON-AMERICAN FISHERIES ACT CRAB VESSEL GROUNDFISH HARVEST SIDEBOARD LIMITS—Continued

[Values are rounded to the nearest metric ton]

Species	Season/gear	Area/component/gear	Ratio of 1996–2000 non-AFA crab vessel catch to 1996–2000 total harvest	Proposed 2016 and 2017 TACs	Proposed 2016 and 2017 non-AFA crab vessel sideboard limit
		C Pot CV	0.0474	27,594	1,308
		C Pot C/P	0.0136	27,594	375
		C Trawl CV	0.0012	27,594	33
	B Season,[2] September 1—December 31.	W Jig CV	0.0000	10,837	0
		W Hook-and-line CV	0.0004	10,837	4
		W Pot CV	0.0997	10,837	1,080
		W Pot C/P	0.0078	10,837	85
		W Trawl CV	0.0007	10,837	8
		C Jig CV	0.0000	18,396	0
		C Hook-and-line CV	0.0001	18,396	2
		C Pot CV	0.0474	18,396	872
		C Pot C/P	0.0136	18,396	250
		C Trawl CV	0.0012	18,396	22
	Annual	E inshore	0.0110	1,909	21
		E offshore	0.0000	212	0
Sablefish	Annual, trawl gear	W	0.0000	268	0
		C	0.0000	846	0
		E	0.0000	199	0
Flatfish, shallow-water	Annual	W	0.0059	13,250	78
		C	0.0001	17,114	2
		E	0.0000	2,513	0
Flatfish, deep-water	Annual	W	0.0035	299	1
		C	0.0000	3,645	0
		E	0.0000	9,233	0
Rex sole	Annual	W	0.0000	1,234	0
		C	0.0000	5,707	0
		E	0.0000	2,038	0
Arrowtooth flounder	Annual	W	0.0004	14,500	6
		C	0.0001	75,000	8
		E	0.0000	13,800	0
Flathead sole	Annual	W	0.0002	8,650	2
		C	0.0004	15,400	6
		E	0.0000	3,709	0
Pacific ocean perch	Annual	W	0.0000	2,358	0
		C	0.0000	16,184	0
		E	0.0000	2,894	0
Northern rockfish	Annual	W	0.0005	1,158	1
		C	0.0000	3,563	0
Shortraker rockfish	Annual	W	0.0013	92	0
		C	0.0012	397	0
		E	0.0009	834	1
Dusky rockfish	Annual	W	0.0017	273	0
		C	0.0000	3,077	0
		E	0.0000	1,361	0
Rougheye rockfish	Annual	W	0.0067	117	1
		C	0.0047	643	3
		E	0.0008	382	0
Demersal shelf rockfish	Annual	SEO	0.0000	225	0
Thornyhead rockfish	Annual	W	0.0047	235	1
		C	0.0066	875	6
		E	0.0045	731	3
Other rockfish	Annual	W	0.0035	.....	.....
		C	0.0033	1,031	3
		E	0.0000	780	0
Atka mackerel	Annual	Gulfwide	0.0000	2,000	0
Big skate	Annual	W	0.0392	731	29
		C	0.0159	1,257	20
		E	0.0000	1,267	0
Longnose skate	Annual	W	0.0392	152	6
		C	0.0159	2,090	33
		E	0.0000	976	0
Other skates	Annual	Gulfwide	0.0176	2,235	39
Sculpins	Annual	Gulfwide	0.0176	5,569	98
Sharks	Annual	Gulfwide	0.0176	5,989	105

TABLE 15—PROPOSED 2016 AND 2017 GOA NON-AMERICAN FISHERIES ACT CRAB VESSEL GROUNDFISH HARVEST SIDEBOARD LIMITS—Continued

[Values are rounded to the nearest metric ton]

Species	Season/gear	Area/component/gear	Ratio of 1996–2000 non-AFA crab vessel catch to 1996–2000 total harvest	Proposed 2016 and 2017 TACs	Proposed 2016 and 2017 non-AFA crab vessel sideboard limit
Squids	Annual	Gulfwide	0.0176	1,148	20
Octopuses	Annual	Gulfwide	0.0176	1,507	27

[1] The Pacific cod A season for trawl gear does not open until January 20.
[2] The Pacific cod B season for trawl gear closes November 1.

Rockfish Program Groundfish Sideboard and Halibut PSC Limitations

The Rockfish Program establishes three classes of sideboard provisions: CV groundfish sideboard restrictions, C/P rockfish sideboard restrictions, and C/P opt-out vessel sideboard restrictions. These sideboards are intended to limit the ability of rockfish harvesters to expand into other fisheries.

CVs participating in the Rockfish Program may not participate in directed fishing for dusky rockfish, northern rockfish, and Pacific ocean perch in the Western GOA and West Yakutat Districts from July 1 through July 31. Also, CVs may not participate in directed fishing for arrowtooth flounder, deep-water flatfish, and rex sole in the GOA from July 1 through July 31 (§ 679.82(d)).

C/Ps participating in Rockfish Program cooperatives are restricted by rockfish and halibut PSC sideboard limits. These C/Ps are prohibited from directed fishing for northern rockfish, Pacific ocean perch, and dusky rockfish in the Western GOA and West Yakutat District from July 1 through July 31. Holders of C/P-designated LLP licenses that opt out of participating in a rockfish cooperative will receive the portion of each sideboard limit that is not assigned to rockfish cooperatives. Table 16 lists the proposed 2016 and 2017 Rockfish Program C/P rockfish sideboard limits in the Western GOA and West Yakutat District. Due to confidentiality requirements associated with fisheries data, the sideboard limits for the West Yakutat District are not displayed.

TABLE 16—PROPOSED 2016 AND 2017 ROCKFISH PROGRAM HARVEST LIMITS FOR THE WESTERN GOA AND WEST YAKUTAT DISTRICT BY FISHERY FOR THE CATCHER/PROCESSOR (C/P) SECTOR

[Values are rounded to the nearest metric ton]

Area	Fishery	C/P sector (% of TAC)	Proposed 2016 and 2017 TACs	Proposed 2016 and 2017 C/P limit
Western GOA	Dusky rockfish	72.3	273	197
	Pacific ocean perch	50.6	2,358	1,193
	Northern rockfish	74.3	1,158	860
West Yakutat District	Dusky rockfish	Confid.[1]	1,187	N/A
	Pacific ocean perch	Confid.[1]	2,055	N/A

[1] Not released due to confidentiality requirements associated with fish ticket data, as established by NMFS and the State of Alaska.

Under the Rockfish Program, the C/P sector is subject to halibut PSC sideboard limits for the trawl deep-water and shallow-water species fisheries from July 1 through July 31. No halibut PSC sideboard limits apply to the CV sector as vessels participating in a rockfish cooperative receive a portion of the annual halibut PSC limit. C/Ps that opt out of the Rockfish Program would be able to access that portion of the deep-water and shallow-water halibut PSC sideboard limit not assigned to C/P rockfish cooperatives. The sideboard provisions for C/Ps that elect to opt out of participating in a rockfish cooperative are described in § 679.82(c), (e), and (f). Sideboard limits are linked to the catch history of specific vessels that may choose to opt out. After March 1, NMFS will determine which C/Ps have opted-out of the Rockfish Program in 2016, and will know the ratios and amounts used to calculate opt-out sideboard ratios. NMFS will then calculate any applicable opt-out sideboard limits and post these limits on the Alaska Region Web site at *http://alaskafisheries.noaa.gov/sustainablefisheries/rockfish/.* Table 17 lists the 2016 and 2017 proposed Rockfish Program halibut PSC limits for the C/P sector. These proposed 2016 and 2017 halibut PSC limits proportionately incorporate reductions made to the annual trawl halibut PSC limits and associated seasonal apportionments (see Table 10).

TABLE 17—PROPOSED 2016 AND 2017 ROCKFISH PROGRAM HALIBUT MORTALITY LIMITS FOR THE CATCHER/PROCESSOR SECTOR

[Values are rounded to the nearest metric ton]

Sector	Shallow-water species fishery halibut PSC sideboard ratio (percent)	Deep-water species fishery halibut PSC sideboard ratio (percent)	Annual halibut mortality limit (mt)	Annual shallow-water species fishery halibut PSC sideboard limit (mt)	Annual deep-water species fishery halibut PSC sideboard limit (mt)
Catcher/processor	0.10	2.50	1,706	2	43

Amendment 80 Program Groundfish Sideboard and PSC Limits

Amendment 80 to the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (Amendment 80 Program) established a limited access privilege program for the non-AFA trawl C/P sector. The Amendment 80 Program established groundfish and halibut PSC limits for Amendment 80 Program participants to limit the ability of participants eligible for the Amendment 80 Program to expand their harvest efforts in the GOA.

Section 679.92 establishes groundfish harvesting sideboard limits on all Amendment 80 Program vessels, other than the F/V *Golden Fleece,* to amounts no greater than the limits shown in Table 37 to part 679. Under § 679.92(d), the F/V *Golden Fleece* is prohibited from directed fishing for pollock, Pacific cod, Pacific ocean perch, dusky rockfish, and northern rockfish in the GOA.

Groundfish sideboard limits for Amendment 80 Program vessels operating in the GOA are based on their average aggregate harvests from 1998 through 2004. Table 18 lists the proposed 2016 and 2017 sideboard limits for Amendment 80 Program vessels. NMFS will deduct all targeted or incidental catch of sideboard species made by Amendment 80 Program vessels from the sideboard limits in Table 18.

TABLE 18—PROPOSED 2016 AND 2017 GOA GROUNDFISH SIDEBOARD LIMITS FOR AMENDMENT 80 PROGRAM VESSELS

[Values are rounded to the nearest metric ton]

Species	Season	Area	Ratio of Amendment 80 sector vessels 1998–2004 catch to TAC	Proposed 2016 and 2017 TAC (mt)	Proposed 2016 and 2017 Amendment 80 vessel sideboard limits (mt)
Pollock	A Season, January 20–February 25.	Shumagin (610)	0.003	4,760	14
		Chirikof (620)	0.002	39,992	80
		Kodiak (630)	0.002	14,839	30
	B Season, March 10–May 31	Shumagin (610)	0.003	4,760	14
		Chirikof (620)	0.002	49,586	99
		Kodiak (630)	0.002	5,245	10
	C Season, August 25–September 15.	Shumagin (610)	0.003	15,975	48
		Chirikof (620)	0.002	19,179	38
		Kodiak (630)	0.002	24,437	49
	D Season, October 1–November 1.	Shumagin (610)	0.003	15,975	48
		Chirikof (620)	0.002	19,179	38
		Kodiak (630)	0.002	24,437	49
	Annual	WYK (640)	0.002	6,187	12
Pacific cod	A Season [1], January 1–June 10.	W	0.020	16,255	325
		C	0.044	27,594	1,214
	B Season [2], September 1–December 31.	W	0.020	10,837	217
		C	0.044	18,396	809
	Annual	WYK	0.034	2,121	72
Pacific ocean perch	Annual	W	0.994	2,358	2,344
		WYK	0.961	2,055	1,975
Northern rockfish	Annual	W	1.000	1,158	1,158
Dusky rockfish	Annual	W	0.764	273	209
		WYK	0.896	1,187	1,064

[1] The Pacific cod A season for trawl gear does not open until January 20.
[2] The Pacific cod B season for trawl gear closes November 1.

The halibut PSC sideboard limits for Amendment 80 Program vessels in the GOA are based on the historic use of halibut PSC by Amendment 80 Program vessels in each PSC target category from 1998 through 2004. These values are

slightly lower than the average historic use to accommodate two factors: Allocation of halibut PSC cooperative quota under the Rockfish Program and the exemption of the F/V *Golden Fleece* from this restriction (§ 679.92(b)(2)). Table 19 lists the proposed 2016 and 2017 halibut PSC sideboard limits for Amendment 80 Program vessels. These tables incorporate the maximum percentages of the halibut PSC sideboard limits that may be used by Amendment 80 Program vessels, as contained in Table 38 to 50 CFR part 679. These proposed 2016 and 2017 PSC sideboard limits proportionately incorporate the reductions made to the annual trawl halibut PSC limits and associated seasonal apportionments (see Table 10).

TABLE 19—PROPOSED 2016 AND 2017 HALIBUT PSC SIDEBOARD LIMITS FOR AMENDMENT 80 PROGRAM VESSELS IN THE GOA

[Values are rounded to the nearest metric ton]

Season	Season dates	Fishery category	Historic Amendment 80 use of the annual halibut PSC limit (ratio)	Proposed 2016 annual PSC limit (mt)	Proposed 2016 Amendment 80 vessel PSC sideboard limit (mt)
1	January 20–April 1	shallow-water	0.0048	1,706	8
		deep-water	0.0115	1,706	20
2	April 1–July 1	shallow-water	0.0189	1,706	32
		deep-water	0.1072	1,706	183
3	July 1–September 1	shallow-water	0.0146	1,706	25
		deep-water	0.0521	1,706	89
4	September 1–October 1	shallow-water	0.0074	1,706	13
		deep-water	0.0014	1,706	2
5	October 1–December 31	shallow-water	0.0227	1,706	39
		deep-water	0.0371	1,706	63
Total					474

Classification

NMFS has determined that the proposed harvest specifications are consistent with the FMP and preliminarily determined that the proposed harvest specifications are consistent with the Magnuson-Stevens Act and other applicable laws, subject to further review after public comment.

This action is authorized under 50 CFR 679.20 and is exempt from review under Executive Orders 12866 and 13563.

NMFS prepared an EIS for this action and made it available to the public on January 12, 2007 (72 FR 1512). On February 13, 2007, NMFS issued the Record of Decision (ROD) for the Final EIS. A Supplemental Information Report (SIR) that assesses the need to prepare a Supplemental EIS is being prepared for the final action. Copies of the Final EIS, ROD, and SIR for this action are available from NMFS (see **ADDRESSES**). The Final EIS analyzes the environmental consequences of the proposed groundfish harvest specifications and alternative harvest strategies on resources in the action area. The Final EIS found no significant environmental consequences from the proposed action or its alternatives.

NMFS prepared an Initial Regulatory Flexibility Analysis (IRFA) as required by section 603 of the Regulatory Flexibility Act (RFA), analyzing the methodology for establishing the relevant TACs. The IRFA evaluated the impacts on small entities of alternative harvest strategies for the groundfish fisheries in the EEZ off Alaska. As set forth in the methodology, TACs are set to a level that fall within the range of ABCs recommended by the SSC; the sum of the TACs must achieve the OY specified in the FMP. While the specific numbers that the methodology produces may vary from year to year, the methodology itself remains constant.

A description of the proposed action, why it is being considered, and the legal basis for this proposed action are contained in the preamble above. A copy of the analysis is available from NMFS (see **ADDRESSES**). A summary of the IRFA follows.

The action under consideration is a harvest strategy to govern the catch of groundfish in the GOA. The preferred alternative is the existing harvest strategy in which TACs fall within the range of ABCs recommended by the SSC. This action is taken in accordance with the FMP prepared by the Council pursuant to the Magnuson-Stevens Act.

The entities directly regulated by this action are those that harvest groundfish in the EEZ of the GOA and in parallel fisheries within State of Alaska waters. These include entities operating CVs and C/Ps within the action area and entities receiving direct allocations of groundfish.

The Small Business Administration has established size standards for all major industry sectors in the United States. A business primarily involved in finfish harvesting is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual gross receipts not in excess of $20.5 million, for all its affiliated operations worldwide. Fishing vessels are considered small entities if their total annual gross receipts, from all their activities combined, are less than $20.5 million. The IRFA estimates the number of harvesting vessels that are considered small entities, but these estimates may overstate the number of small entities because (1) some vessels may also be active as tender vessels in the salmon fishery, fish in areas other than Alaska and the West Coast, or generate revenue from other non-fishing sources; and (2) all affiliations are not taken into account, especially if the vessel has affiliations not tracked in available data (*i.e.,* ownership of multiple vessel or affiliation with processors) and may be misclassified as a small entity.

The IRFA shows that, in 2014, there were 915 individual CVs with gross revenues less than or equal to $20.5 million. This estimate accounts for corporate affiliations among vessels, and for cooperative affiliations among fishing entities, since some of the

fishing vessels operating in the GOA are members of AFA inshore pollock cooperatives, GOA rockfish cooperatives, or BSAI Crab Rationalization Program cooperatives. Therefore, under the RFA, it is the aggregate gross receipts of all participating members of the cooperative that must meet the ''under $20.5 million'' threshold. Vessels that participate in these cooperatives are considered to be large entities within the meaning of the RFA. After accounting for membership in these cooperatives, there are an estimated 915 small CV entities remaining in the GOA groundfish sector. This latter group of vessels had average gross revenues that varied by gear type. Average gross revenues for hook-and-line CVs, pot gear vessels, and trawl gear vessels are estimated to be $400,000, $740,000, and $2.5 million, respectively. Revenue data for the four C/Ps considered to be small entities are confidential.

The preferred alternative (Alternative 2) was compared to four other alternatives. Alternative 1 would have set TACs to generate fishing rates equal to the maximum permissible ABC (if the full TAC were harvested), unless the sum of TACs exceeded the GOA OY, in which case harvests would be limited to the OY. Alternative 3 would have set TACs to produce fishing rates equal to the most recent 5-year average fishing rate. Alternative 4 would have set TACs to equal the lower limit of the GOA OY range. Alternative 5, the ''no action alternative,'' would have set TACs equal to zero.

The TACs associated with the preferred harvest strategy are those adopted by the Council in October 2015, as per Alternative 2. OFLs and ABCs for the species were based on recommendations prepared by the Council's GOA Plan Team in September 2015, and reviewed by the Council's SSC in October 2015. The Council based its TAC recommendations on those of its AP, which were consistent with the SSC's OFL and ABC recommendations.

Alternative 1 selects harvest rates that would allow fishermen to harvest stocks at the level of ABCs, unless total harvests were constrained by the upper bound of the GOA OY of 800,000 mt. As shown in Table 1 of the preamble, the sum of ABCs in 2016 and 2017 would be 731,049 mt, which falls below the upper bound of the OY range. The sum of TACs is 590,161 mt, which is less than the sum of ABCs. In this instance, Alternative 1 is consistent with the preferred alternative (Alternative 2), meets the objectives of that action, and has small entity impacts that are equivalent to the preferred alternative. In some instances, the selection of Alternative 1 would not reflect the practical implications that increased TACs (where the sum of TACs equals the sum of ABCs) for some species probably would not be fully harvested. This could be due to a lack of commercial or market interest in such species. Additionally, an underharvest of some TACs could result due to constraints such as the fixed, and therefore constraining, PSC limits associated with the harvest of the GOA groundfish species.

Alternative 3 selects harvest rates based on the most recent 5 years of harvest rates (for species in Tiers 1 through 3) or for the most recent 5 years of harvests (for species in Tiers 4 through 6). This alternative is inconsistent with the objectives of this action, the Council's preferred harvest strategy, because it does not take account of the most recent biological information for this fishery. NMFS annually conducts at-sea stock surveys for different species, as well as statistical modeling, to estimate stock sizes and permissible harvest levels. Actual harvest rates or harvest amounts are a component of these estimates, but in and of themselves may not accurately portray stock sizes and conditions. Harvest rates are listed for each species category for each year in the SAFE report (see **ADDRESSES**).

Alternative 4 would lead to significantly lower harvests of all species and reduce the TACs from the upper end of the OY range in the GOA, to its lower end of 116,000 mt. Overall, this would reduce 2016 TACs by about 80 percent and would lead to significant reductions in harvests of species harvested by small entities. While reductions of this size would be associated with offsetting price increases, the size of these increases is very uncertain. There are close substitutes for GOA groundfish species available in significant quantities from the Bering Sea and Aleutian Islands management area. While production declines in the GOA would undoubtedly be associated with significant price increases in the GOA, these increases would still be constrained by production of substitutes, and are very unlikely to offset revenue declines from smaller production. Thus, this alternative would have a detrimental impact on small entities.

Alternative 5, which sets all harvests equal to zero, would have a significant adverse economic impact on small entities and would be contrary to obligations to achieve OY on a continuing basis, as mandated by the Magnuson-Stevens Act. Under Alternative 5, all 915 individual CVs impacted by this rule would have gross revenues of $0. Additionally, the four small C/Ps impacted by this rule also would have gross revenues of $0.

The proposed harvest specifications (Alternative 2) extend the current 2016 OFLs, ABCs, and TACs to 2016 and 2017. As noted in the IRFA, the Council may modify these OFLs, ABCs, and TACs in December 2015, when it reviews the November 2015 SAFE report from its Groundfish Plan Team, and the December 2015 Council meeting reports of its SSC and AP. Because 2016 TACs in the proposed 2016 and 2017 harvest specifications are unchanged from the 2016 TACs, NMFS does not expect adverse impacts on small entities. Also, NMFS does not expect any changes made by the Council in December 2015 to have significant adverse impacts on small entities.

This action does not modify recordkeeping or reporting requirements, or duplicate, overlap, or conflict with any Federal rules.

Adverse impacts on marine mammals or endangered species resulting from fishing activities conducted under this rule are discussed in the Final EIS and its accompanying annual SIRs (see **ADDRESSES**).

Authority: 16 U.S.C. 773 *et seq.;* 16 U.S.C. 1540(f); 16 U.S.C. 1801 *et seq.;* 16 U.S.C. 3631 *et seq.;* Pub. L. 105–277; Pub. L. 106–31; Pub. L. 106–554; Pub. L. 108–199; Pub. L. 108–447; Pub. L. 109–241; Pub. L. 109–479.

Dated: December 3, 2015.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 150916863–5863–01]

RIN 0648–XE202

Fisheries of the Exclusive Economic Zone Off Alaska; Bering Sea and Aleutian Islands; 2016 and 2017 Harvest Specifications for Groundfish

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

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes 2016 and 2017 harvest specifications, apportionments, and prohibited species catch allowances for the groundfish fisheries of the Bering Sea and Aleutian Islands (BSAI) management area. This action is necessary to establish harvest limits for groundfish during the 2016 and 2017 fishing years, and to accomplish the goals and objectives of the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area. The intended effect of this action is to conserve and manage the groundfish resources in the BSAI in accordance with the Magnuson-Stevens Fishery Conservation and Management Act.

DATES: Comments must be received by January 8, 2016.

ADDRESSES: You may submit comments on this document, identified by NOAA–NMFS–2015–0118, by any of the following methods:

• *Electronic Submission:* Submit all electronic public comments via the Federal e-Rulemaking Portal. Go to *www.regulations.gov/#!docketDetail;D=NOAA-NMFS-2015-0118,* click the ''Comment Now!'' icon, complete the required fields, and enter or attach your comments.

• *Mail:* Submit written comments to Glenn Merrill, Assistant Regional Administrator, Sustainable Fisheries Division, Alaska Region NMFS, Attn: Ellen Sebastian. Mail comments to P.O. Box 21668, Juneau, AK 99802–1668.

Instructions: Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered by NMFS. All comments received are a part of the public record and will generally be posted for public viewing on *www.regulations.gov* without change. All personal identifying information (*e.g.,* name, address), confidential business information, or otherwise sensitive information submitted voluntarily by the sender will be publicly accessible. NMFS will accept anonymous comments (enter ''N/A'' in the required fields if you wish to remain anonymous).

Electronic copies of the Alaska Groundfish Harvest Specifications Final Environmental Impact Statement (Final EIS), Record of Decision (ROD), Supplementary Information Report (SIR), and the Initial Regulatory Flexibility Analysis (IRFA) prepared for this action may be obtained from *http://www.regulations.gov* or from the Alaska Region Web site at *http://alaskafisheries.noaa.gov.* The final 2014 Stock Assessment and Fishery Evaluation (SAFE) report for the groundfish resources of the BSAI, dated November 2014, is available from the North Pacific Fishery Management Council (Council) at 605 West 4th Avenue, Suite 306, Anchorage, AK 99501–2252, phone 907–271–2809, or from the Council's Web site at *http://www.npfmc.org/.* The draft 2015 SAFE report for the BSAI is available from the same source.

FOR FURTHER INFORMATION CONTACT: Steve Whitney, 907–586–7228.

SUPPLEMENTARY INFORMATION: Federal regulations at 50 CFR part 679 implement the Fishery Management Plan for Groundfish of the Bering Sea and Aleutian Islands Management Area (FMP) and govern the groundfish fisheries in the BSAI. The Council prepared the FMP and NMFS approved it under the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act). General regulations governing U.S. fisheries also appear at 50 CFR part 600.

The FMP and its implementing regulations require NMFS, after consultation with the Council, to specify annually the total allowable catch (TAC) for each target species category. The sum TAC for all groundfish species must be within the optimum yield (OY) range of 1.4 million to 2.0 million metric tons (mt) (see § 679.20(a)(1)(i)). Section 679.20(c)(1) further requires NMFS to publish proposed harvest specifications in the **Federal Register** and solicit public comments on proposed annual TACs and apportionments thereof, prohibited species catch (PSC) allowances, prohibited species quota (PSQ) reserves established by § 679.21, seasonal allowances of pollock, Pacific cod, and Atka mackerel TAC, American Fisheries Act allocations, Amendment 80 allocations, and Community Development Quota (CDQ) reserve amounts established by § 679.20(b)(1)(ii). The proposed harvest specifications set forth in Tables 1 through 17 of this action satisfy these requirements.

Under § 679.20(c)(3), NMFS will publish the final harvest specifications for 2016 and 2017 after (1) considering comments received within the comment period (see **DATES**), (2) consulting with the Council at its December 2015 meeting, (3) considering information presented in the SIR that assesses the need to prepare a Supplemental EIS (see **ADDRESSES**) and (4) considering information presented in the final 2015 SAFE reports prepared for the 2016 and 2017 groundfish fisheries.

Other Actions Affecting the 2016 and 2017 Harvest Specifications

On November 30, 2015, the Alaska Board of Fisheries (BOF), a regulatory body for the State of Alaska Department of Fish and Game (State), established a guideline harvest level (GHL) in State waters between 164 and 167 degrees west longitude in the Bering Sea subarea (BS) equal to 6.4 percent of the Pacific cod acceptable biological catch (ABC) for the BS. The action by the State will require a downward adjustment of the proposed 2016 and 2017 Bering Sea subarea Pacific cod TAC because the combined TAC and GHL is greater than the proposed ABC of 255,000 mt.

The BOF for the State established a GHL in State waters in the Aleutian Islands subarea (AI) equal to 27 percent of the Pacific cod ABC for the AI. The action by the State does not require a downward adjustment of the proposed Aleutian Islands subarea Pacific cod TAC because the combined TAC and GHL (14,174 mt) is less than the proposed ABC of 17,600 mt.

Accordingly, the Council will need to consider these GHLs when recommending the final 2016 and 2017 BSAI TACs. The Council is expected to set the final Bering Sea subarea and Aleutian Islands subarea Pacific cod TACs less than the ABCs by amounts that account for these 2016 and 2017 GHLs.

In addition, the Council's BSAI Groundfish Plan Team (Plan Team) is reviewing the stock structure of BSAI groundfish and may recommend allocating current overfishing levels (OFLs) or ABCs by subareas or reporting areas.

At its June 2015 meeting, the Council recommended reductions to the BSAI halibut PSC limits by 21 percent through Amendment 111 to the FMP. A notice of availability associated with those recommendations was published on October 29, 2015 (80 FR 66486). The specific reductions are 25 percent for Amendment 80 cooperatives, 15 percent for BSAI trawl limited access fisheries, 20 percent for CDQ fisheries, and 15 percent for non-trawl fisheries. These reductions are expected to be implemented in 2016, pending Secretarial approval of Amendment 111. On implementation of the reductions, the 2016 and 2017 halibut PSC limits proposed by this action would be reduced.

Proposed ABC and TAC Harvest Specifications

At the October 2015 Council meeting, the Scientific and Statistical Committee (SSC), Advisory Panel (AP), and Council

reviewed the most recent biological and harvest information on the condition of the BSAI groundfish stocks. The Plan Team compiled and presented this information, which was initially compiled by the Plan Team and presented in the final 2014 SAFE report for the BSAI groundfish fisheries, dated November 2014 (see **ADDRESSES**). The amounts proposed for the 2016 and 2017 harvest specifications are based on the 2014 SAFE report, and are subject to change in the final harvest specifications to be published by NMFS following the Council's December 2015 meeting. In November 2015, the Plan Team updated the 2014 SAFE report to include new information collected during 2015, such as NMFS stock surveys, revised stock assessments, and catch data. At its December 2015 meeting, the Council will consider information contained in the final 2015 SAFE report, recommendations from the November 2015 Plan Team meeting, public testimony from the December 2015 SSC and AP meetings, and relevant written comments in making its recommendations for the final 2016 and 2017 harvest specifications.

In previous years, the OFLs and ABCs that have had the most significant changes (relative to the amount of assessed tonnage of fish) from the proposed to the final harvest specifications have been for OFLs and ABCs that are based on the most recent NMFS stock surveys, which provide updated estimates of stock biomass and spatial distribution, and changes to the models used in the stock assessments. These changes were recommended by the Plan Team in November 2015 and are included in the final 2015 SAFE report. The final 2015 SAFE report includes the most recent information, such as 2015 catch data. The final harvest specification amounts for these stocks are not expected to vary greatly from the proposed harvest specification amounts published here.

If the final 2015 SAFE report indicates that the stock biomass trend is increasing for a species, then the final 2016 and 2017 harvest specifications may reflect an increase from the proposed harvest specifications. Conversely, if the final 2015 SAFE report indicates that the stock biomass trend is decreasing for a species, then the final 2016 and 2017 harvest specifications may reflect a decrease from the proposed harvest specifications. In addition to changes driven by biomass trends, there may be changes in TACs due to the sum of ABCs exceeding 2 million mt. Since the FMP requires TACs to be set to an OY between 1.4 and 2 million mt, the Council may be required to recommend TACs that are lower than the ABCs recommended by the Plan Team, if setting TACs equal to ABCs would cause TACs to exceed an OY of 2 million mt. Generally, ABCs greatly exceed 2 million mt in years with a large pollock biomass. NMFS anticipates that, both for 2016 and 2017, the sum of the ABCs will exceed 2 million mt. NMFS expects that the final total TAC for the BSAI for both 2016 and 2017 will equal 2 million mt.

The proposed ABCs and TACs are based on the best available biological and socioeconomic data, including projected biomass trends, information on assumed distribution of stock biomass, and revised methods used to calculate stock biomass. In general, the development of ABCs and OFLs involves statistical modeling of fish populations. The FMP specifies a series of six tiers to define OFLs and ABCs based on the level of reliable information available to fishery scientists. Tier 1 represents the highest level of information quality available while Tier 6 represents the lowest.

In October 2015, the SSC adopted the proposed 2016 and 2017 OFLs and ABCs recommended by the Plan Team for all groundfish species. The Council adopted the SSC's OFL and ABC recommendations. These amounts are unchanged from the final 2016 harvest specifications published in the **Federal Register** on March 5, 2015 (80 FR 11919). The Council adopted the AP's TAC recommendations. For 2016 and 2017, the Council recommended and NMFS proposes the OFLs, ABCs, and TACs listed in Table 1. The proposed ABCs reflect harvest amounts that are less than the specified OFLs. The sum of the proposed 2016 and 2017 ABCs for all assessed groundfish is 2,731,897 mt, which is the same as the final 2016 ABC total in the final 2015 and 2016 BSAI groundfish harvest specifications (80 FR 11919, March 5, 2015).

Specification and Apportionment of TAC Amounts

The Council recommended proposed TACs for 2016 and 2017 that are equal to proposed ABCs for Bering Sea sablefish, AI sablefish, AI ''other rockfish'' and eastern Aleutian Islands (EAI) Pacific ocean perch. The Council recommended proposed TACs for 2016 and 2017 that are less than the proposed ABCs for Bering Sea pollock, AI pollock, Bogoslof pollock, Bering Sea Pacific cod, AI Pacific cod, yellowfin sole, Bering Sea Greenland turbot, AI Greenland turbot, arrowtooth flounder, rock sole, flathead sole, Alaska plaice, ''other flatfish,'' Bering Sea Pacific ocean perch, central Aleutian Islands (CAI) Pacific ocean perch, western Aleutian Islands (WAI) Pacific ocean perch, northern rockfish, eastern Bering Sea (EBS)/EAI rougheye rockfish, CAI/WAI rougheye rockfish, shortraker rockfish, Bering Sea ''other rockfish,'' Bering Sea/EAI, CAI, and WAI Atka mackerel, skates, sculpins, sharks, squids, and octopuses. Section 679.20(a)(5)(iii)(B)(*1*) requires the AI pollock TAC to be set at 19,000 mt when the AI pollock ABC equals or exceeds 19,000 mt. The Bogoslof pollock TAC is set to accommodate incidental catch amounts. TACs are set so that the sum of the overall TAC does not exceed the BSAI OY.

The proposed groundfish OFLs, ABCs, and TACs are subject to change pending the completion of the final 2015 SAFE report and the Council's recommendations for final 2016 and 2017 harvest specifications during its December 2015 meeting. These proposed amounts are consistent with the biological condition of groundfish stocks as described in the 2014 SAFE report, and have been adjusted for other biological and socioeconomic considerations. Pursuant to Section 3.2.3.4.1 of the FMP, the Council could recommend adjusting the TACs if ''warranted on the basis of bycatch considerations, management uncertainty; or socioeconomic considerations, or if required in order to cause the sum of the TACs to fall within the OY range.'' Table 1 lists the proposed 2016 and 2017 OFL, ABC, TAC, initial TAC (ITAC), and CDQ amounts for groundfish for the BSAI. The proposed apportionment of TAC amounts among fisheries and seasons is discussed below.

TABLE 1— PROPOSED 2016 AND 2017 OVERFISHING LEVEL (OFL), ACCEPTABLE BIOLOGICAL CATCH (ABC), TOTAL ALLOWABLE CATCH (TAC), INITIAL TAC (ITAC), AND CDQ RESERVE ALLOCATION OF GROUNDFISH IN THE BSAI [1]

[Amounts are in metric tons]

Species	Area	Proposed 2016 and 2017				
		OFL	ABC	TAC	ITAC [2]	CDQ [3 4 5]
Pollock	BS	3,490,000	1,554,000	1,310,000	1,179,000	131,000
	AI	38,699	31,900	19,000	17,100	1,900
	Bogoslof	21,200	15,900	100	100	0
Pacific cod	BS	389,000	255,000	240,000	214,320	25,680
	AI	23,400	17,600	9,422	8,414	1,008
Sablefish	BS	1,431	1,211	1,211	515	167
	AI	1,934	1,637	1,637	348	276
Yellowfin sole	BSAI	262,900	245,500	149,000	133,057	15,943
Greenland turbot	BSAI	6,453	5,248	2,648	2,251	0
	BS	n/a	4,050	2,448	2,081	262
	AI	n/a	1,198	200	170	0
Arrowtooth flounder	BSAI	91,663	78,661	22,000	18,700	2,354
Kamchatka flounder	BSAI	11,000	9,500	6,500	5,525	0
Rock sole [6]	BSAI	170,100	164,800	69,250	61,840	7,410
Flathead sole [7]	BSAI	76,504	63,711	24,250	21,655	2,595
Alaska plaice	BSAI	51,600	42,900	18,500	15,725	0
Other flatfish [8]	BSAI	17,700	13,250	3,620	3,077	0
Pacific ocean perch	BSAI	40,809	33,550	31,991	28,223	2,565
	BS	n/a	8,411	8,021	6,818	0
	EAI	n/a	7,970	7,970	7,117	853
	CAI	n/a	7,406	7,000	6,251	749
	WAI	n/a	9,763	9,000	8,037	963
Northern rockfish	BSAI	15,100	12,295	3,250	2,763	0
Rougheye rockfish [9]	BSAI	688	555	349	297	0
	EBS/EAI	n/a	178	149	127	0
	CAI/WAI	n/a	377	200	170	0
Shortraker rockfish	BSAI	690	518	250	213	0
Other rockfish [10]	BSAI	1,667	1,250	880	748	0
	BS	n/a	695	325	276	0
	AI	n/a	555	555	472	0
Atka mackerel	BSAI	115,908	98,137	54,817	48,952	5,865
	EAI/BS	n/a	35,637	27,317	24,394	2,923
	CAI	n/a	30,652	17,000	15,181	1,819
	WAI	n/a	31,848	10,500	9,377	1,124
Skates	BSAI	47,035	39,468	25,700	21,845	0
Sculpins	BSAI	52,365	39,725	4,700	3,995	0
Sharks	BSAI	1,363	1,022	125	106	0
Squids	BSAI	2,624	1,970	400	340	0
Octopuses	BSAI	3,452	2,589	400	340	0
TOTAL		4,935,285	2,731,897	2,000,000	1,789,447	197,025

[1] These amounts apply to the entire BSAI management area unless otherwise specified. With the exception of pollock, and for the purpose of these harvest specifications, the (BS) includes the Bogoslof District.

[2] Except for pollock, the portion of the sablefish TAC allocated to hook-and-line and pot gear, and the Amendment 80 species (Atka mackerel, Aleutian Islands Pacific ocean perch, yellowfin sole, rock sole, flathead sole, and Pacific cod), 15 percent of each TAC is put into a reserve. The ITAC for these species is the remainder of the TAC after the subtraction of these reserves.

[3] Under § 679.20(a)(5)(i)(A)(*1*), the annual Bering Sea subarea pollock TAC, after subtracting first for the CDQ directed fishing allowance (10 percent) and second for the incidental catch allowance (4.0 percent), is further allocated by sector for a directed pollock fishery as follows: inshore—50 percent; catcher/processor—40 percent; and motherships—10 percent. Under § 679.20(a)(5)(iii)(B)(*2*)(*i*) and (*ii*), the annual Aleutian Islands subarea pollock TAC, after subtracting first for the CDQ directed fishing allowance (10 percent) and second for the incidental catch allowance (2,400 mt), is allocated to the Aleut Corporation for a directed pollock fishery.

[4] The Bering Sea subarea and Aleutian Islands subarea Pacific cod TACs are set to account for the State of Alaska guideline harvest level in state waters of the Aleutian Islands subarea.

[5] For the Amendment 80 species (Atka mackerel, Aleutian Islands Pacific ocean perch, yellowfin sole, rock sole, flathead sole, and Pacific cod), 10.7 percent of the TAC is reserved for use by CDQ participants (see §§ 679.20(b)(1)(ii)(C) and 679.31). Twenty percent of the sablefish TAC is allocated to hook-and-line gear or pot gear, and 7.5 percent of the sablefish TAC is allocated to trawl gear. The 2016 hook-and-line and pot gear portion of the sablefish ITAC and CDQ reserve will not be specified until the final 2016 and 2017 harvest specifications. 10.7 percent of the TACs for Bering Sea Greenland turbot and arrowtooth flounder are reserved for use by CDQ participants (see § 679.20(b)(1)(ii)(B) and (D)). Aleutian Islands Greenland turbot, ''other flatfish,'' Alaska plaice, Bering Sea Pacific ocean perch, Kamchatka flounder, northern rockfish, shortraker rockfish, rougheye rockfish, ''other rockfish,'' squids, octopuses, skates, sculpins, and sharks are not allocated to the CDQ program.

[6] ''Rock sole'' includes *Lepidopsetta polyxystra* (Northern rock sole) and *Lepidopsetta bilineata* (Southern rock sole).

[7] ''Flathead sole'' includes *Hippoglossoides elassodon* (flathead sole) and *Hippoglossoides robustus* (Bering flounder).

[8] ''Other flatfish'' includes all flatfish species, except for halibut (a prohibited species), flathead sole, Greenland turbot, rock sole, yellowfin sole, arrowtooth flounder, Kamchatka flounder, and Alaska plaice.

[9] ''Rougheye rockfish'' includes *Sebastes aleutianus* (rougheye) and *Sebastes melanostictus* (blackspotted).

[10] ''Other rockfish'' includes all *Sebastes* and *Sebastolobus* species except for Pacific ocean perch, northern, shortraker, and rougheye rockfish.

Groundfish Reserves and the Incidental Catch Allowance (ICA) for Pollock, Atka Mackerel, Flathead Sole, Rock Sole, Yellowfin Sole, and AI Pacific Ocean Perch

Section 679.20(b)(1)(i) requires NMFS to reserve 15 percent of the TAC for each target species category, except for pollock, hook-and-line or pot gear allocation of sablefish, and Amendment 80 species, in a non-specified reserve. Section 679.20(b)(1)(ii)(B) requires NMFS to allocate 20 percent of the hook-and-line or pot gear allocation of sablefish to the fixed gear sablefish CDQ reserve. Section 679.20(b)(1)(ii)(D) requires NMFS to allocate 7.5 percent of the trawl gear allocation of sablefish and 10.7 percent of Bering Sea Greenland turbot and arrowtooth flounder to the respective CDQ reserves. Section 679.20(b)(1)(ii)(C) requires NMFS to allocate 10.7 percent of the TACs for Atka mackerel, AI Pacific ocean perch, yellowfin sole, rock sole, flathead sole, and Pacific cod to the CDQ reserves. Sections 679.20(a)(5)(i)(A) and 679.31(a) also require allocation of 10 percent of the BSAI pollock TACs to the pollock CDQ directed fishing allowance (DFA). The entire Bogoslof District pollock TAC is allocated as an ICA (see § 679.20(a)(5)(ii)). With the exception of the hook-and-line and pot gear sablefish CDQ reserve, the regulations do not further apportion the CDQ reserves by gear.

Pursuant to § 679.20(a)(5)(i)(A)(*1*), NMFS proposes a pollock ICA of 4.0 percent or 47,160 mt of the Bering Sea subarea pollock TAC after subtracting the 10 percent CDQ reserve. This allowance is based on NMFS' examination of the pollock incidentally retained and discarded catch, including the incidental catch by CDQ vessels, in target fisheries other than pollock from 2000 through 2015. During this 16-year period, the pollock incidental catch ranged from a low of 2.4 percent in 2006 to a high of 4.8 percent in 2014, with a 16-year average of 3.2 percent. Pursuant to § 679.20(a)(5)(iii)(B)(*2*)(*i*) and (*ii*), NMFS proposes a pollock ICA of 2,400 mt of the AI subarea TAC after subtracting the 10 percent CDQ DFA. This allowance is based on NMFS' examination of the pollock incidental catch, including the incidental catch by CDQ vessels, in target fisheries other than pollock from 2003 through 2014. During this 12-year period, the incidental catch of pollock ranged from a low of 5 percent in 2006 to a high of 17 percent in 2013, with a 12-year average of 8 percent.

Pursuant to § 679.20(a)(8) and (10), NMFS proposes ICAs of 5,000 mt of flathead sole, 6,000 mt of rock sole, 3,500 mt of yellowfin sole, 10 mt of Western Aleutian District Pacific ocean perch, 75 mt of Central Aleutian District Pacific ocean perch, 200 mt of Eastern Aleutian District Pacific ocean perch, 40 mt of Western Aleutian District Atka mackerel, 75 mt of Central Aleutian District Atka mackerel, and 1,000 mt of Eastern Aleutian District and Bering Sea subarea Atka mackerel after subtracting the 10.7 percent CDQ reserve. These ICAs are based on NMFS' examination of the average incidental retained and discarded catch in other target fisheries from 2003 through 2014.

The regulations do not designate the remainder of the non-specified reserve by species or species group. Any amount of the reserve may be apportioned to a target species that contributed to the non-specified reserve, provided that such apportionments do not result in overfishing (see § 679.20(b)(1)(i)).

Allocations of Pollock TAC Under the American Fisheries Act (AFA)

Section 679.20(a)(5)(i)(A) requires that Bering Sea pollock TAC be apportioned after subtracting 10 percent for the CDQ program and 4.0 percent for the ICA as a DFA as follows: 50 percent to the inshore sector, 40 percent to the catcher/processor sector, and 10 percent to the mothership sector. In the Bering Sea subarea, 40 percent of the DFA is allocated to the A season (January 20 to June 10) and 60 percent of the DFA is allocated to the B season (June 10 to November 1) (§ 679.20(a)(5)(i)(B)). The AI directed pollock fishery allocation to the Aleut Corporation is the amount of pollock remaining in the AI subarea after subtracting 1,900 mt for the CDQ DFA (10 percent), and 2,400 mt for the ICA (§ 679.20(a)(5)(iii)(B)(*2*)(*ii*)). In the AI subarea, the A season pollock TAC may equal up to 40 percent of the ABC, and the remainder of the pollock TAC is allocated to the B season. Table 2 lists these proposed 2016 and 2017 amounts.

Section 679.20(a)(5)(iii)(B)(*6*) sets harvest limits for pollock in the A season (January 20 to June 10) in Areas 543, 542, and 541. In Area 543, the A season pollock harvest limit is no more than 5 percent of the Aleutian Islands pollock ABC. In Area 542, the A season pollock harvest limit is no more than 15 percent of the Aleutian Islands ABC. In Area 541, the A season pollock harvest limit is no more than 30 percent of the Aleutian Islands ABC.

Section 679.20(a)(5)(i)(A)(*4*) also includes several specific requirements regarding Bering Sea subarea pollock allocations. First, it requires that 8.5 percent of the pollock allocated to the catcher/processor sector be available for harvest by AFA catcher vessels with catcher/processor sector endorsements, unless the Regional Administrator receives a cooperative contract that allows the distribution of harvest among AFA catcher/processors and AFA catcher vessels in a manner agreed to by all members. Second, AFA catcher/processors not listed in the AFA are limited to harvesting not more than 0.5 percent of the pollock allocated to the catcher/processor sector. Table 2 lists the proposed 2016 and 2017 allocations of pollock TAC. Tables 14 through 17 list the AFA catcher/processor and catcher vessel harvesting sideboard limits. The Bering Sea subarea inshore pollock cooperative and open access sector allocations are based on the submission of AFA inshore cooperative applications due to NMFS on December 1 of each calendar year. Because AFA inshore cooperative applications for 2016 have not been submitted to NMFS, and NMFS therefore cannot calculate 2016 allocations, NMFS has not included inshore cooperative text and tables in these proposed harvest specifications. NMFS will post 2016 AFA inshore cooperative allocations on the Alaska Region Web site at *http://alaskafisheries.noaa.gov* prior to the start of the fishing year on January 1, 2016, based on the harvest specifications effective on that date.

Table 2 also lists proposed seasonal apportionments of pollock and harvest limits within the Steller Sea Lion Conservation Area (SCA). The harvest of pollock within the SCA, as defined at § 679.22(a)(7)(vii), is limited to no more than 28 percent of the DFA before noon, April 1, as provided in § 679.20(a)(5)(i)(C). The A season pollock SCA harvest limit will be apportioned to each sector in proportion to each sector's allocated percentage of the DFA. Table 2 lists these proposed 2016 and 2017 amounts by sector.

TABLE 2—PROPOSED 2016 AND 2017 ALLOCATIONS OF POLLOCK TACS TO THE DIRECTED POLLOCK FISHERIES AND TO THE CDQ DIRECTED FISHING ALLOWANCES (DFA) [1]

[Amounts are in metric tons]

Area and sector	2016 and 2017 Allocations	A season [1]		B season [1]
		A season DFA	SCA harvest limit [2]	B season DFA
Bering Sea subarea TAC	1,310,000	n/a	n/a	n/a
CDQ DFA	131,000	52,400	36,680	78,600
ICA [1]	47,160	n/a	n/a	n/a
AFA Inshore	565,920	226,368	158,458	339,552
AFA Catcher/Processors [3]	452,736	181,094	126,766	271,642
Catch by C/Ps	414,253	165,701	n/a	248,552
Catch by C/Vs [3]	38,483	15,393	n/a	23,090
Unlisted C/P Limit [4]	2,264	905	n/a	1,358
AFA Motherships	113,184	45,274	31,692	67,910
Excessive Harvesting Limit [5]	198,072	n/a	n/a	n/a
Excessive Processing Limit [6]	339,552	n/a	n/a	n/a
Total Bering Sea DFA (non-CDQ)	1,131,840	452,736	316,915	679,104
Aleutian Islands subarea ABC	31,900	n/a	n/a	n/a
Aleutian Islands subarea TAC	19,000	n/a	n/a	n/a
CDQ DFA	1,900	760	n/a	1,140
ICA	2,400	1,200	n/a	1,200
Aleut Corporation	14,700	13,520	n/a	1,180
Area 541 harvest limit [7]	9,570	n/a	n/a	n/a
Area 542 harvest limit [7]	4,785	n/a	n/a	n/a
Area 543 harvest limit [7]	1,595	n/a	n/a	n/a
Bogoslof District ICA [7]	100	n/a	n/a	n/a

[1] Pursuant to § 679.20(a)(5)(i)(A), the annual Bering Sea subarea pollock TAC, after subtracting the CDQ DFA (10 percent) and the ICA (4.0 percent), is allocated as a DFA as follows: inshore sector 50 percent, catcher/processor sector 40 percent, and mothership sector 10 percent. In the Bering Sea subarea, 40 percent of the DFA is allocated to the A season (January 20–June 10) and 60 percent of the DFA is allocated to the B season (June 10–November 1). Pursuant to § 679.20(a)(5)(iii)(B)(*2*)(*i*) and (*ii*), the annual AI pollock TAC, after subtracting first for the CDQ DFA (10 percent) and second the ICA (2,400 mt), is allocated to the Aleut Corporation for a directed pollock fishery. In the AI subarea, the A season is allocated 40 percent of the ABC, and the B season is allocated the remainder of the directed pollock fishery.

[2] In the Bering Sea subarea, no more than 28 percent of each sector's annual DFA may be taken from the SCA before noon, April 1.

[3] Pursuant to § 679.20(a)(5)(i)(A)(*4*), not less than 8.5 percent of the DFA allocated to listed catcher/processors (C/Ps) shall be available for harvest only by eligible catcher vessels (CVs) delivering to listed C/Ps.

[4] Pursuant to § 679.20(a)(5)(i)(A)(*4*)(*iii*), the AFA unlisted catcher/processors are limited to harvesting not more than 0.5 percent of the catcher/processor sector's allocation of pollock.

[5] Pursuant to § 679.20(a)(5)(i)(A)(*6*), NMFS establishes an excessive harvesting share limit equal to 17.5 percent of the sum of the pollock DFAs not including CDQ.

[6] Pursuant to § 679.20(a)(5)(i)(A)(*7*), NMFS establishes an excessive processing share limit equal to 30.0 percent of the sum of the pollock DFAs not including CDQ.

[7] Pursuant to § 679.20(a)(5)(iii)(B)(*6*), NMFS establishes harvest limits for pollock in the A season in Area 541 no more than 30 percent, in Area 542 no more than 15 percent, and in Area 543 no more than 5 percent of the Aleutian Islands pollock ABC.

Allocation of the Atka Mackerel TACs

Section 679.20(a)(8) allocates the Atka mackerel TACs to the Amendment 80 and BSAI trawl limited access sectors, after subtracting the CDQ reserves, jig gear allocation, and ICAs for the BSAI trawl limited access sector and non-trawl gear sectors (Table 3). The percentage of the ITAC for Atka mackerel allocated to the Amendment 80 and BSAI trawl limited access sectors is listed in Table 33 to part 679 and in § 679.91. Pursuant to § 679.20(a)(8)(i), up to 2 percent of the Eastern Aleutian District and Bering Sea subarea Atka mackerel ITAC may be allocated to jig gear. The percent of this allocation is recommended annually by the Council based on several criteria, including the anticipated harvest capacity of the jig gear fleet. The Council recommended and NMFS proposes a 0.5 percent allocation of the Atka mackerel ITAC in the Eastern Aleutian District and Bering Sea subarea to jig gear in 2016 and 2017. This percentage is applied to the TAC after subtracting the CDQ reserve and the ICA.

Section 679.20(a)(8)(ii)(A) apportions the Atka mackerel TAC into two equal seasonal allowances. Section 679.23(e)(3) sets the first seasonal allowance for directed fishing with trawl gear from January 20 through June 10 (A season), and the second seasonal allowance from June 10 through December 31 (B season). Section 679.23(e)(4)(iii) applies Atka mackerel seasons to CDQ Atka mackerel fishing. The ICA and jig gear allocations are not apportioned by season.

Sections 679.20(a)(8)(ii)(C)(*1*)(*i*) and (*ii*) limit Atka mackerel catch within waters 0 nm to 20 nm of Steller sea lion sites listed in Table 6 to this part and located west of 178° W longitude to no more than 60 percent of the annual TACs in Areas 542 and 543; and equally divides the annual TAC between the A and B seasons as defined at § 679.23(e)(3). Section 679.20(a)(8)(ii)(C)(*2*) requires the annual TAC in Area 543 will be no more than 65 percent of the ABC in Area 543. Section 679.20(a)(8)(ii)(D) requires that any unharvested Atka mackerel A season allowance that is added to the B season be prohibited from being harvested within waters 0 nm to 20 nm of Steller sea lion sites listed in Table 6 to this part and located in Areas 541, 542, and 543.

Two Amendment 80 cooperatives have formed for the 2016 fishing year. Because all Amendment 80 vessels are part of a cooperative, no allocation to the Amendment 80 limited access sector is required. NMFS will post 2016 Amendment 80 cooperative allocations on the Alaska Region Web site at *http://alaskafisheries.noaa.gov* prior to the start of the fishing year on January 1, 2016, based on the harvest specifications effective on that date.

Table 3 lists these 2016 and 2017 Atka mackerel season allowances, area allowances, and the sector allocations. The 2017 allocations for Amendment 80 species between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2016. NMFS will post 2017 Amendment 80 cooperatives and Amendment 80 limited access allocations on the Alaska Region Web site at *http://alaskafisheries.noaa.gov* prior to the start of the fishing year on January 1, 2017, based on the harvest specifications effective on that date.

TABLE 3–PROPOSED 2016 AND 2017 SEASONAL AND SPATIAL ALLOWANCES, GEAR SHARES, CDQ RESERVE, INCIDENTAL CATCH ALLOWANCE, AND AMENDMENT 80 ALLOCATIONS OF THE BSAI ATKA MACKEREL TAC

[Amounts are in metric tons]

Sector [1]	Season [2 3 4]	Allocation by area		
		Eastern Aleutian District/Bering Sea	Central Aleutian District	Western Aleutian District
TAC	n/a	27,317	17,000	10,500
CDQ reserve	Total	2,923	1,819	1,124
	A	1,461	910	562
	Critical habitat [5]	n/a	91	n/a
	B	1,461	910	562
	Critical habitat [5]	n/a	91	n/a
ICA	Total	1,000	75	40
Jig [6]	Total	117	0	0
BSAI trawl limited access	Total	2,328	1,511	0
	A	1,164	755	0
	B	1,164	755	0
Amendment 80 [7]	Total	20,949	13,595	9,337
Alaska Groundfish Cooperative for 2016.	Total	11,766	8,114	5,742
	A	5,883	4,057	2,871
	Critical habitat [5]	n/a	406	n/a
	B	5,883	4,057	2,871
	Critical habitat [5]	n/a	406	n/a
Alaska Seafood Cooperative for 2016	Total	9,183	5,481	3,595
	A	4,592	2,741	1,798
	Critical habitat [5]	n/a	274	n/a
	B	4,592	2,741	1,798
	Critical habitat [5]	n/a	274	n/a

[1] Section 679.20(a)(8)(ii) allocates the Atka mackerel TACs, after subtracting the CDQ reserves, ICAs, and the jig gear allocation, to the Amendment 80 and BSAI trawl limited access sectors. The allocation of the ITAC for Atka mackerel to the Amendment 80 and BSAI trawl limited access sectors is established in Table 33 to part 679 and § 679.91. The CDQ reserve is 10.7 percent of the TAC for use by CDQ participants (see §§ 679.20(b)(1)(ii)(C) and 679.31).

[2] Sections 679.20(a)(8)(ii)(A) and 679.22(a) establish temporal and spatial limitations for the Atka mackerel fishery.

[3] The seasonal allowances of Atka mackerel are 50 percent in the A season and 50 percent in the B season.

[4] Section 679.23(e)(3) authorizes directed fishing for Atka mackerel with trawl gear during the A season from January 20 to June 10, and the B season from June 10 to December 31.

[5] Section 679.20(a)(8)(ii)(C)(*1*)(*i*) limits no more than 60 percent of the annual TACs in Areas 542 and 543 to be caught inside of critical habitat; paragraph (a)(ii)(C)(*1*)(*ii*) equally divides the annual TACs between the A and B seasons as defined at § 679.23(e)(3); and paragraph (a)(8)(ii)(C)(*2*) requires the TAC in Area 543 shall be no more than 65 percent of ABC.

[6] Section 679.20(a)(8)(i) requires that up to 2 percent of the Eastern Aleutian District and Bering Sea subarea TAC be allocated to jig gear after subtraction of the CDQ reserve and ICA. The amount of this allocation is 0.5 percent. The jig gear allocation is not apportioned by season.

[7] The 2017 allocations for Amendment 80 Atka mackerel between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2016.

Allocation of the Pacific Cod TAC

The Council recommended and NMFS proposes separate BS and AI subarea OFLs, ABCs, and TACs for Pacific cod. Section 679.20(b)(1)(ii)(C) allocates 10.7 percent of the BS TAC and the AI TAC to the CDQ program. After CDQ allocations have been deducted from the respective BS and AI Pacific cod TACs, the remaining BS and AI Pacific cod TACs are combined for calculating further BSAI Pacific cod sector allocations. However, if the non-CDQ Pacific cod TAC is or will be reached in either the BS or AI subareas, NMFS will prohibit non-CDQ directed fishing for Pacific cod in that subarea, as provided in § 679.20(d)(1)(iii).

Sections 679.20(a)(7)(i) and (ii) allocate the Pacific cod TAC in the combined BSAI TAC, after subtracting 10.7 percent for the CDQ program, as follows: 1.4 percent to vessels using jig gear, 2.0 percent to hook-and-line and pot catcher vessels less than 60 ft (18.3 m) length overall (LOA), 0.2 percent to hook-and-line catcher vessels greater than or equal to 60 ft (18.3 m) LOA, 48.7 percent to hook-and-line catcher/processors, 8.4 percent to pot catcher vessels greater than or equal to 60 ft (18.3 m) LOA, 1.5 percent to pot catcher/processors, 2.3 percent to AFA trawl catcher/processors, 13.4 percent to non-AFA trawl catcher/processors, and 22.1 percent to trawl catcher vessels. The BSAI ICA for the hook-and-line and pot sectors will be deducted from the aggregate portion of BSAI Pacific cod TAC allocated to the hook-and-line and pot sectors. For 2016 and 2017, the Regional Administrator proposes a BSAI ICA of 500 mt, based on anticipated incidental catch by these sectors in other fisheries.

The BSAI ITAC allocation of Pacific cod to the Amendment 80 sector is established in Table 33 to part 679 and § 679.91. Two Amendment 80 cooperatives have formed for the 2016 fishing year. Because all Amendment 80 vessels are part of a cooperative, no

allocation to the Amendment 80 limited access sector is required. NMFS will post 2016 Amendment 80 cooperative allocations on the Alaska Region Web site at *http://alaskafisheries.noaa.gov* prior to the start of the fishing year on January 1, 2016, based on the harvest specifications effective on that date.

The 2017 allocations for Amendment 80 species between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2016. NMFS will post 2017 Amendment 80 cooperatives and Amendment 80 limited access allocations on the Alaska Region Web site at *http://alaskafisheries.noaa.gov* prior to the start of the fishing year on January 1, 2017, based on the harvest specifications effective on that date.

The Pacific cod ITAC is apportioned into seasonal allowances to disperse the Pacific cod fisheries over the fishing year (see §§ 679.20(a)(7) and 679.23(e)(5)). In accordance with § 679.20(a)(7)(iv)(B) and (C), any unused portion of a seasonal Pacific cod allowance will become available at the beginning of the next seasonal allowance.

Section 679.20(a)(7)(vii) requires the Regional Administrator to establish an Area 543 Pacific cod harvest limit based on Pacific cod abundance in Area 543. Based on the 2014 stock assessment, the Regional Administrator determined the Area 543 Pacific cod harvest limit to be 26.3 percent of the AI Pacific cod TAC for 2016 and 2017. NMFS first subtracted the State GHL Pacific cod amount from the AI Pacific cod ABC and then multiplied the remaining ABC for AI Pacific cod by the percentage of Pacific cod estimated in Area 543. Based on these calculations, the Area 543 harvest limit is 2,478 mt.

The CDQ and non-CDQ season allowances by gear based on the proposed 2016 and 2017 Pacific cod TACs are listed in Table 4 based on the sector allocation percentages of Pacific cod set forth at § 679.20(a)(7)(i)(B) and (a)(7)(iv)(A); and the seasonal allowances of Pacific cod set forth at § 679.23(e)(5).

TABLE 4—PROPOSED 2016 AND 2017 GEAR SHARES AND SEASONAL ALLOWANCES OF THE BSAI [1] PACIFIC COD TAC

[Amounts are in metric tons]

Sector	Percent	2016 and 2017 share of gear sector total	2016 and 2017 share of sector total	2016 and 2017 seasonal apportionment	
				Season	Amount
Total Bering Sea TAC	n/a	240,000	n/a	n/a	n/a
Bering Sea CDQ	n/a	25,680	n/a	See § 679.20(a)(7)(i)(B)	n/a
Bering Sea non-CDQ TAC	n/a	214,320	n/a	n/a	n/a
Total Aleutian Islands TAC	n/a	9,422	n/a	n/a	n/a
Aleutian Islands CDQ	n/a	1,008	n/a	See § 679.20(a)(7)(i)(B)	n/a
Aleutian Islands non-CDQ TAC	n/a	8,414	n/a	n/a	n/a
Western Aleutians Islands Limit	n/a	2,478	n/a	n/a	n/a
Total BSAI non-CDQ TAC [1]	100	222,734	n/a	n/a	n/a
Total hook-and-line/pot gear	60.8	135,422	n/a	n/a	n/a
Hook-and-line/pot ICA [2]	n/a	n/a	500	n/a	n/a
Hook-and-line/pot sub-total	n/a	134,922	n/a	n/a	n/a
Hook-and-line catcher/processors	48.7	n/a	08,071	Jan 1–Jun 10	55,116
				Jun 10–Dec 31	52,955
Hook-and-line catcher vessels ≥60 ft LOA	0.2	n/a	444	Jan 1–Jun 10	226
				Jun 10–Dec 31	217
Pot catcher/processors	1.5	n/a	3,329	Jan 1–Jun 10	1,698
				Sept 1–Dec 31	1,631
Pot catcher vessels >60 ft LOA	8.4	n/a	18,641	Jan 1–Jun 10	9,507
				Sept 1–Dec 31	9,134
Catcher vessels <60 ft LOA using hook-and-line or pot gear.	2	n/a	4,438	n/a	n/a
Trawl catcher vessels	22.1	49,224	n/a	Jan 20–Apr 1	36,426
				Apr 1–Jun 10	5,415
				Jun 10–Nov 1	7,384
AFA trawl catcher/processors	2.3	5,123	n/a	Jan 20–Apr 1	3,842
				Apr 1–Jun 10	1,281
				Jun 10–Nov 1	0
Amendment 80	13.4	29,846	n/a	Jan 20–Apr 1	22,385
				Apr 1–Jun 10	7,462
				Jun 10–Nov 1	0
Alaska Groundfish Cooperative for 2016 [3]	n/a	4,711	n/a	Jan 20–Apr 1	3,533
				Apr 1–Jun 10	1,178
				Jun 10–Nov 1	0
Alaska Seafood Cooperative for 2016 [3]	n/a	25,135	n/a	Jan 20–Apr 1	18,851
				Apr 1–Jun 10	6,284
				Jun 10–Nov 1	0
Jig	1.4	3,118	n/a	Jan 1–Apr 30	1,871
				Apr 30–Aug 31	624
				Aug 31–Dec 31	624

[1] The gear shares and seasonal allowances for BSAI Pacific cod TAC are based on the sum of the BS and AI Pacific cod TACs. If the TAC for Pacific cod in either the AI or BS is reached, then directed fishing for Pacific cod in that subarea may be prohibited, even if a BSAI allowance remains.

[2] The ICA for the hook-and-line and pot sectors will be deducted from the aggregate portion of Pacific cod TAC allocated to the hook-and-line and pot sectors. The Regional Administrator proposes an ICA of 500 mt for 2016 and 2017 based on anticipated incidental catch in these fisheries.

[3] The 2017 allocations for Amendment 80 species between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2016.

Sablefish Gear Allocation

Sections 679.20(a)(4)(iii) and (iv) require allocation of sablefish TACs for the Bering Sea and AI subareas between trawl gear and hook-and-line or pot gear. Gear allocations of the TACs for the Bering Sea subarea are 50 percent for trawl gear and 50 percent for hook-and-line or pot gear. Gear allocations for the TACs for the AI subarea are 25 percent for trawl gear and 75 percent for hook-and-line or pot gear. Section 679.20(b)(1)(ii)(B) requires NMFS to apportion 20 percent of the hook-and-line and pot gear allocation of sablefish to the CDQ reserve. Additionally, § 679.20(b)(1)(ii)(D)(*1*) requires that 7.5 percent of the trawl gear allocation of sablefish from the nonspecified reserves, established under § 679.20(b)(1)(i), be assigned to the CDQ reserve. The Council recommended that only trawl sablefish TAC be established biennially. The harvest specifications for the hook-and-line gear and pot gear sablefish Individual Fishing Quota (IFQ) fisheries will be limited to the 2016 fishing year to ensure those fisheries are conducted concurrently with the halibut IFQ fishery. Concurrent sablefish and halibut IFQ fisheries would reduce the potential for discards of halibut and sablefish in those fisheries. The sablefish IFQ fisheries would remain closed at the beginning of each fishing year until the final harvest specifications for the sablefish IFQ fisheries are in effect. Table 5 lists the proposed 2016 and 2017 gear allocations of the sablefish TAC and CDQ reserve amounts.

TABLE 5—PROPOSED 2016 AND 2017 GEAR SHARES AND CDQ RESERVE OF BSAI SABLEFISH TACS

[Amounts are in metric tons]

Subarea and gear	Percent of TAC	2016 share of TAC	2016 ITAC [1]	2016 CDQ reserve	2017 share of TAC	2017 ITAC	2017 CDQ reserve
Bering Sea:							
Trawl	50	606	515	45	606	515	45
Hook-and-line gear [2]	50	606	n/a	121	n/a	n/a	n/a
Total	100	1,211	515	167	606	515	45
Aleutian Islands:							
Trawl	25	409	348	31	409	348	31
Hook-and-line gear [2]	75	1,228	n/a	246	n/a	n/a	n/a
Total	100	1,637	348	276	409	348	31

[1] Except for the sablefish hook-and-line or pot gear allocation, 15 percent of TAC is apportioned to the reserve. The ITAC is the remainder of the TAC after the subtraction of these reserves.

[2] For the portion of the sablefish TAC allocated to vessels using hook-and-line or pot gear, 20 percent of the allocated TAC is reserved for use by CDQ participants. Section 679.20(b)(1) does not provide for the establishment of an ITAC for sablefish allocated to hook-and-line or pot gear.

Note: Seasonal or sector apportionments may not total precisely due to rounding.

Allocation of the Aleutian Islands Pacific Ocean Perch, and BSAI Flathead Sole, Rock Sole, and Yellowfin Sole TACs

Sections 679.20(a)(10)(i) and (ii) require that NMFS allocate AI Pacific ocean perch, and BSAI flathead sole, rock sole, and yellowfin sole TACs between the Amendment 80 and BSAI trawl limited access sectors, after subtracting 10.7 percent for the CDQ reserve and an ICA for the BSAI trawl limited access sector and vessels using non-trawl gear. The allocation of the ITAC for AI Pacific ocean perch, and BSAI flathead sole, rock sole, and yellowfin sole to the Amendment 80 sector is established in Tables 33 and 34 to part 679 and in § 679.91.

Two Amendment 80 cooperatives have formed for the 2016 fishing year. Because all Amendment 80 vessels are part of a cooperative, no allocation to the Amendment 80 limited access sector is required. NMFS will post 2016 Amendment 80 cooperative allocations on the Alaska Region Web site at *http://alaskafisheries.noaa.gov* prior to the start of the fishing year on January 1, 2016, based on the harvest specifications effective on that date.

The 2017 allocations for Amendment 80 species between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2016. NMFS will post 2017 Amendment 80 cooperatives and Amendment 80 limited access allocations on the Alaska Region Web site at *http://alaskafisheries.noaa.gov* prior to the start of the fishing year on January 1, 2017, based on the harvest specifications effective on that date. Table 6 lists the proposed 2016 and 2017 allocations of the AI Pacific ocean perch, and BSAI flathead sole, rock sole, and yellowfin sole TACs.

TABLE 6—PROPOSED 2016 AND 2017 COMMUNITY DEVELOPMENT QUOTA (CDQ) RESERVES, INCIDENTAL CATCH AMOUNTS (ICAS), AND AMENDMENT 80 ALLOCATIONS OF THE ALEUTIAN ISLANDS PACIFIC OCEAN PERCH, AND BSAI FLATHEAD SOLE, ROCK SOLE, AND YELLOWFIN SOLE TACS

[Amounts are in metric tons]

Sector	2016 and 2017 allocations					
	Pacific ocean perch			Flathead sole	Rock sole	Yellowfin sole
	Eastern Aleutian District	Central Aleutian District	Western Aleutian District	BSAI	BSAI	BSAI
TAC	7,970	7,000	9,000	24,250	69,250	149,000
CDQ	853	749	963	2,595	7,410	15,943
ICA	200	75	10	5,000	6,000	3,500
BSAI trawl limited access	692	618	161	0	0	16,765
Amendment 80	6,225	5,558	7,866	16,655	55,840	112,792

TABLE 6—PROPOSED 2016 AND 2017 COMMUNITY DEVELOPMENT QUOTA (CDQ) RESERVES, INCIDENTAL CATCH AMOUNTS (ICAS), AND AMENDMENT 80 ALLOCATIONS OF THE ALEUTIAN ISLANDS PACIFIC OCEAN PERCH, AND BSAI FLATHEAD SOLE, ROCK SOLE, AND YELLOWFIN SOLE TACS—Continued

[Amounts are in metric tons]

Sector	2016 and 2017 allocations					
	Pacific ocean perch			Flathead sole	Rock sole	Yellowfin sole
	Eastern Aleutian District	Central Aleutian District	Western Aleutian District	BSAI	BSAI	BSAI
Alaska Groundfish Cooperative for 2016 [1]	3,301	2,947	4,171	1,708	13,813	44,812
Alaska Seafood Cooperative for 2016 [1]	2,924	2,611	3,695	14,947	42,027	67,980

[1] The 2017 allocations for Amendment 80 species between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2016.

Section 679.2 defines the ABC surplus for flathead sole, rock sole, and yellowfin sole as the difference between the annual ABC and TAC for each species. Section 679.20(b)(1)(iii) establishes ABC reserves for flathead sole, rock sole, and yellowfin sole. The ABC surpluses and the ABC reserves are necessary to mitigate the operational variability, environmental conditions, and economic factors that may constrain the CDQ groups and the Amendment 80 cooperatives from achieving, on a continuing basis, the optimum yield in the BSAI groundfish fisheries. NMFS, after consultation with the Council, may set the ABC reserve at or below the ABC surplus for each species thus maintaining the TAC below ABC limits. An amount equal to 10.7 percent of the ABC reserves will be allocated as CDQ reserves for flathead sole, rock sole, and yellowfin sole. The Amendment 80 ABC reserves shall be the ABC reserves minus the CDQ ABC reserves. Section 679.91(i)(2) establishes each Amendment 80 cooperative ABC reserve to be the ratio of each cooperatives' quota share (QS) units and the total Amendment 80 QS units, multiplied by the Amendment 80 ABC reserve for each respective species. Table 7 lists the 2016 and 2017 ABC surplus and ABC reserves for BSAI flathead sole, rock sole, and yellowfin sole.

TABLE 7—PROPOSED 2016 AND 2017 ABC SURPLUS, COMMUNITY DEVELOPMENT QUOTA (CDQ) ABC RESERVES, AND AMENDMENT 80 ABC RESERVES IN THE BSAI FOR FLATHEAD SOLE, ROCK SOLE, AND YELLOWFIN SOLE

[Amounts are in metric tons]

Sector	Flathead sole	Rock sole	Yellowfin sole
ABC	63,711	164,800	245,500
TAC	24,250	69,250	149,000
ABC surplus	39,461	95,550	96,500
ABC reserve	39,461	95,550	96,500
CDQ ABC reserve	4,222	10,224	10,326
Amendment 80 ABC reserve	35,239	85,326	86,175
Alaska Groundfish Cooperative for 2016 [1]	3,615	21,107	34,240
Alaska Seafood Cooperative for 2016 [1]	31,624	64,219	51,935

[1] The 2017 allocations for Amendment 80 species between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2016.

Proposed PSC Limits for Halibut, Salmon, Crab, and Herring

As discussed above, NMFS published a notice of availability to implement Amendment 111 to the FMP (80 FR 66486, October 29, 2015). Amendment 95 would reduce halibut PSC limits in the BSAI by 25 percent for Amendment 80 cooperatives, 15 percent for BSAI trawl limited access fisheries, 20 percent for CDQ fisheries, and 15 percent for non-trawl fisheries. These reductions are expected to be implemented in 2016, pending Secretarial approval of Amendment 111. On implementation of the reductions, the 2016 and 2017 halibut PSC limits proposed by this action would be reduced.

Section 679.21(e) sets forth the BSAI PSC limits. Pursuant to § 679.21(e)(1)(iv) and (e)(2), the 2016 and 2017 BSAI halibut mortality limits are 3,675 mt for trawl fisheries, and 900 mt for the non-trawl fisheries. Sections 679.21(e)(3)(i)(A)(*2*) and (e)(4)(i)(A) allocate 326 mt of the trawl halibut mortality limit and 7.5 percent, or 67 mt, of the non-trawl halibut mortality limit as the PSQ reserve for use by the groundfish CDQ program.

Section 679.21(e)(4)(i) authorizes apportionment of the non-trawl halibut PSC limit into PSC bycatch allowances among six fishery categories. Table 10 lists the fishery bycatch allowances for the trawl fisheries, and Table 11 lists the fishery bycatch allowances for the non-trawl fisheries.

Pursuant to Section 3.6 of the FMP, the Council recommends, and NMFS agrees, that certain specified non-trawl fisheries be exempt from the halibut PSC limit. As in past years after consultation with the Council, NMFS exempts pot gear, jig gear, and the sablefish IFQ hook-and-line gear fishery categories from halibut bycatch restrictions for the following reasons: (1) The pot gear fisheries have low halibut bycatch mortality; (2) NMFS estimates halibut mortality for the jig gear fleet to be negligible because of the small size of the fishery and the selectivity of the gear; and (3) the sablefish and halibut IFQ fisheries have low halibut bycatch

mortality because the IFQ program requires legal-size halibut to be retained by vessels using hook-and-line gear if a halibut IFQ permit holder or a hired master is aboard and is holding unused halibut IFQ (subpart D of 50 CFR part 679). In 2015, total groundfish catch for the pot gear fishery in the BSAI was 35,298 mt, with an associated halibut bycatch mortality of 1.8 mt.

The 2015 jig gear fishery harvested about 28 mt of groundfish. Most vessels in the jig gear fleet are exempt from observer coverage requirements. As a result, observer data are not available on halibut bycatch in the jig gear fishery. However, as mentioned above, NMFS estimates a negligible amount of halibut bycatch mortality because of the selective nature of jig gear and the low mortality rate of halibut caught with jig gear and released.

Under § 679.21(f)(2), NMFS annually allocates portions of either 47,591 or 60,000 Chinook salmon PSC among the AFA sectors, depending on past catch performance and on whether Chinook salmon bycatch incentive plan agreements are formed. If an AFA sector participates in an approved Chinook salmon bycatch incentive plan agreement, then NMFS will allocate a portion of the 60,000 PSC limit to that sector as specified in § 679.21(f)(3)(iii)(A). If no Chinook salmon bycatch incentive plan agreement is approved, or if the sector has exceeded its performance standard under § 679.21(f)(6), NMFS will allocate a portion of the 47,591 Chinook salmon PSC limit to that sector as specified in § 679.21(f)(3)(iii)(B). In 2016, the Chinook salmon PSC limit is 60,000, and the AFA sector Chinook salmon allocations are seasonally allocated with 70 percent of the allocation for the A season pollock fishery, and 30 percent of the allocation for the B season pollock fishery as stated in § 679.21(f)(3)(iii)(A). The basis for these PSC limits is described in detail in the final rule implementing management measures for Amendment 91 (75 FR 53026, August 30, 2010). NMFS publishes the approved Chinook salmon bycatch incentive plan agreements, allocations, and reports at *http://alaskafisheries.noaa.gov/sustainablefisheries/bycatch/default.htm.*

Section 679.21(e)(1)(viii) specifies 700 fish as the 2016 and 2017 Chinook salmon PSC limit for the AI subarea pollock fishery. Section 679.21(e)(3)(i)(A)(*3*)(*i*) allocates 7.5 percent, or 53 Chinook salmon, as the AI subarea PSQ for the CDQ program and allocates the remaining 647 Chinook salmon to the non-CDQ fisheries.

Section 679.21(e)(1)(vii) specifies 42,000 fish as the 2016 and 2017 non-Chinook salmon PSC limit in the Catcher Vessel Operational Area (CVOA). Section 679.21(e)(3)(i)(A)(*3*)(*ii*) allocates 10.7 percent, or 4,494, non-Chinook salmon in the CVOA as the PSQ for the CDQ program, and allocates the remaining 37,506 non-Chinook salmon to the non-CDQ fisheries.

PSC limits for crab and herring are specified annually based on abundance and spawning biomass. Due to the lack of new information as of October 2015 regarding herring PSC limits and apportionments, the Council recommended and NMFS proposes basing the herring 2016 and 2017 PSC limits and apportionments on the 2014 survey data. The Council will reconsider these amounts in December 2015.

Section § 679.21(e)(3)(i)(A)(*1*) allocates 10.7 percent of each trawl gear PSC limit specified for crab as a PSQ reserve for use by the groundfish CDQ program.

Based on 2015 survey data, the red king crab mature female abundance is estimated at 18.6 million red king crabs, which is above the threshold of 8.4 million red king crabs, and the effective spawning biomass is estimated at 46.5 million lbs (21,092 mt). Based on the criteria set out at § 679.21(e)(1)(i), the proposed 2016 and 2017 PSC limit of red king crab in Zone 1 for trawl gear is 97,000 animals. This limit derives from the mature female abundance estimate of more than 8.4 million red king crab and the effective spawning biomass estimate of more than 14.5 million lbs (6,577 mt) but less than 55 million lbs (24,948 mt).

Section 679.21(e)(3)(ii)(B)(*2*) establishes criteria under which NMFS must specify an annual red king crab bycatch limit for the Red King Crab Savings Subarea (RKCSS). The regulations limit the RKCSS to up to 25 percent of the red king crab PSC allowance based on the need to optimize the groundfish harvest relative to red king crab bycatch. NMFS proposes the Council's recommendation that the red king crab bycatch limit be equal to 25 percent of the red king crab PSC allowance within the RKCSS (Table 8). Based on 2015 survey data, Tanner crab (*Chionoecetes bairdi*) abundance is estimated at 329 million animals. Pursuant to criteria set out at § 679.21(e)(1)(ii), the calculated 2016 and 2017 *C. bairdi* crab PSC limit for trawl gear is 830,000 animals in Zone 1, and 2,520,000 animals in Zone 2. In Zone 1, *C. bairdi* abundance was estimated to be greater than 270 million and less than 400 million animals. In Zone 2, *C. bairdi* abundance was estimated to be greater than 290 million animals and less than 400 million animals.

Pursuant to § 679.21(e)(1)(iii), the PSC limit for snow crab (*C. opilio*) is based on total abundance as indicated by the NMFS annual bottom trawl survey. The *C. opilio* crab PSC limit in the *C. opilio* bycatch limitation zone (COBLZ) is set at 0.1133 percent of the Bering Sea abundance index minus 150,000 crabs. Based on the 2015 survey estimate of 4.288 billion animals, the calculated *C. opilio* crab PSC limit is 4,708,314 animals.

Pursuant to § 679.21(e)(1)(v), the PSC limit of Pacific herring caught while conducting any trawl operation for BSAI groundfish is 1 percent of the annual eastern Bering Sea herring biomass. The best estimate of 2016 and 2017 herring biomass is 274,236 mt. This amount was developed by the Alaska Department of Fish and Game based on spawning location estimates. Therefore, the herring PSC limit proposed for 2016 and 2017 is 2,742 mt for all trawl gear as listed in Tables 8 and 9.

Section 679.21(e)(3)(i)(A) requires PSQ reserves to be subtracted from the total trawl PSC limits. The amount of the 2016 PSC limits assigned to the Amendment 80 and BSAI trawl limited access sectors are specified in Table 35 to part 679. The resulting allocations of PSC limits to CDQ PSQ, the Amendment 80 sector, and the BSAI trawl limited access sector are listed in Table 8. Pursuant to § 679.21(e)(1)(iv) and § 679.91(d) through (f), crab and halibut trawl PSC limits assigned to the Amendment 80 sector is then further allocated to Amendment 80 cooperatives as PSC cooperative quota as listed in Table 12. Two Amendment 80 cooperatives have formed for the 2016 fishing year. Because all Amendment 80 vessels are part of a cooperative, no allocation to the Amendment 80 limited access sector is required. NMFS will post 2016 Amendment 80 cooperative allocations on the Alaska Region Web site at *http://alaskafisheries.noaa.gov* prior to the start of the fishing year on January 1, 2016, based on the harvest specifications effective on that date.

The 2017 PSC limit allocations between Amendment 80 cooperatives and the Amendment 80 limited access sector will not be known until eligible participants apply for participation in the program by November 1, 2016. NMFS will post 2017 Amendment 80 cooperatives and Amendment 80 limited access allocations on the Alaska

Region Web site at *http://alaskafisheries.noaa.gov* prior to the start of the fishing year on January 1, 2017, based on the harvest specifications effective on that date.

Section 679.21(e)(5) authorizes NMFS, after consulting with the Council, to establish seasonal apportionments of PSC amounts for the BSAI trawl limited access and Amendment 80 limited access sectors to maximize the ability of the fleet to harvest the available groundfish TAC and to minimize bycatch. The factors considered are (1) seasonal distribution of prohibited species, (2) seasonal distribution of target groundfish species, (3) PSC bycatch needs on a seasonal basis relevant to prohibited species biomass, (4) expected variations in bycatch rates throughout the year, (5) expected start of fishing effort, and (6) economic effects of seasonal PSC apportionments on industry sectors. The Council recommended and NMFS proposes the seasonal PSC apportionments in Table 10 to maximize harvest among gear types, fisheries, and seasons while minimizing bycatch of PSC based on the above criteria.

TABLE 8—PROPOSED 2016 AND 2017 APPORTIONMENT OF PROHIBITED SPECIES CATCH ALLOWANCES TO NON–TRAWL GEAR, THE CDQ PROGRAM, AMENDMENT 80, AND THE BSAI TRAWL LIMITED ACCESS SECTORS

PSC species and area [1]	Total non-trawl PSC	Non-trawl PSC remaining after CDQ PSQ [2]	Total trawl PSC	Trawl PSC remaining after CDQ PSQ [2]	CDQ PSQ reserve [2]	Amendment 80 sector [3]	BSAI trawl limited access fishery
Halibut mortality (mt) BSAI	900	832	3,675	3,349	393	2,325	875
Herring (mt) BSAI	n/a	n/a	2,742	n/a	n/a	n/a	n/a
Red king crab (animals) Zone 1	n/a	n/a	97,000	86,621	10,379	43,293	26,489
C. opilio (animals) COBLZ	n/a	n/a	4,708,314	4,204,524	503,790	2,066,524	1,351,334
C. bairdi crab (animals) Zone 1	n/a	n/a	830,000	741,190	88,810	312,115	348,285
C. bairdi crab (animals) Zone 2	n/a	n/a	2,520,000	2,250,360	269,640	532,660	1,053,394

[1] Refer to § 679.2 for definitions of zones.
[2] Section 679.21(e)(3)(i)(A)(*2*) allocates 326 mt of the trawl halibut mortality limit and § 679.21(e)(4)(i)(A) allocates 7.5 percent, or 67 mt, of the non-trawl halibut mortality limit as the PSQ reserve for use by the groundfish CDQ program. The PSQ reserve for crab species is 10.7 percent of each crab PSC limit.
[3] The Amendment 80 program reduced apportionment of the trawl PSC limits by 150 mt for halibut mortality and 20 percent for crab PSC. These reductions are not apportioned to other gear types or sectors.

TABLE 9—PROPOSED 2016 AND 2017 HERRING AND RED KING CRAB SAVINGS SUBAREA PROHIBITED, SPECIES CATCH ALLOWANCES FOR ALL TRAWL SECTORS

Fishery categories	Herring (mt) BSAI	Red king crab (animals) Zone [1]
Yellowfin sole	187	n/a
Rock sole/flathead sole/other flatfish [1]	30	n/a
Greenland turbot/arrowtooth flounder/Kamchatka flounder/sablefish	20	n/a
Rockfish	14	n/a
Pacific cod	42	n/a
Midwater trawl pollock	2,242	n/a
Pollock/Atka mackerel/other species [2 3]	207	n/a
Red king crab savings subarea non-pelagic trawl gear [4]	n/a	24,250
Total trawl PSC	2,742	97,000

[1] "Other flatfish" for PSC monitoring includes all flatfish species, except for halibut (a prohibited species), arrowtooth flounder, flathead sole, Greenland turbot, Kamchatka flounder, rock sole, and yellowfin sole.
[2] Pollock other than pelagic trawl pollock, Atka mackerel, and "other species" fishery category.
[3] "Other species" for PSC monitoring includes sculpins, sharks, skates, squids, and octopuses.
[4] In October 2015 the Council recommended that the red king crab bycatch limit for non-pelagic trawl fisheries within the RKCSS be limited to 25 percent of the red king crab PSC allowance (see § 679.21(e)(3)(ii)(B)(*2*)).

TABLE 10—PROPOSED 2016 AND 2017 PROHIBITED SPECIES BYCATCH ALLOWANCES FOR THE BSAI TRAWL LIMITED ACCESS SECTOR

BSAI trawl limited access fisheries	Prohibited species and area [1]				
	Halibut mortality (mt) BSAI	Red king crab (animals) Zone 1	*C. opilio* (animals) COBLZ	*C. bairdi* (animals)	
				Zone 1	Zone 2
Yellowfin sole	167	23,338	1,273,886	293,234	1,005,879
Rock sole/flathead sole/other flatfish [2]	0	0	0	0	0
Greenland turbot/arrowtooth flounder/Kamchatka flounder/sablefish	0	0	0	0	0
Rockfish April 15–December 31	5	0	2,104	0	849
Pacific cod	453	2,954	54,298	50,816	42,424
Pollock/Atka mackerel/other species [3]	250	197	21,046	4,235	4,242
Total BSAI trawl limited access PSC	875	26,489	1,351,334	348,285	1,053,394

[1] Refer to § 679.2 for definitions of areas.
[2] "Other flatfish" for PSC monitoring includes all flatfish species, except for halibut (a prohibited species), arrowtooth flounder, flathead sole, Greenland turbot, Kamchatka flounder, rock sole, and yellowfin sole.
[3] "Other species" for PSC monitoring includes sculpins, sharks, skates, squids, and octopuses.

TABLE 11—PROPOSED 2016 AND 2017 HALIBUT PROHIBITED SPECIES BYCATCH ALLOWANCES FOR NON-TRAWL FISHERIES

Halibut mortality (mt) BSAI				
Non-trawl fisheries	Seasons	Catcher/ processor	Catcher vessel	All Non-trawl
Pacific cod	Total Pacific cod	760	15	775
	January 1–June 10	455	10	n/a
	June 10–August 15	190	3	n/a
	August 15–December 31	115	2	n/a
Non-Pacific cod non-trawl	May 1–December 31	n/a	n/a	58
Groundfish pot and jig	n/a	n/a	n/a	Exempt
Sablefish hook-and-line	n/a	n/a	n/a	Exempt
Total for all non-trawl PSC	n/a	n/a	n/a	833

TABLE 12—PROPOSED 2016 PROHIBITED SPECIES BYCATCH ALLOWANCE FOR THE BSAI AMENDMENT 80 COOPERATIVES

Cooperative	Prohibited species and zones [1]				
	Halibut mortality (mt) BSAI	Red king crab (animals) Zone 1	*C. opilio* (animals) COBLZ	*C. bairdi* (animals)	
				Zone 1	Zone 2
Alaska Groundfish Cooperative	632	12,459	650,551	82,136	137,369
Alaska Seafood Cooperative	1,693	30,834	1,415,973	229,979	395,291

[1] Refer to § 679.2 for definitions of zones.

Halibut Discard Mortality Rates (DMRs)

To monitor halibut bycatch mortality allowances and apportionments, the Regional Administrator uses observed halibut bycatch rates, DMRs, and estimates of groundfish catch to project when a fishery's halibut bycatch mortality allowance or seasonal apportionment is reached. The DMRs are based on the best information available, including information contained in the annual SAFE report.

NMFS proposes the halibut DMRs developed and recommended by the International Pacific Halibut Commission (IPHC) and the Council for the 2016 and 2017 BSAI groundfish fisheries for use in monitoring the 2016 and 2017 halibut bycatch allowances (see Tables 8, 10, 11, and 12). The IPHC developed these DMRs for the 2016 to 2017 BSAI fisheries using the 10-year mean DMRs for those fisheries. The IPHC will analyze observer data annually and recommend changes to the DMRs when a fishery DMR shows large variation from the mean. A discussion of the DMRs and their justification is available from the Council (see **ADDRESSES**). Table 13 lists the 2016 and 2017 DMRs.

TABLE 13—PROPOSED 2016 AND 2017 ASSUMED PACIFIC HALIBUT DISCARD MORTALITY RATES FOR THE BSAI

Gear	Fishery	Halibut discard mortality rate (percent)
Non-CDQ hook-and-line	Greenland turbot	11
	Other species [1]	9
	Pacific cod	9
	Rockfish	4
Non-CDQ trawl	Alaska plaice	66
	Arrowtooth flounder	84
	Atka mackerel	82
	Flathead sole	72
	Greenland turbot	82
	Kamchatka flounder	84
	Non-pelagic pollock	81
	Pelagic pollock	88
	Other flatfish [2]	63
	Other species [1]	66
	Pacific cod	66
	Rockfish	83
	Rock sole	86
	Sablefish	75
	Yellowfin sole	84
Non-CDQ pot	Other species [1]	20
	Pacific cod	20
CDQ trawl	Atka mackerel	82
	Arrowtooth flounder	84
	Flathead sole	79
	Kamchatka flounder	84
	Non-pelagic pollock	86

TABLE 13—PROPOSED 2016 AND 2017 ASSUMED PACIFIC HALIBUT DISCARD MORTALITY RATES FOR THE BSAI—Continued

Gear	Fishery	Halibut discard mortality rate (percent)
	Pelagic pollock	90
	Pacific cod	87
	Greenland turbot	89
	Rockfish	69
	Rock sole	86
	Yellowfin sole	85
CDQ hook-and-line	Greenland turbot	4
	Pacific cod	10
CDQ pot	Pacific cod	8
	Sablefish	41

[1] ''Other species'' includes skates, sculpins, sharks, squids, and octopuses.
[2] ''Other flatfish'' includes all flatfish species, except for halibut (a prohibited species), flathead sole, Greenland turbot, rock sole, yellowfin sole, Kamchatka flounder, and arrowtooth flounder.

Listed AFA Catcher/Processor Sideboard Limits

Pursuant to § 679.64(a), the Regional Administrator is responsible for restricting the ability of listed AFA catcher/processors to engage in directed fishing for groundfish species other than pollock, to protect participants in other groundfish fisheries from adverse effects resulting from the AFA and from fishery cooperatives in the directed pollock fishery. These restrictions are set out as ''sideboard'' limits on catch. The basis for these proposed sideboard limits is described in detail in the final rules implementing the major provisions of the AFA (67 FR 79692, December 30, 2002) and Amendment 80 (72 FR 52668, September 14, 2007). Table 14 lists the proposed 2016 and 2017 catcher/processor sideboard limits.

All harvests of groundfish sideboard species by listed AFA catcher/processors, whether as targeted catch or incidental catch, will be deducted from the sideboard limits in Table 14. However, groundfish sideboard species that are delivered to listed AFA catcher/processors by catcher vessels will not be deducted from the 2016 and 2017 sideboard limits for the listed AFA catcher/processors.

TABLE 14—PROPOSED 2016 AND 2017 BSAI GROUNDFISH SIDEBOARD LIMITS FOR LISTED AMERICAN FISHERIES ACT CATCHER/PROCESSORS (C/PS)

[Amounts are in metric tons]

Target species	Area	1995–1997			2016 and 2017 ITAC available to all trawl C/Ps [1]	2016 and 2017 AFA C/P sideboard limit
		Retained catch	Total catch	Ratio of retained catch to total catch		
Sablefish trawl	BS	8	497	0.016	515	8
	AI	0	145	0	348	0
Greenland turbot	BS	121	17,305	0.007	2,081	15
	AI	23	4,987	0.005	170	1
Arrowtooth flounder	BSAI	76	33,987	0.002	18,700	37
Kamchatka flounder	BSAI	76	33,987	0.002	5,525	11
Rock sole	BSAI	6,317	169,362	0.037	61,840	2,288
Flathead sole	BSAI	1,925	52,755	0.036	21,655	780
Alaska plaice	BSAI	14	9,438	0.001	15,725	16
Other flatfish	BSAI	3,058	52,298	0.058	3,077	178
Pacific ocean perch	BS	12	4,879	0.002	6,818	14
	Eastern AI	125	6,179	0.02	7,117	142
	Central AI	3	5,698	0.001	6,251	6
	Western AI	54	13,598	0.004	8,037	32
Northern rockfish	BSAI	91	13,040	0.007	2,763	19
Rougheye rockfish	EBS/EAI	50	2,811	0.018	149	3
	CAI/WAI	50	2,811	0.018	200	4
Shortraker rockfish	BSAI	50	2,811	0.018	250	5
Other rockfish	BS	18	621	0.029	325	9
	AI	22	806	0.027	555	15
Atka mackerel	Central AI					
	A season [2]	n/a	n/a	0.115	7,591	873
	B season [2]	n/a	n/a	0.115	7,591	873
	Western AI					
	A season [2]	n/a	n/a	0.2	4,689	938
	B season [2]	n/a	n/a	0.2	4,689	938
Skates	BSAI	553	68,672	0.008	21,845	175
Sculpins	BSAI	553	68,672	0.008	3,995	32
Sharks	BSAI	553	68,672	0.008	125	1
Squids	BSAI	73	3,328	0.022	340	7

TABLE 14—PROPOSED 2016 AND 2017 BSAI GROUNDFISH SIDEBOARD LIMITS FOR LISTED AMERICAN FISHERIES ACT CATCHER/PROCESSORS (C/PS)—Continued

[Amounts are in metric tons]

Target species	Area	1995–1997			2016 and 2017 ITAC available to all trawl C/Ps [1]	2016 and 2017 AFA C/P sideboard limit
		Retained catch	Total catch	Ratio of retained catch to total catch		
Octopuses	BSAI	553	68,672	0.008	400	3

[1] Aleutians Islands Pacific ocean perch, and BSAI Atka mackerel, flathead sole, rock sole, and yellowfin sole are multiplied by the remainder of the TAC after the subtraction of the CDQ reserve under § 679.20(b)(1)(ii)(C).

[2] The seasonal apportionment of Atka mackerel in the open access fishery is 50 percent in the A season and 50 percent in the B season. Listed AFA catcher/processors are limited to harvesting no more than zero in the Eastern Aleutian District and Bering Sea subarea, 20 percent of the annual ITAC specified for the Western Aleutian District, and 11.5 percent of the annual ITAC specified for the Central Aleutian District.

Note: Section 679.64(a)(1)(v) exempts AFA catcher/processors from a yellowfin sole sideboard limit because the 2016 and 2017 aggregate ITAC of yellowfin sole assigned to the Amendment 80 sector and BSAI trawl limited access sector is greater than 125,000 mt.

Section 679.64(a)(2) and Tables 40 and 41 to part 679 establish a formula for calculating PSC sideboard limits for listed AFA catcher/processors. The basis for these sideboard limits is described in detail in the final rules implementing the major provisions of the AFA (67 FR 79692, December 30, 2002) and Amendment 80 (72 FR 52668, September 14, 2007).

PSC species listed in Table 15 that are caught by listed AFA catcher/processors participating in any groundfish fishery other than pollock will accrue against the proposed 2016 and 2017 PSC sideboard limits for the listed AFA catcher/processors. Section 679.21(e)(3)(v) authorizes NMFS to close directed fishing for groundfish other than pollock for listed AFA catcher/processors once a proposed 2016 or 2017 PSC sideboard limit listed in Table 15 is reached.

Crab or halibut PSC caught by listed AFA catcher/processors while fishing for pollock will accrue against the bycatch allowances annually specified for either the midwater pollock or the pollock/Atka mackerel/''other species'' fishery categories, according to § 679.21(e)(3)(iv).

TABLE 15–PROPOSED 2016 AND 2017 BSAI PROHIBITED SPECIES SIDEBOARD LIMITS FOR AMERICAN FISHERIES ACT LISTED CATCHER/PROCESSORS

PSC species and area [1]	Ratio of PSC to total PSC	Proposed 2016 and 2017 PSC available to trawl vessels after subtraction of PSQ [2]	Proposed 2016 and 2017 C/P sideboard limit [2]
BSAI Halibut mortality	n/a	n/a	286
Red king crab Zone 1	0.007	86,621	606
C. opilio (COBLZ)	0.153	4,204,524	643,292
C. bairdi	n/a	n/a	n/a
Zone 1	0.14	741,190	103,767
Zone 2	0.05	2,250,360	112,518

[1] Refer to § 679.2 for definitions of areas.

[2] Halibut amounts are in metric tons of halibut mortality. Crab amounts are in numbers of animals.

AFA Catcher Vessel Sideboard Limits

Pursuant to § 679.64(b), the Regional Administrator is responsible for restricting the ability of AFA catcher vessels to engage in directed fishing for groundfish species other than pollock, to protect participants in other groundfish fisheries from adverse effects resulting from the AFA and from fishery cooperatives in the directed pollock fishery. Section 679.64(b) establishes formulas for setting AFA catcher vessel groundfish and PSC sideboard limits for the BSAI. The basis for these sideboard limits is described in detail in the final rules implementing the major provisions of the AFA (67 FR 79692, December 30, 2002) and Amendment 80 (72 FR 52668, September 14, 2007).

Tables 16 and 17 list the proposed 2016 and 2017 AFA catcher vessel sideboard limits.

All catch of groundfish sideboard species made by non-exempt AFA catcher vessels, whether as targeted catch or as incidental catch, will be deducted from the 2016 and 2017 sideboard limits listed in Table 16.

TABLE 16–PROPOSED 2016 AND 2017 BSAI GROUNDFISH SIDEBOARD LIMITS FOR AMERICAN FISHERIES ACT CATCHER VESSELS (CVS)

[Amounts are in metric tons]

Species	Fishery by area/gear/season	Ratio of 1995–1997 AFA CV catch to 1995–1997 TAC	2016 and 2017 initial TAC [1]	2016 and 2017 AFA catcher vessel sideboard limits
Pacific cod	BSAI	n/a	n/a	n/a
	Jig gear	0	3,118	0
	Hook-and-line CV	n/a	n/a	n/a
	Jan 1–Jun 10	0.0006	226	0
	Jun 10–Dec 31	0.0006	217	0
	Pot gear CV	n/a	n/a	n/a
	Jan 1–Jun 10	0.0006	9,507	6
	Sept 1–Dec 31	0.0006	9,134	5
	CV <60 ft LOA using hook-and-line or pot gear.	0.0006	4,438	3
	Trawl gear CV	n/a	n/a	n/a
	Jan 20–Apr 1	0.8609	36,426	31,359
	Apr 1–Jun 10	0.8609	5,415	4,662
	Jun 10–Nov 1	0.8609	7,384	6,357
Sablefish	BS trawl gear	0.0906	514	47
	AI trawl gear	0.0645	348	22
Greenland turbot	BS	0.0645	2,081	134
	AI	0.0205	170	3
Arrowtooth flounder	BSAI	0.069	18,700	1,290
Kamchatka flounder	BSAI	0.069	5,525	381
Rock sole	BSAI	0.0341	61,840	2,109
Flathead sole	BS trawl gear	0.0505	21,655	1,094
Alaska plaice	BSAI	0.0441	15,725	693
Other flatfish	BSAI	0.0441	3,077	136
Pacific ocean perch	BS	0.1	6,818	682
	Eastern AI	0.0077	7,117	55
	Central AI	0.0025	6,251	16
	Western AI	0	8,037	0
Northern rockfish	BSAI	0.0084	2,763	23
Rougheye rockfish	EBS/EAI	0.0037	149	1
	CAI/WAI	0.0037	200	1
Shortraker rockfish	BSAI	0.0037	250	1
Other rockfish	BS	0.0048	325	2
	AI	0.0095	555	5
Atka mackerel	Eastern AI/BS	n/a	n/a	n/a
	Jan 1–Jun 10	0.0032	12,197	39
	Jun 10–Nov 1	0.0032	12,197	39
	Central AI	n/a	n/a	n/a
	Jan 1–Jun 10	0.0001	7,591	1
	Jun 10–Nov 1	0.0001	7,591	1
	Western AI	n/a	n/a	n/a
	Jan 1–Jun 10	0	4,689	0
	Jun 10–Nov 1	0	4,689	0
Skates	BSAI	0.0541	21,845	1,182
Sculpins	BSAI	0.0541	3,995	216
Sharks	BSAI	0.0541	125	7
Squids	BSAI	0.3827	340	130
Octopuses	BSAI	0.0541	400	22

[1] Aleutians Islands Pacific ocean perch, Atka mackerel, flathead sole, rock sole, and yellowfin sole are multiplied by the remainder of the TAC of that species after the subtraction of the CDQ reserve under § 679.20(b)(1)(ii)(C).

Note: Section 679.64(b)(6) exempts AFA catcher vessels from a yellowfin sole sideboard limit because the 2016 and 2017 aggregate ITAC of yellowfin sole assigned to the Amendment 80 sector and BSAI trawl limited access sector is greater than 125,000 mt.

Halibut and crab PSC limits listed in Table 17 that are caught by AFA catcher vessels participating in any groundfish fishery other than pollock will accrue against the 2016 and 2017 PSC sideboard limits for the AFA catcher vessels. Sections 679.21(e)(7) and 679.21(e)(3)(v) authorize NMFS to close directed fishing for groundfish other than pollock for AFA catcher vessels once a proposed 2016 and 2017 PSC sideboard limit listed in Table 17 is reached. The PSC that is caught by AFA catcher vessels while fishing for pollock in the Bering Sea subarea will accrue against the bycatch allowances annually specified for either the midwater pollock or the pollock/Atka mackerel/''other species'' fishery categories under § 679.21(e)(3)(iv).

TABLE 17–PROPOSED 2016 AND 2017 AMERICAN FISHERIES ACT CATCHER VESSEL PROHIBITED SPECIES CATCH SIDEBOARD LIMITS FOR THE BSAI [1]

PSC species and area [1]	Target fishery category [2]	AFA catcher vessel PSC sideboard limit ratio	Proposed 2016 and 2017 PSC limit after subtraction of PSQ reserves [3]	Proposed 2016 and 2017 AFA catcher vessel PSC sideboard limit [3]
Halibut	Pacific cod trawl	n/a	n/a	887
	Pacific cod hook-and-line or pot	n/a	n/a	2
	Yellowfin sole total	n/a	n/a	101
	Rock sole/flathead sole/other flatfish [4]	n/a	n/a	228
	Greenland turbot/arrowtooth/Kamchatka flounder/sablefish	n/a	n/a	0
	Rockfish	n/a	n/a	2
	Pollock/Atka mackerel/other species [5]	n/a	n/a	5
Red king crab Zone 1	n/a	0.299	86,621	25,900
C. opilio COBLZ	n/a	0.168	4,204,524	706,360
C. bairdi Zone 1	n/a	0.33	741,190	244,593
C. bairdi Zone 2	n/a	0.186	2,250,360	418,567

[1] Refer to § 679.2 for definitions of areas.
[2] Target fishery categories are defined at § 679.21(e)(3)(iv).
[3] Halibut amounts are in metric tons of halibut mortality. Crab amounts are in numbers of animals.
[4] ''Other flatfish'' for PSC monitoring includes all flatfish species, except for halibut (a prohibited species), arrowtooth flounder, flathead sole, Greenland turbot, rock sole, and yellowfin sole.
[5] ''Other species'' for PSC monitoring includes skates, sculpins, sharks, squids, and octopuses.

Classification

NMFS has determined that the proposed harvest specifications are consistent with the FMP and preliminarily determined that the proposed harvest specifications are consistent with the Magnuson-Stevens Act and other applicable laws, and subject to further review after public comment.

This action is authorized under 50 CFR 679.20 and is exempt from review under Executive Orders 12866 and 13563.

NMFS prepared an EIS for this action and made it available to the public on January 12, 2007 (72 FR 1512). On February 13, 2007, NMFS issued the Record of Decision (ROD) for the Final EIS. A Supplemental Information Report (SIR) that assesses the need to prepare a Supplemental EIS is being prepared for the final action. Copies of the Final EIS, ROD, and SIR for this action are available from NMFS (see **ADDRESSES**). The Final EIS analyzes the environmental consequences of the proposed groundfish harvest specifications and alternative harvest strategies on resources in the action area. The Final EIS found no significant environmental consequences from the proposed action or its alternatives.

NMFS prepared an Initial Regulatory Flexibility Analysis (IRFA), as required by section 603 of the Regulatory Flexibility Act, analyzing the methodology for establishing the relevant TACs. The IRFA evaluates the impacts on small entities of alternative harvest strategies for the groundfish fisheries in the exclusive economic zone off Alaska. As set forth in the methodology, TACs are set to a level that falls within the range of ABCs recommended by the SSC; the sum of the TACs must achieve OY specified in the FMP. While the specific numbers that the methodology may produce vary from year to year, the methodology itself remains constant.

A description of the proposed action, why it is being considered, and the legal basis for this proposed action are contained in the preamble above. A copy of the analysis is available from NMFS (see **ADDRESSES**). A summary of the IRFA follows.

The action under consideration is a harvest strategy to govern the catch of groundfish in the BSAI. The preferred alternative is the existing harvest strategy in which TACs fall within the range of ABCs recommended by the SSC, but, as discussed below, NMFS considered other alternatives. This action is taken in accordance with the FMP prepared by the Council pursuant to the Magnuson-Stevens Act.

The entities directly regulated by this action are those that harvest groundfish in the exclusive economic zone of the BSAI and in parallel fisheries within State waters. These include entities operating catcher vessels and catcher/processors within the action area and entities receiving direct allocations of groundfish.

The Small Business Administration has established size standards for all major industry sectors in the United States. A business primarily involved in finfish harvesting is classified as a small business if it is independently owned and operated, is not dominant in its field of operation (including its affiliates), and has combined annual gross receipts not in excess of $20.5 million, for all its affiliated operations worldwide. The IRFA estimates the number of harvesting vessels that are considered small entities, but these estimates may overstate the number of small entities because (1) some vessels may also be active as tender vessels in the salmon fishery, fish in areas other than Alaska and the West Coast, or generate revenue from other non-fishing sources; and (2) all affiliations are not taken into account, especially if the vessel has affiliations not tracked in available data (*i.e.,* ownership of multiple vessel or affiliation with processors) and may be misclassified as a small entity. Because some catcher vessels and catcher/processors meet this size standard, they are considered to be small entities for the purposes of this analysis.

The estimated directly regulated small entities include approximately 190 catcher vessels, two catcher/processors, and six CDQ groups. Some of these vessels are members of AFA inshore pollock cooperatives, GOA rockfish cooperatives, or crab rationalization cooperatives, and, since under the Regulatory Flexibility Act (RFA) it is the aggregate gross receipts of all participating members of the cooperative that must meet the ''under $20.5 million'' threshold, they are considered to be large entities within the meaning of the RFA. Thus, the

estimate of 190 catcher vessels may be an overstatement of the number of small entities. Average gross revenues were $446,000 for small hook-and-line vessels, $1.31 million for small pot vessels, and $2.28 million for small trawl vessels. Revenue data for catcher/processors is confidential; however, in 2014, NMFS estimates that there are two catcher/processor small entities with gross receipts less than $20.5.

The preferred alternative (Alternative 2) was compared to four other alternatives. Alternative 1 would have set TACs to generate fishing rates equal to the maximum permissible ABC (if the full TAC were harvested), unless the sum of TACs exceeded the BSAI OY, in which case TACs would have been limited to the OY. Alternative 3 would have set TACs to produce fishing rates equal to the most recent 5-year average fishing rates. Alternative 4 would have set TACs equal to the lower limit of the BSAI OY range. Alternative 5, the ''no action'' alternative, would have set TACs equal to zero.

The TACs associated with the preferred harvest strategy are those adopted by the Council in October 2015, as per Alternative 2. OFLs and ABCs for the species were based on recommendations prepared by the Council's BSAI Plan Team in September 2015, and reviewed and modified by the Council's SSC in October 2015. The Council based its TAC recommendations on those of its AP, which were consistent with the SSC's OFL and ABC recommendations.

Alternative 1 selects harvest rates that would allow fishermen to harvest stocks at the level of ABCs, unless total harvests were constrained by the upper bound of the BSAI OY of two million mt. As shown in Table 1 of the preamble, the sum of ABCs in 2016 and 2017 would be about 2,731,897 mt, which falls above the upper bound of the OY range. The sum of TACs is equal to the sum of ABCs. In this instance, Alternative 1 is consistent with the preferred alternative (Alternative 2), meets the objectives of that action, and has small entity impacts that are equivalent to the preferred alternative.

Alternative 3 selects harvest rates based on the most recent 5 years of harvest rates (for species in Tiers 1 through 3) or for the most recent 5 years of harvests (for species in Tiers 4 through 6). This alternative is inconsistent with the objectives of this action, (the Council's preferred harvest strategy) because it does not take account of the most recent biological information for this fishery. NMFS annually conducts at-sea stock surveys for different species, as well as statistical modeling, to estimate stock sizes and permissible harvest levels. Actual harvest rates or harvest amounts are a component of these estimates, but in and of themselves may not accurately portray stock sizes and conditions. Harvest rates are listed for each species category for each year in the SAFE report (see **ADDRESSES**).

Alternative 4 would lead to significantly lower harvests of all species and reduce TACs from the upper end of the OY range in the BSAI, to its lower end of 1.4 million mt. Overall, this would reduce 2015 TACs by about 30 percent, which would lead to significant reductions in harvests of species by small entities. While reductions of this size would be associated with offsetting price increases, the size of these increases is very uncertain. While production declines in the BSAI would undoubtedly be associated with significant price increases in the BSAI, these increases would still be constrained by production of substitutes, and are very unlikely to offset revenue declines from smaller production. Thus, this alternative action would have a detrimental impact on small entities.

Alternative 5, which sets all harvests equal to zero, would have a significant adverse impact on small entities and would be contrary to obligations to achieve OY on a continuing basis, as mandated by the Magnuson-Stevens Act.

The proposed harvest specifications extend the current 2016 OFLs, ABCs, and TACs to 2016 and 2017. As noted in the IRFA, the Council may modify these OFLs, ABCs, and TACs in December 2015, when it reviews the November 2015 SAFE report from its groundfish Plan Team, and the December Council meeting reports of its SSC and AP. Because 2016 TACs in the proposed 2016 and 2017 harvest specifications are unchanged from the 2016 harvest specification TACs, NMFS does not expect adverse impacts on small entities. Also, NMFS does not expect any changes made by the Council in December 2015 to be large enough to have an impact on small entities.

This action does not modify recordkeeping or reporting requirements, or duplicate, overlap, or conflict with any Federal rules.

Adverse impacts on marine mammals resulting from fishing activities conducted under these harvest specifications are discussed in the Final EIS (see **ADDRESSES**), and in the 2015 SIR (*http://alaskafisheries.noaa.gov/analyses/specs/15_16bsaigoasir.pdf*).

Authority: 16 U.S.C. 773 *et seq.;* 16 U.S.C. 1540(f); 16 U.S.C. 1801 *et seq.;* 16 U.S.C. 3631 *et seq.;* Pub. L. 105–277; Pub. L. 106–31; Pub. L. 106–554; Pub. L. 108–199; Pub. L. 108–447; Pub. L. 109–241; Pub. L. 109–479.

Dated: December 4, 2015.

Samuel D. Rauch III,

Deputy Assistant Administrator for Regulatory Programs, National Marine Fisheries Service.

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Notices

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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 COMMERCE

Foreign-Trade Zones Board

[B–82–2015]

Foreign-Trade Zone 149—Freeport, Texas; Application for Subzone Expansion, Subzone 149C, Phillips 66 Company, Brazoria County, Texas

An application has been submitted to the Foreign-Trade Zones Board (the Board) by Port Freeport, grantee of FTZ 149, requesting additional acreage within Subzone 149C on behalf of Phillips 66 Company located in Brazoria County, Texas. The application was submitted pursuant to the provisions of the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally docketed on December 4, 2015.

Subzone 149C was approved by the Board on September 25, 1997 (Board Order 920, 62 FR 51830, October 3, 1997) and currently consists of six sites totaling 2,095 acres: *Site 1* (1,315 acres)—main refinery and petrochemical complex located at Texas State Highway 35 at Farm Market Road 524, south of Sweeney; *Site 2* (160 acres)—Freeport I Terminal and storage facility located at County Road 731, some 28 miles southeast of the refinery; *Site 3* (183 acres)—six crude oil storage tanks at Jones Creek Terminal located at 6215 State Highway 36, some 17 miles southeast of the refinery; *Site 4* (34 acres)—San Bernard Terminal and storage facility located at County Road 378, 5 miles southeast of the refinery; *Site 5* (403 acres)—Clemens Terminal underground LPG storage located at County Road 314, 15 miles east of the refinery; and, *Site 6*—consisting of a six-mile pipeline. The applicant is requesting authority to expand existing Site 5 to include an additional 75 acres (new site total—478 acres). No authorization for production activity has been requested at this time.

In accordance with the Board's regulations, Camille Evans of the FTZ Staff is designated examiner to review the application and make recommendations to the Executive Secretary.

Public comment is invited from interested parties. Submissions shall be addressed to the Board's Executive Secretary at the address below. The closing period for their receipt is January 19, 2016. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to February 2, 2016.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the ''Reading Room'' section of the Board's Web site, which is accessible via *www.trade.gov/ftz.*

For further information, contact Camille Evans at *Camille.Evans@trade.gov* or (202) 482–2350.

Dated: December 4, 2015.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2015–31056 Filed 12–8–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[B–81–2015]

Foreign-Trade Zone 257—Imperial County, California; Application for Reorganization Under Alternative Site Framework

An application has been submitted to the Foreign-Trade Zones (FTZ) Board by the County of Imperial, California, grantee of FTZ 257, requesting authority to reorganize the zone under the alternative site framework (ASF) adopted by the FTZ Board (15 CFR 400.2(c)). The ASF is an option for grantees for the establishment or reorganization of zones and can permit significantly greater flexibility in the designation of new subzones or ''usage-driven'' FTZ sites for operators/users located within a grantee's ''service area'' in the context of the FTZ Board's standard 2,000-acre activation limit for a zone. The application was submitted pursuant to the Foreign-Trade Zones Act, as amended (19 U.S.C. 81a–81u), and the regulations of the Board (15 CFR part 400). It was formally docketed on December 3, 2015.

FTZ 257 was approved by the FTZ Board on October 9, 2003 (Board Order 1286, 68 FR 61393, October 28, 2003).

The current zone includes the following sites: *Site 1:* (597 acres)—Gateway of the Americas, State Route 7 and State Highway 98, Calexico; *Site 2:* (32 acres)—Airport Industrial Park, Jones Drive and Best Road with adjacent parcel on Duarte Street, Brawley; *Site 3:* (240.36 acres)—Calexico International Airport, 254–256 E. Anza Road and Second Street and Airport Road, Calexico; *Site 4:* (104 acres)—Calipatria Airport Industrial Park, Main Street, International Road and Lyerly Road, Calipatria; *Site 5:* (531 acres)—El Centro Community Redevelopment Agency project area, Danenberg Road, Dogwood Road and I–8, El Centro; *Site 6:* (3.46 acres)—Coppel Corporation, 503 Scaroni Road, Calexico; *Site 7:* (43 acres)—Imperial County Airport, State Highway 86 and Aten Road; *Site 8:* (115 acres)—Drewry Warehousing complex, 340 West Ralph Road, Imperial; *Site 9:* (45 acres)—Lucky Ranch Industrial Park, Best Road and Shank Road, Brawley; *Site 10:* (78.11 acres)—Desert Real Estate parcels, Cole Road and Sunset Boulevard, Calexico; *Site 11:* (35.47 acres)—Portico Industrial Park, Cole Road and Enterprise Boulevard, Calexico; *Site 12* (59.49 acres)—Kloke Tract, Cole Road and Camacho Road, Calexico; *Site 13* (57.45 acres)—Las Palmas/Estrada Business Park, Estrada Boulevard and Arguelles Street, Calexico; *Site 14* (7.54 acres)—Calexico Industrial Park, 190 East Cole Road and 2360, 2420, 2430, 4360 M.L. King Avenue, Calexico; *Site 15* (1.3 acres)—JE Exports, 701 Cesar Chavez Boulevard, Calexico; and, *Site 16* (0.96 acres)—JE Exports, 224 Grant Street, Calexico.

The grantee's proposed service area under the ASF would be Imperial County, California, as described in the application. If approved, the grantee would be able to serve sites throughout the service area based on companies' needs for FTZ designation. The application indicates that the proposed service area is within and adjacent to

the Calexico U.S. Customs and Border Protection port of entry.

The applicant is requesting authority to reorganize its existing zone to include existing Sites 1 through 5 and 7 through 14 as ''magnet'' sites and existing Sites 6, 15 and 16 as ''usage-driven'' sites. The ASF allows for the possible exemption of one magnet site from the ''sunset'' time limits that generally apply to sites under the ASF, and the applicant proposes that Site 1 be so exempted. No new subzones/usage-driven sites are being requested at this time.

In accordance with the FTZ Board's regulations, Christopher Kemp of the FTZ Staff is designated examiner to evaluate and analyze the facts and information presented in the application and case record and to report findings and recommendations to the FTZ Board.

Public comment is invited from interested parties. Submissions shall be addressed to the FTZ Board's Executive Secretary at the address below. The closing period for their receipt is February 8, 2016. Rebuttal comments in response to material submitted during the foregoing period may be submitted during the subsequent 15-day period to February 22, 2016.

A copy of the application will be available for public inspection at the Office of the Executive Secretary, Foreign-Trade Zones Board, Room 21013, U.S. Department of Commerce, 1401 Constitution Avenue NW., Washington, DC 20230–0002, and in the ''Reading Room'' section of the FTZ Board's Web site, which is accessible via *www.trade.gov/ftz.* For further information, contact Christopher Kemp at *Christopher.Kemp@trade.gov* or (202) 482–0862.

Dated: December 3, 2015.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2015–31079 Filed 12–8–15; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

[A–602–809, A–351–845, A–588–874, A–421–813, C–351–846]

Antidumping Duty Investigations of Certain Hot-Rolled Steel Flat Products From Australia, Brazil, Japan, and the Netherlands and Countervailing Duty Investigation of Certain Hot-Rolled Steel Flat Products From Brazil: Preliminary Determinations of Critical Circumstances

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On August 11, 2015, the Department of Commerce (the Department) received antidumping duty (AD) petitions concerning imports of certain hot-rolled steel flat products (hot-rolled steel) from Australia, Brazil, Japan, and the Netherlands, and a countervailing duty (CVD) petition concerning hot-rolled steel from Brazil.[1] On October 23, 2015, the Department received timely allegations, pursuant to sections 703(e)(1) and 733(e)(1) of the Tariff Act of 1930, as amended (the Act), and 19 CFR 351.206, that critical circumstances exist with respect to imports of the merchandise under investigation.[2] Based on information provided by the petitioners, data placed on the record of these investigations by the mandatory respondents, and data collected by the Department from Global Trade Atlas (GTA), the Department preliminarily determines that critical circumstances exist for imports of hot-rolled steel from certain producers and exporters from Brazil and Japan.

DATES: *Effective Date:* December 9, 2015.

FOR FURTHER INFORMATION CONTACT: Dmitry Vladimirov or Minoo Hatten, 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) 482–0665, and (202) 482–1690, respectively.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to 19 CFR 351.206(c)(2), the petitioners requested that the Department issue a preliminary affirmative determination of critical circumstances on an expedited basis. In accordance with sections 703(e)(1) and 733(e)(1) of the Act, because the petitioners submitted their critical circumstances allegations more than 20 days before the scheduled date of the final determination, the Department must promptly issue preliminary critical circumstances determinations.

Section 703(e)(1) of the Act provides that the Department will determine that critical circumstances exist in CVD investigations if there is a reasonable basis to believe or suspect: (A) That ''the alleged countervailable subsidy'' is inconsistent with the Agreement on Subsidies and Countervailing Measures (SCM Agreement) of the World Trade Organization, and (B) that ''there have been massive imports of the subject merchandise over a relatively short period.'' Section 733(e)(1) of the Act provides that the Department will preliminarily determine that critical circumstances exist in AD investigations if there is a reasonable basis to believe or suspect: (A)(i) That ''there is a history of dumping and material injury by reason of dumped imports in the United States or elsewhere of the subject merchandise,'' or (ii) that ''the person by whom, or for whose account, the merchandise was imported knew or should have known that the exporter was selling the subject merchandise at less than its fair value and that there was likely to be material injury by reason of such sales,'' and (B) that ''there have been massive imports of the subject merchandise over a relatively short period.'' Section 351.206(h)(2) of the Department's regulations provides that, generally, imports must increase by at least 15 percent during the ''relatively short period'' to be considered ''massive'' and section 351.206(i) defines a ''relatively short period'' as normally being the period beginning on the date the proceeding begins (*i.e.,* the date the petition is filed) [3] and ending at least three months later.[4] The

[1] *See* Petitions for the Imposition of Antidumping Duties on Imports of Certain Hot-Rolled Steel Flat Products from Australia, Brazil, Japan, Korea, the Netherlands, Turkey, and the United Kingdom, dated August 11, 2015, and Petitions for the Imposition of Countervailing Duties on Imports of Certain Hot-Rolled Steel Flat Products from Brazil, Korea, and Turkey, dated August 11, 2015 (collectively, the petitions). The petitioners for these investigations are AK Steel Corporation, ArcelorMittal USA LLC, Nucor Corporation, SSAB Enterprises, LLC, Steel Dynamics, Inc., and United States Steel Corporation (the petitioners).

[2] *See* Certain Hot-Rolled Steel Flat Products From Australia, Brazil, Japan and the Netherlands—Critical Circumstances Allegations, October 23, 2105, and Certain Hot-Rolled Steel Flat Products From Australia, Brazil, Japan and the Netherlands—Critical Circumstances Allegations, November 2, 2015 (making public certain information in Attachment 2 of original submission) (collectively, Critical Circumstances Allegation).

[3] *See* 19 CFR 351.102(b)(40) (providing that a proceeding begins on the date of the filing of a petition).

[4] *See* 19 CFR 351.206(i).

regulations also provide, however, that, if the Department ''finds that importers, or exporters or producers, had reason to believe, at some time prior to the beginning of the proceeding, that a proceeding was likely,'' the Department ''may consider a period of not less than three months from that earlier time.'' [5]

Alleged Countervailable Subsidies Are Inconsistent With the SCM Agreement

To determine whether an alleged countervailable subsidy is inconsistent with the SCM Agreement, in accordance with section 703(e)(1)(A) of the Act, the Department considered the evidence currently on the record of the Brazil CVD investigation. Specifically, as determined in our initiation checklist, the following subsidy programs, alleged in the petition and supported by information reasonably available to the petitioners, appear to be either export contingent or contingent upon the use of domestic goods over imported goods, which would render them inconsistent with the SCM Agreement: Reduction of Tax on Industrialized Products (IPI) for Machines and Equipment,[6] Brazil's Export Financing Program (PROEX),[7] Reintegra Program,[8] RECAP: Special Regime for the Acquisition of Capital Goods for Export Companies,[9] Integrated Drawback Scheme,[10] Export Credit Insurance and Guarantees,[11] Export Guarantee Fund,[12] Export Promotion and Marketing Assistance,[13] Banco do Brasil and Banco Nacional de Desenvolvimento Econômico e Social (BNDES) ExIm loans,[14] FINAME loans,[15] and Automatic BNDES.[16]

Therefore, the Department preliminarily determines for purposes of this critical circumstances determination that there are alleged subsidies in the Brazil CVD investigation that are inconsistent with the SCM Agreement.

History of Dumping and Material Injury/Knowledge of Sales Below Fair Value and Material Injury

In order to determine whether there is a history of dumping pursuant to section 733(e)(1)(A)(i) of the Act, the Department generally considers current or previous AD orders on subject merchandise from the country in question in the United States and current orders imposed by other countries with regard to imports of the same merchandise.[17] The Department has previously issued AD orders on hot-rolled flat-rolled carbon-quality steel products from Japan [18] and Brazil.[19] Moreover, there are current AD orders imposed by other World Trade Organization members against hot-rolled steel products from Brazil and Japan.[20] Certain HTS numbers subject to these Brazil and Japan orders overlap with HTS numbers listed in the scope of these hot-rolled steel investigations. Therefore, there is evidence of a history of dumping of subject merchandise exported from Brazil and Japan.

To determine whether importers knew or should have known that exporters were selling at less than fair value, we typically consider the magnitude of dumping margins, including margins alleged in petitions.[21] The Department has found margins of 15 to 25 percent (depending on whether sales are export price sales or constructed export price sales) to be sufficient for this purpose.[22] The Department initiated these AD investigations based on the following estimated dumping margins: 99.20 percent (Australia); 34.28 percent (Brazil); 16.15 to 34.53 percent (Japan); and 55.21 to 173.17 percent (Netherlands). All of these margins are above the 15 to 25 percent threshold.[23] Therefore, on that basis, we preliminarily conclude that importers knew or should have known that exporters in all four countries were selling subject merchandise at less than fair value.

To determine whether importers knew or should have known that there was likely to be material injury, we typically consider the preliminary injury determinations of the International Trade Commission (ITC).[24] If the ITC finds material injury (rather than the threat of injury), we normally find that the ITC's determination provided importers with sufficient knowledge of injury. In these investigations, the ITC's finding of material injury by reason of imports of hot-rolled steel from, *inter alia,* Australia, Brazil, Japan, and the Netherlands is sufficient to impute knowledge of the likelihood of material injury for each of these countries.[25]

Massive Imports

In determining whether there have been ''massive imports'' over a ''relatively short period,'' pursuant to sections 703(e)(1)(B) and 733(e)(1)(B) of the Act, the Department normally compares the import volumes of the subject merchandise for at least three months immediately preceding the filing of the petition (*i.e.,* the ''base

[5] *Id.*

[6] *See* Brazil CVD Initiation Checklist, August 31, 2015, at 7.

[7] *Id.,* at 12.

[8] *Id.*

[9] *Id.,* at 13.

[10] *Id.,* at 14.

[11] *Id.,* at 15.

[12] *Id.,* at 16.

[13] *Id.,* at 17.

[14] *Id.,* at 34.

[15] *Id.,* at 35.

[16] *Id.,* at 38.

[17] *See Certain Oil Country Tubular Goods From the People's Republic of China: Notice of Preliminary Determination of Sales at Less Than Fair Value, Affirmative Preliminary Determination of Critical Circumstances and Postponement of Final Determination,* 74 FR 59117, 59120 (November 17, 2009) unchanged in *Certain Oil Country Tubular Goods from the People's Republic of China: Final Determination of Sales at Less Than Fair Value, Affirmative Final Determination of Critical Circumstances and Final Determination of Targeted Dumping,* 75 FR 20335 (April 19, 2010).

[18] *See Antidumping Duty Order; Certain Hot-Rolled Flat-Rolled Carbon-Quality Steel Products From Japan,* 64 FR 34778 (June 29, 1999).

[19] *See Antidumping Duty Order: Certain Hot-Rolled Flat-Rolled Carbon Quality Steel Products from Brazil,* 67 FR 11093 (March 12, 2002).

[20] *See* Attachment 1 of Critical Circumstances Allegation (containing ''Semi-Annual Report Under Article 16.4 of the Agreement'' from Australia to World Trade Organization depicting ''Definitive Anti-Dumping Measures in Force, as of December 31, 2014'' which lists Hot Rolled Steel Coil from, Japan, *et.al.*; Semi-Annual Report Under Article 16.4 of the Agreement'' from Canada to World Trade Organization depicting ''Definitive Anti-Dumping Measures in Force, as of December 31, 2014'' which lists Certain Flat Hot-Rolled Carbon and Alloy Steel Sheet and Strip from Brazil, *et.al.*; and ''Semi-Annual Report Under Article 16.4 of the Agreement'' from Thailand to World Trade Organization depicting ''Definitive Anti-Dumping Measures in Force, as of December 31, 2014'' which lists Flat Hot Rolled Steel in Coils and not in Coils from Japan, *et.al.*).

[21] *See, e.g., Notice of Preliminary Determinations of Critical Circumstances: Certain Cold-Rolled Carbon Steel Flat Products from Australia, the People's Republic of China, India, the Republic of Korea, the Netherlands, and the Russian Federation,* 67 FR 19157, 19158 (April 18, 2002) (unchanged in the final determination).

[22] *See, e.g., Preliminary Determination of Sales at Less Than Fair Value: Certain Cut-to-Length Carbon Steel Plate from the People's Republic of China,* 62 FR 31972, 31978 (June 11, 1997) (unchanged in the final determination) and *Notice of Preliminary Determination of Sales at Less Than Fair Value, Negative Preliminary Determination of Critical Circumstances and Postponement of Final Determination: Certain Frozen and Canned Warmwater Shrimp From the Socialist Republic of Vietnam,* 69 FR 42672 (July 16, 2004) (unchanged in the final determination).

[23] *See Certain Hot-Rolled Steel Flat Products from Australia, Brazil, Japan, the Republic of Korea, the Netherlands, the Republic of Turkey, and the United Kingdom: Initiation of Less-Than-Fair-Value Investigations,* 80 FR 54261, 54265 (September 9, 2015).

[24] *See, e.g., Certain Potassium Phosphate Salts from the People's Republic of China: Preliminary Affirmative Determination of Critical Circumstances in the Antidumping Duty Investigation,* 75 FR 24572, 24573 (May 5, 2010), unchanged in *Certain Potassium Phosphate Salts from the People's Republic of China: Final Determination of Sales at Less Than Fair Value and Termination of Critical Circumstances Inquiry,* 75 FR 30377 (June 1, 2010).

[25] *See Certain Hot-Rolled Steel Flat Products from Australia, Brazil, Japan, Korea, the Netherlands, Turkey, and the United Kingdom,* Inv. Nos. 701–TA–545–547 and 731–TA–1291–1297 (Prelim), USITC Pub. 4570 (Oct. 2015) at 1.

period'') to a comparable period of at least three months following the filing of the petition (*i.e.,* the ''comparison period''). Imports normally will be considered massive when imports during the comparison period have increased by 15 percent or more compared to imports during the base period.

Based on evidence provided by the petitioners, the Department finds that pursuant to 19 CFR 351.206(i), importers, exporters or producers had reason to believe, at some time prior to the filing of the petition, that a proceeding was likely. Specifically, the Department concludes that the available factual information provided by the petitioners indicates that by June 2015, importers, exporters or producers had reason to believe that a proceeding was likely. The Department finds the following information relevant from the press articles the petitioners provided to support their claim of ''early knowledge'':

• On May 11, 2015, American Metal Market issued an article acknowledging an industry analyst at Morgan Stanley Equity Research indicating that ''flat-rolled steel trade cases could move forward soon due to congressional bickering surrounding Trade Promotion Authority (TPA).'' [26] That article included statements about the past and current state of hot-rolled coil prices, thereby indicating that the potential trade cases included hot-rolled steel.[27]

• On May 29, 2015, another industry source, Steel Business Briefer, indicated that an informant of a service center executive stated that he was 90 percent sure that a filing on flat-rolled products will take place next week (*i.e.,* in June). According to the informant, ''US sheet mills are waiting . . . to finish data collection . . . and that {one} mill has already contacted him to gather information. {US mills are} having trouble with their customers finding out how much import they're buying.'' [28] The article also included assessments on hot-rolled and cold-rolled coil prices, thereby demonstrating that the potential trade cases concerned both hot-rolled and cold-rolled products.[29]

• On June 4, 2015, a day after trade cases were filed on corrosion-resistant steel products, American Metal Market issued an article stating that this case was the ''first of many expected across U.S. steel markets in the coming weeks and months.'' Additionally, an industry analyst at Morgan Stanley Equity Research was quoted as saying that he believed that ''the {U.S} industry is also working on cold-rolled and potentially hot-rolled cases as well.'' [30]

• On June 9, 2015, American Metal Market issued an article providing commentary from the chairman, president, and chief executive officer (CEO) of AK Steel Corporation (one of the petitioning companies in this investigation), confirming that the trade cases on hot-rolled and cold-rolled coil were likely to come shortly after the already-filed trade case on corrosion-resistant steel. In particular, the author indicated that, according to the CEO, ''{d}omestic steelmakers are considering trade petitions against imports of hot-rolled and cold-rolled coil.'' Further, the CEO was quoted as saying, ''All aspects of the carbon product are being analyzed. Whether (hot-rolled coil) is the next case or the third case, all three are being looked at and one has been filed. . . The others are being evaluated . . . At this point, we look to our advisors and our lawyers to give us the go-ahead. . .'' [31]

The above references, by industry specialists and authorities, to the impending trade cases on hot-rolled steel indicate that steel importers, exporters, and producers had, by the end of June 2015, sufficiently credible reasons to believe that forthcoming petitions were likely.[32]

Thus, in order to determine whether there has been a massive surge in imports for each cooperating mandatory respondent, the Department compared the total volume of shipments during the period June 2015 through October 2015 (all months for which data was available) with the volume of shipments during the preceding five-month period of January 2015 through May 2015. For ''all others,'' the Department compared GTA data for the period June 2015 through September 2015 (the last month for which GTA data is currently available) with data for the preceding four-month period of February 2014 through May 2015.[33] We subtracted shipments reported by the mandatory respondents from the GTA data. With respect to Australia and the Netherlands, the shipment data do not demonstrate massive surges in imports for any producers/exporters. Therefore, we are reaching a preliminary negative critical circumstances determination with respect to Australia and the Netherlands. With respect to Brazil and Japan, we preliminarily determine the following producers/exporters had massive surges in imports.[34]

• Brazil (A–351–845 and C–351–846): Companhia Siderugica Nacional (CSN), Usinas Siderurgicas da Minas Gerais S.A. (Usiminas);

[26] *See* Critical Circumstances Allegation at Attachment 2.

[27] *Id.*

[28] *Id.*

[29] *Id.*

[30] *Id.*

[31] *Id.*

[32] In its November 3, 2015, submission, a Japanese producer, Nippon Steel & Sumitomo Metal Corporation, commented that the Department has previously rejected the mere presence of rumors in press articles as being too speculative to form a basis for imputing knowledge that a petition was likely. Similarly, in its November 13, 2015, comments, a Dutch producer, Tata Steel IJmuiden B.V., commented that none of the articles the petitioners cited rise to anything above speculation, claiming that the strongest characterization of the articles that could be made concerning hot-rolled steel is that the U.S. industry was looking into whether a case could be brought, not that a case would be initiated and that such an initiation was imminent. In its November 2, 2015, submission, an Australian producer/exporter, BlueScope Steel Ltd. (BlueScope) asserted that ''the existence of one or two uncorroborated rumors reported in the press articles in June 2015, hardly constitutes a 'reason to believe' that a case against hot-rolled steel . . . was 'likely,' as required by the regulations.'' On the basis of the information in various industry articles it submitted, BlueScope notes that, in many months leading up to the filing of a case against imports of coated steel in June 2015, a case against imports of hot-rolled steel had not been mentioned since the time it was first rumored in July 2014; and cases against imports of cold-rolled and coated steel had been repeatedly rumored but not filed. BlueScope argues that, given the repeated unreliability of rumors in the past, importers would have been understandably skeptical of any reports emerging in June 2015 of a case against imports of hot-rolled steel. We do not find interested parties' arguments persuasive. The records of these investigations show that rumors on trade cases against imports of corrosion-resistant, cold-rolled, and hot-rolled steels cases had been circulating as far back as 2014. The records also show that these three cases were often referenced collectively, or were simply referred to as ''flat rolled'' cases. When trade cases were actually filed on imports of corrosion-resistant steel in early June 2015, we find that this solidified rumors into the expectation among steel importers, exporters, and producers that forthcoming petitions on the remaining products (*i.e.,* cold-rolled and hot-rolled steels) were inevitable. This is corroborated by the statements from the CEO of AK Steel Corporation in the June 9, 2015, article by American Metal Market, which illuminated the imminence of trade cases on imports of cold-rolled and hot-rolled steel, stating that the requisite data were ''available'' and that other cases are ''going to follow'' pending legal approval.

[33] The Department gathered GTA data under the following harmonized tariff schedule numbers: 7208.10.1500, 7208.10.3000, 7208.10.6000, 7208.25.3000, 7208.25.6000, 7208.26.0030, 7208.26.0060, 7208.27.0030, 7208.27.0060, 7208.36.0030, 7208.36.0060, 7208.37.0030, 7208.37.0060, 7208.38.0015, 7208.38.0030, 7208.38.0090, 7208.39.0015, 7208.39.0030, 7208.39.0090, 7208.40.6030, 7208.40.6060, 7208.53.0000, 7208.54.0000, 7208.90.0000, 7210.70.3000, 7211.14.0030, 7211.14.0090, 7211.19.1500, 7211.19.2000, 7211.19.3000, 7211.19.4500, 7211.19.6000, 7211.19.7530, 7211.19.7560, 7211.19.7590, 7225.11.0000, 7225.19.0000, 7225.30.3050, 7225.30.7000, 7225.40.7000, 7225.99.0090, 7226.11.1000, 7226.11.9030, 7226.11.9060, 7226.19.1000, 7226.19.9000, 7226.91.5000, 7226.91.7000, and 7226.91.8000.

[34] *See* respective preliminary critical circumstances memoranda for each proceeding, dated concurrently with this notice.

• Japan (A–588–874): Nippon Steel & Sumikin Bussan Corporation (Nippon), JFE Steel Corporation (JFE);

Conclusion

Based on the criteria and findings discussed above, we preliminarily determine that critical circumstances exist with respect to imports of hot-rolled steel shipped by certain producers/exporters. Our findings are summarized as follows.

Country	Case No.	Affirmative preliminary critical circumstances determinations	Negative preliminary critical circumstances determinations
Australia	A–602–809	None	BlueScope; all other producers/exporters.
Brazil	A–351–845 C–351–846	CSN; Usiminas	All other producers/exporters.
Japan	A–588–874	Nippon; JFE	All other producers/exporters.
Netherlands	A–421–813	None	Tata; all other producers/exporters.

Final Critical Circumstances Determinations

We will issue final determinations concerning critical circumstances when we issue our final countervailing duty and less than fair value determinations. All interested parties will have the opportunity to address these determinations in case briefs to be submitted after completion of the preliminary countervailing duty and less than fair value determinations.

ITC Notification

In accordance with sections 703(f) and 733(f) of the Act, we have notified the ITC of our determinations.

Suspension of Liquidation

In accordance with section 703(e)(2) of the Act, because we have preliminarily found that critical circumstances exist with regard to exports made by certain producers and/or exporters, if we make an affirmative preliminary determination that countervailable subsidies have been provided to these same producers/exporters at above *de minimis* rates,[35] we will instruct U.S. Customs and Border Protection (CBP) to suspend liquidation of all entries of subject merchandise from these producers/exporters that are entered, or withdrawn from warehouse, for consumption on or after the date that is 90 days prior to the effective date of ''provisional measures'' (*e.g.,* the date of publication in the **Federal Register** of the notice of an affirmative preliminary determination that countervailable subsidies have been provided at above *de minimis* rates). At such time, we will also instruct CBP to require a cash deposit equal to the estimated preliminary subsidy rates reflected in the preliminary determination published in the **Federal Register**. This suspension of liquidation will remain in effect until further notice.

In accordance with section 733(e)(2) of the Act, because we have preliminarily found that critical circumstances exist with regard to exports made by certain producers and/or exporters, if we make an affirmative preliminary determination that sales at less than fair value have been made by these same producers/exporters at above *de minimis* rates,[36] we will instruct CBP to suspend liquidation of all entries of subject merchandise from these producers/exporters that are entered, or withdrawn from warehouse, for consumption on or after the date that is 90 days prior to the effective date of ''provisional measures'' (*e.g.,* the date of publication in the **Federal Register** of the notice of an affirmative preliminary determination of sales at less than fair value at above *de minimis* rates). At such time, we will also instruct CBP to require a cash deposit equal to the estimated preliminary dumping margins reflected in the preliminary determination published in the **Federal Register**. This suspension of liquidation will remain in effect until further notice.

This notice is issued and published pursuant to section 777(i) of the Act and 19 CFR 351.206(c)(2).

Dated: December 2, 2015.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2015–31083 Filed 12–8–15; 8:45 am]

BILLING CODE 3510–DS–P

[35] The preliminary determination in the countervailing duty investigation for Brazil is currently scheduled for January 8, 2016.

[36] The preliminary determinations concerning sales at less than fair value are due on March 8, 2016.

DEPARTMENT OF COMMERCE

International Trade Administration

[A–201–837; A–570–954]

Certain Magnesia Carbon Bricks From Mexico and the People's Republic of China: Final Results of Expedited Sunset Review of the Antidumping Duty Orders

AGENCY: Enforcement and Compliance, International Trade Administration, Department of Commerce.

SUMMARY: On August 3, 2015, the Department of Commerce (the ''Department'') initiated the first five-year (''sunset'') review of the antidumping duty orders on certain magnesia carbon bricks (''MCBs'') from Mexico and the People's Republic of China (''PRC'') pursuant to section 751(c) of the Tariff Act of 1930, as amended (the ''Act'').[1] On the basis of a notice of intent to participate and an adequate substantive response, filed on behalf of the domestic interested parties, as well as a lack of response from respondent interested parties, the Department conducted an expedited sunset review of the antidumping duty orders, pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2). As a result of this sunset review, the Department finds that revocation of the *Orders* would be likely to lead to continuation or recurrence of dumping at the levels indicated in the ''Final Results of Review'' section of this notice.

DATES: *Effective Date:* December 9, 2015.

FOR FURTHER INFORMATION CONTACT: Kenneth Hawkins, Enforcement and Compliance, Office V, International Trade Administration, U.S. Department of Commerce, 14th Street and

[1] *See Initiation of Five-Year (''Sunset'') Review,* 80 FR 45945 (August 3, 2015) (''*Initiation Notice*''); *see also Notice of Antidumping Duty Order: Certain Magnesia Carbon Bricks from Mexico and the People's Republic of China: Antidumping Orders,* 75 FR 57257 (September 20, 2010) (''*Orders*'').

Constitution Avenue NW., Washington, DC 20230; telephone: (202) 482–6491.

SUPPLEMENTARY INFORMATION:

Background

On August 3, 2015, the Department initiated the first sunset review of the antidumping duty orders on MCBs from Mexico and the PRC, pursuant to section 751(c) of the Act and 19 CFR 351.218(c)(1).[2] The Department received a notice of intent to participate from the Magnesia Carbon Bricks Fair Trade Committee (Petitioners) within the deadline specified in 19 CFR 351.218(d)(1)(i).[3] Petitioners claimed interested party status under section 771(9)(C) of the Act, as manufacturers of a domestic like product in the United States.

We received a complete substantive response from Petitioners within the 30-day deadline specified in 19 CFR 351.218(d)(3)(i).[4] We received no responses from respondent interested parties. As a result, the Department conducted an expedited sunset review of the *Order,* pursuant to section 751(c)(3)(B) of the Act and 19 CFR 351.218(e)(1)(ii)(C)(2).

Scope of the Orders

Imports covered by the *Orders* consist of certain chemically bonded (resin or pitch), MCBs with a magnesia component of at least 70 percent magnesia (''MgO'') by weight, regardless of the source of raw materials for the MgO, with carbon levels ranging from trace amounts to 30 percent by weight, regardless of enhancements, (for example, MCBs can be enhanced with coating, grinding, tar impregnation or coking, high temperature heat treatments, anti-slip treatments or metal casing) and regardless of whether or not anti-oxidants are present (for example, antioxidants can be added to the mix from trace amounts to 15 percent by weight as various metals, metal alloys, and metal carbides). Certain MCBs that are the subject of this investigation are currently classifiable under subheadings 6902.10.1000, 6902.10.5000, 6815.91.0000, 6815.99.2000, and 6815.99.4000 of the Harmonized Tariff Schedule of the United States (''HTSUS''). While HTSUS subheadings are provided for convenience and customs purposes, the written description is dispositive.

[2] *See Initiation Notice.*

[3] *See* Letter from the domestic interested parties, dated August 18, 2015.

[4] *See* Substantive Responses of the domestic interested parties, dated September 2, 2015.

Analysis of Comments Received

All issues raised in this review are addressed in the ''Issues and Decision Memorandum for the Expedited Sunset Review of the Antidumping Duty Order on Certain Magnesia Carbon Bricks from Mexico and the People's Republic of China'' (''Decision Memorandum'') from Christian Marsh, Deputy Assistant Secretary, Office V, Antidumping and Countervailing Duty Operations, to Paul Piquado, Assistant Secretary for Enforcement and Compliance, dated concurrently with and hereby adopted by this notice. The issues discussed in the Decision Memorandum include the likelihood of continuation or recurrence of dumping and the magnitude of the margins likely to prevail if the *Orders* were to be revoked. Parties may find a complete discussion of all issues raised in the review and the corresponding recommendations in this public memorandum which is on file electronically via Enforcement and Compliance's Antidumping and Countervailing Duty Centralized Electronic Services System (''ACCESS''). Access to ACCESS is available in the Central Records Unit Room B8024 of the main Commerce building. In addition, a complete version of the Decision Memorandum can be accessed directly on the Web at *http://trade.gov/enforcement.* The signed Decision Memorandum and the electronic version of the Decision Memorandum are identical in content.

Final Results of Review

Pursuant to sections 752(c)(1) and (3) of the Act, we determine that revocation of the antidumping duty order on MCBs from Mexico and the PRC would be likely to lead to continuation or recurrence of dumping at weighted-average margins up to 57.90 percent for Mexico and up to 236 percent for the PRC.

Notice Regarding Administrative Protective Order (''APO'')

This notice also serves as the only reminder to parties subject to administrative protective order (''APO'') of their responsibility concerning the return or destruction of proprietary information disclosed under APO in accordance with 19 CFR 351.305. Timely notification of the return or destruction of APO materials or conversion to judicial protective order is hereby requested. Failure to comply with the regulations and terms of an APO is a violation which is subject to sanction.

This sunset review and notice are in accordance with sections 751(c), 752(c), and 777(i)(1) of the Act and 19 CFR 351.218.

Dated: December 1, 2015.

Christian Marsh,

Deputy Assistant Secretary for Antidumping and Countervailing Duty Operations.

[FR Doc. 2015–31084 Filed 12–8–15; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648–XE282

Takes of Marine Mammals Incidental to Specified Activities; Taking Marine Mammals Incidental to Rocky Intertidal Monitoring Surveys Along the Oregon and California Coasts

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

ACTION: Notice; proposed incidental harassment authorization; request for comments.

SUMMARY: NMFS has received an application from the Partnership for Interdisciplinary Study of Coastal Oceans (PISCO) at the University of California (UC) Santa Cruz for an Incidental Harassment Authorization (IHA) to take marine mammals, by harassment, incidental to rocky intertidal monitoring surveys. Pursuant to the Marine Mammal Protection Act (MMPA), NMFS is requesting comments on its proposal to issue an IHA to PISCO to incidentally take, by Level B harassment only, marine mammals during the specified activity.

DATES: Comments and information must be received no later than January 8, 2016.

ADDRESSES: Comments on the application should be addressed to Jolie Harrison, Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service, 1315 East-West Highway, Silver Spring, MD 20910. The mailbox address for providing email comments is *ITP.Pauline@noaa.gov.* NMFS is not responsible for email comments sent to addresses other than the one provided here. Comments sent via email, including all attachments, must not exceed a 25-megabyte file size.

Instructions: All comments received are a part of the public record and will generally be posted to *http://www.nmfs.noaa.gov/pr/permits/incidental/research.htm* without change. All Personal Identifying Information (*e.g.,*

name, address) voluntarily submitted by the commenter may be publicly accessible. Do not submit Confidential Business Information or otherwise sensitive or protected information.

An electronic copy of the application containing a list of the references used in this document may be obtained by writing to the address specified above, telephoning the contact listed below (see **FOR FURTHER INFORMATION CONTACT**), or visiting the Internet at: *http://www.nmfs.noaa.gov/pr/permits/incidental/research.htm.* PISCO's 2014–2015 monitoring report can also be found at this Web site. Documents cited in this notice may also be viewed, by appointment, during regular business hours, at the aforementioned address.

FOR FURTHER INFORMATION CONTACT: Rob Pauline, 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.

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, other means of effecting the least practicable impact on the species or stock and its habitat, 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 August 10, 2015 NMFS received an application from PISCO for the taking of marine mammals incidental to rocky intertidal monitoring surveys along the Oregon and California coasts. NMFS determined that the application was adequate and complete on October 9, 2015. In December 2012, NMFS issued a 1-year IHA to PISCO to take marine mammals incidental to these same proposed activities (77 FR 72327, December 5, 2012). In December 2013, NMFS issued a second 1-year IHA to PISCO to take marine mammals incidental to these same proposed activities (78 FR 79403, December 30, 2013). The 2013 IHA expired on December 16, 2014. A third IHA was issued to PISCO with an effective date of December 17, 2014 (79 FR 73048, December 9, 2014) to take animals for these identical activities and expires on December 16, 2015.

The research group at UC Santa Cruz operates in collaboration with two large-scale marine research programs: PISCO and the Multi-agency Rocky Intertidal Network (MARINe). The research group at UC Santa Cruz (PISCO) is responsible for many of the ongoing rocky intertidal monitoring programs along the Pacific coast. Monitoring occurs at rocky intertidal sites, often large bedrock benches, from the high intertidal to the water's edge. Long-term monitoring projects include Community Structure Monitoring, Intertidal Biodiversity Surveys, Marine Protected Area Baseline Monitoring, Intertidal Recruitment Monitoring, and Ocean Acidification. Research is conducted throughout the year along the California and Oregon coasts and will continue indefinitely. Most sites are sampled one to two times per year over a 4–6 hour period during a negative low tide series. This IHA, if issued, would only be effective for a 12-month period. The following specific aspects of the proposed activities are likely to result in the take of marine mammals: Presence of survey personnel near pinniped haulout sites and unintentional approach of survey personnel towards hauled out pinnipeds. Take, by Level B harassment only, of individuals of California sea lions (*Zalophus californianus*), harbor seals (*Phoca vitulina richardii*), Steller sea lions (*Eumetopias jubatus*) and northern elephant seals (*Mirounga angustirostris*) is anticipated to result from the specified activity.

Description of the Specified Activity

Overview

PISCO proposes to continue rocky intertidal monitoring work that has been ongoing for 20 years. PISCO focuses on understanding the nearshore ecosystems of the U.S. west coast through a number of interdisciplinary collaborations. The program integrates long-term monitoring of ecological and oceanographic processes at dozens of sites with experimental work in the lab and field. A short description of each project is contained here. Additional information can be found in PISCO's application (see **ADDRESSES**).

Dates and Duration

PISCO's research is conducted throughout the year. Most sites are sampled one to two times per year over a 1-day period (4–6 hours per site) during a negative low tide series. Due to the large number of research sites, scheduling constraints, the necessity for negative low tides and favorable weather/ocean conditions, exact survey dates are variable and difficult to predict. Some sampling is anticipated to occur in all months.

Specified Geographic Region

Sampling sites occur along the California and Oregon coasts. Community Structure Monitoring sites range from Ecola State Park near Cannon Beach, Oregon to Government Point located northwest of Santa Barbara, California. Biodiversity Survey sites extend from Ecola State Park south to Cabrillo National Monument in San Diego County, California. Exact locations of sampling sites can be found in Tables 1 and 2 of PISCO's application (see **ADDRESSES**).

Detailed Description of Activities

Community Structure Monitoring involves the use of permanent photoplot quadrats which target specific algal and invertebrate assemblages (*e.g.*, mussels, rockweeds, barnacles). Each photoplot is photographed and scored for percent cover. The Community Structure Monitoring approach is based largely on surveys that quantify the percent cover and distribution of algae and invertebrates that constitute these communities. This approach allows researchers to quantify both the patterns of abundance of targeted species, as well as characterize changes in the communities in which they reside. Such information provides managers with insight into the causes and consequences of changes in species

abundance. There are 47 Community Structure sites, each of which is surveyed over a 1-day period during a low tide series one to two times a year.

Biodiversity Surveys are part of a long-term monitoring project and are conducted every 3–5 years across 140 established sites. These surveys involve point contact identification along permanent transects, mobile invertebrate quadrat counts, sea star band counts, and tidal height topographic measurements. Five sites will be visited as part of this proposed IHA including Government Point, Arroyo Hondo, Coal Oil Point, Mussel Shoals and Treasure Island.

In September 2007, the state of California began establishing a network of Marine Protected Areas along the California coast as part of the Marine Life Protection Act (MLPA). Under baseline monitoring programs funded by Sea Grant and the Ocean Protection Council, PISCO established additional intertidal monitoring sites in the Central Coast, North Central Coast, and South Coast study regions. Baseline characterization of newly established areas involves sampling of these new sites, as well as established sites both within and outside of marine protected areas. These sites were sampled using existing Community Structure and Biodiversity protocols for consistency. Resampling of these sites may take place as part of future marine protected area evaluation.

The intertidal zones where PISCO conducts intertidal monitoring are also areas where pinnipeds can be found hauled out on the shore at or adjacent to some research sites. Accessing portions of the intertidal habitat may cause incidental Level B (behavioral) harassment of pinnipeds through some unavoidable approaches if pinnipeds are hauled out directly in the study plots or while biologists walk from one location to another. No motorized equipment is involved in conducting these surveys.

Description of Marine Mammals in the Area of the Specified Activity

Several pinniped species can be found along the California and Oregon coasts. The three that are most likely to occur at some of the research sites are California sea lion, harbor seal, and northern elephant seal. On rare occasions, PISCO researchers have seen very small numbers (*i.e.,* five or fewer) of Steller sea lions at one of the sampling sites. However, these sightings are rare.

We refer the public to Carretta *et al.* (2014) for general information on these species which are presented below this section. The publication is available at: *http://www.nmfs.noaa.gov/pr/sars/species.htm.* Additional information on the status, distribution, seasonal distribution, and life history can also be found in PISCO's application.

Northern Elephant Seal

Northern elephant seals are not listed as threatened or endangered under the Endangered Species Act (ESA), nor are they categorized as depleted under the MMPA. The estimated population of the California breeding stock is approximately 179,000 animals with a minimum population of 81,368 (Carretta *et al.,* 2014).

Northern elephant seals range in the eastern and central North Pacific Ocean, from as far north as Alaska and as far south as Mexico. Northern elephant seals spend much of the year, generally about nine months, in the ocean. They are usually underwater, diving to depths of about 330–800 m (1,000–2,500 ft) for 20- to 30-minute intervals with only short breaks at the surface. They are rarely seen out at sea for this reason. While on land, they prefer sandy beaches.

Northern elephant seals breed and give birth in California (U.S.) and Baja California (Mexico), primarily on offshore islands (Stewart *et al.,* 1994), from December to March (Stewart and Huber, 1993). Males feed near the eastern Aleutian Islands and in the Gulf of Alaska, and females feed further south, south of 45° N (Stewart and Huber, 1993; Le Boeuf *et al.,* 1993). Adults return to land between March and August to molt, with males returning later than females. Adults return to their feeding areas again between their spring/summer molting and their winter breeding seasons.

During PISCO research activities, the maximum number of northern elephant seals ever observed at a single site was at least 10 adults plus 10–20 sub-adults and pups. These were observed offshore of Piedras Blancas. The most recent monitoring report recorded 22 pups at Piedras Blancas resulting in the take of 4 pups. At other sites, elephant seals are very rarely observed during research activities.

California Sea Lion

California sea lions are not listed as threatened or endangered under the ESA, nor are they categorized as depleted under the MMPA. The California sea lion is now a full species, separated from the Galapagos sea lion (*Z. wollebaeki*) and the extinct Japanese sea lion (*Z. japonicus*) (Brunner, 2003; Wolf *et al.,* 2007; Schramm *et al.,* 2009). The estimated population of the U.S. stock of California sea lion is approximately 296,750 animals with a minimum of 153,337 individuals, and the current maximum population growth rate is 12 percent (Carretta *et al.,* 2014).

California sea lion breeding areas are on islands located in southern California, in western Baja California, Mexico, and the Gulf of California. During the breeding season, most California sea lions inhabit southern California and Mexico. Rookery sites in southern California are limited to the San Miguel Islands and the southerly Channel Islands of San Nicolas, Santa Barbara, and San Clemente (Carretta *et al.,* 2014). Males establish breeding territories during May through July on both land and in the water. Females come ashore in mid-May and June where they give birth to a single pup approximately 4–5 days after arrival and will nurse pups for about a week before going on their first feeding trip. Females will alternate feeding trips with nursing bouts until the pup is weaned between 4 and 10 months of age. In central California, a small number of pups are born on Ano Nuevo Island, Southeast Farallon Island, and occasionally at a few other locations; otherwise, the central California population is composed of non-breeders.

A 2005 haul-out count of California sea lions between the Oregon/California border and Point Conception as well as the Channel Islands found 141,842 individuals (Carretta *et al.,* 2010). The number of sea lions historically found at any one of PISCO's study sites is variable, and often no California sea lions are observed during sampling. The most recent monitoring report indicated a total of 23 adults and 7 pups distributed among 6 sites resulting in 19 total takes. However, a strong El Niño is underway which may significantly increase the numbers of California sea lions observed.

Pacific Harbor Seal

Pacific harbor seals are not listed as threatened or endangered under the ESA, nor are they categorized as depleted under the MMPA. The estimated population of the California stock of Pacific harbor seals is approximately 30,968 animals with a minimum estimated population size of 27,348. A 1999 census of the Oregon/Washington harbor seal stock found 24,732 (Carretta *et al.,* 2014).

The animals inhabit near-shore coastal and estuarine areas from Baja California, Mexico, to the Pribilof Islands in Alaska. Pacific harbor seals are divided into two subspecies: *P. v. stejnegeri* in the western North Pacific,

near Japan, and *P. v. richardii* in the northeast Pacific Ocean. The latter subspecies, recognized as three separate stocks, inhabits the west coast of the continental U.S., including: The outer coastal waters of Oregon and Washington states; Washington state inland waters; and Alaska coastal and inland waters.

In California, over 500 harbor seal haulout sites are widely distributed along the mainland and offshore islands, and include rocky shores, beaches and intertidal sandbars (Lowry *et al.,* 2005). Harbor seals mate at sea, and females give birth during the spring and summer, although, the pupping season varies with latitude. Pups are nursed for an average of 24 days and are ready to swim minutes after being born. Harbor seal pupping takes place at many locations, and rookery size varies from a few pups to many hundreds of pups. Pupping generally occurs between March and June, and molting occurs between May and July.

At several sites, harbor seals are often observed and have the potential to be disturbed by researchers accessing or sampling the site. The most recent monitoring report described a total of 48 adults and 4 pups distributed among sites. Observers recorded 37 total takes.

Steller Sea Lion

Steller sea lions range throughout the north Pacific from Japan to the Kamchatka Peninsula, along the Aleutian Islands, into the Gulf of Alaska, and down the west coast of North America to central California. Based on distribution, population dynamics, and genotypic data, the species occurring in United States waters has been divided into two stocks, the eastern U.S. stock (east of Cape Suckling, AK) and the western U.S. stock (west of Cape Sucking, AK) (Loughlin 1997). Breeding of the eastern stock occurs in rookeries in Alaska, British Columbia, Oregon, and California.

This species was hunted by indigenous peoples for several thousand years throughout its range and as recently as the 1990s in the Aleutian Islands. Individuals from British Columbia to California were also killed in the early 1900s to reduce competition with commercial fisheries. The species dramatically declined from the 1970s to 1990s due to competition with commercial fishing and long-term environmental changes (Reeves et al. 2002). There has also been a continued decrease in population numbers along the southern and central California coast possibly due to a northward shift, and subsequent southern contraction in breeding locations (Pitcher *et al.* 2007). In 1990, due to accelerating declines across its range, the species was listed as threatened under the ESA.

According to the 2013 Alaska Marine Mammal Stock Assessment, the minimum population size of the eastern Steller sea lion stock is 59,968 and the estimated population size is 63,160 to 78,198 individuals (Allen and Angliss 2014). In 2013 the eastern U.S. stock was determined to be recovered and was delisted from the ESA.

Past monitoring reports have not typically reported Steller sea lion observations. However, several years ago 5 Steller sea lions were observed at the Cape Arago, OR site.

Other Marine Mammals in the Proposed Action Area

California (southern) sea otters (*Enhydra lutris nereis*), listed as threatened under the ESA and categorized as depleted under the MMPA, usually range in coastal waters within 2 km (1.2 mi) of shore. This species is managed by the U.S. Fish and Wildlife Service and is not considered further in this notice. Guadalupe fur seals' (*Arctocephalus townsendi)* and Northern fur seals (*Callorhinus ursinus*) are occasionally observed within the range of the study areas. However, Guadalupe fur seals only known breeding colony is on Guadalupe Island, off the Mexican coast. Increasing numbers have been seen on California's Channel Islands, and in recent years, several Guadalupe fur seals have stranded along the central California coast. It is not yet known whether these strandings are a result of El Niño events (warmer water pushing their prey northward) or a sign of Guadalupe fur seals returning to their former range. Northern fur seals have recently re-established a rookery on the Farallon Islands. They rarely come ashore except during pupping and breeding times and are almost never seen on mainland beaches unless they are sick. Given that the likelihood of observing these two fur seal species is quite low, they are not considered further.

Potential Effects of the Specified Activity on Marine Mammals

This section includes a summary and discussion of the ways that the types of stressors associated with the specified activity (*e.g.,* personnel presence) have been observed to impact marine mammals. This discussion may also include reactions that we consider to rise to the level of a take and those that we do not consider to rise to the level of a take (for example, with acoustics, we may include a discussion of studies that showed animals not reacting at all to sound or exhibiting barely measurable avoidance). This section is intended as a background of potential effects and does not consider either the specific manner in which this activity will be carried out or the mitigation that will be implemented, and how either of those will shape the anticipated impacts from this specific activity.

The appearance of researchers may have the potential to cause Level B harassment of any pinnipeds hauled out at sampling sites. Although marine mammals are never deliberately approached by survey personnel, approach may be unavoidable if pinnipeds are hauled out in the immediate vicinity of the permanent study plots. Disturbance may result in reactions ranging from an animal simply becoming alert to the presence of researchers (*e.g.,* turning the head, assuming a more upright posture) to flushing from the haul-out site into the water. NMFS does not consider the lesser reactions to constitute behavioral harassment, or Level B harassment takes, but rather assumes that pinnipeds that flee some distance (assumed here to be two times their body length) or change the speed or direction of their movement in response to the presence of researchers are behaviorally harassed, and thus subject to Level B taking. Animals that respond to the presence of researchers by becoming alert, but do not move or change the nature of locomotion as described, are not considered to have been subject to behavioral harassment.

Numerous studies have shown that human activity can flush harbor seals off haulout sites (Allen *et al.,* 1985; Calambokidis *et al.,* 1991; Suryan and Harvey, 1999). The Hawaiian monk seal (*Monachus schauinslandi*) has been shown to avoid beaches that have been disturbed often by humans (Kenyon, 1972). And in one case, human disturbance appeared to cause Steller sea lions to desert a breeding area at Northeast Point on St. Paul Island, Alaska (Kenyon, 1962).

There are three ways in which disturbance, as described previously, could result in more than Level B harassment of marine mammals. All three are most likely to be consequences of stampeding, a potentially dangerous occurrence in which large numbers of animals succumb to mass panic and rush away from a stimulus. The three situations are (1) falling when entering the water at high-relief locations; (2) extended separation of mothers and pups; and (3) crushing of elephant seal pups by large males during a stampede.

Because hauled-out animals may move towards the water when disturbed, there is the risk of injury if animals stampede towards shorelines with precipitous relief (*e.g.,* cliffs). If disturbed, hauled-out animals in these situations may move toward the water without risk of encountering barriers or hazards that would otherwise prevent them from leaving the area. In these circumstances, the risk of injury, serious injury, or death to hauled-out animals is very low. Thus, research activity poses no risk that disturbed animals may fall and be injured or killed as a result of disturbance at high-relief locations. Furthermore, few pups are anticipated to be encountered during the proposed monitoring surveys. A small number of harbor seal, northern elephant seal and California sea lion pups, however, have been observed during past years. Though elephant seal pups are occasionally present when researchers visit survey sites, risk of pup mortalities is very low because elephant seals are far less reactive to researcher presence than the other two species. Harbor seals are very precocious with only a short period of time in which separation of a mother from a pup could occur. Pups are also typically found on sand beaches, while study sites are located in the rocky intertidal zone, meaning that there is typically a buffer between researchers and pups. Finally, the caution used by researchers in approaching sites generally precludes the possibility of behavior, such as stampeding, that could result in extended separation of mothers and dependent pups or trampling of pups.

Anticipated Effects on Marine Mammal Habitat

The only habitat modification associated with the proposed activity is the placement of permanent bolts and other sampling equipment in the intertidal. Once a particular study has ended, the respective sampling equipment is removed. No trash or field gear is left at a site. I Sampling activities are also not expected to result in any long-term modifications of haulout use or abandonment of haulouts since these sites are only visited 1–2 times per year which minimizes repeated disturbances. During periods of low tide (*e.g.,* when tides are 0.6 m (2 ft) or less and low enough for pinnipeds to haul-out), we would expect the pinnipeds to return to the haulout site within 60 minutes of the disturbance (Allen *et al.,* 1985). The effects to pinnipeds appear at the most to displace the animals temporarily from their haul out sites, and we do not expect that the pinnipeds would permanently abandon a haul-out site during the conduct of rocky intertidal surveys. Thus, the proposed 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.

Proposed Mitigation

In order to issue an incidental take authorization (ITA) under section 101(a)(5)(D) of the MMPA, NMFS must, where applicable, 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

PISCO proposes to implement several mitigation measures to reduce potential take by Level B (behavioral disturbance) harassment. Measures include: (1) Conducting slow movements and staying close to the ground to prevent or minimize stampeding; (2) avoiding loud noises (*i.e.,* using hushed voices); (3) avoiding pinnipeds along access ways to sites by locating and taking a different access way and vacating the area as soon as sampling of the site is completed; (4) monitoring the offshore area for predators (such as killer whales and white sharks) and avoid flushing of pinnipeds when predators are observed in nearshore waters; (5) using binoculars to detect pinnipeds before close approach to avoid being seen by animals; and (6) only approaching pinnipeds when are located in the sampling plots if there are no other means to accomplish the survey (however, approach must be slow and quiet so as not to cause a stampede).

The methodologies and actions noted in this section will be utilized and included as mitigation measures in any issued IHA to ensure that impacts to marine mammals are mitigated to the lowest level practicable. The primary method of mitigating the risk of disturbance to pinnipeds, which will be in use at all times, is the selection of judicious routes of approach to study sites, avoiding close contact with pinnipeds hauled out on shore, and the use of extreme caution upon approach. In no case will marine mammals be deliberately approached by survey personnel, unless they are located in sampling plots and there is no other method available and in all cases every possible measure will be taken to select a pathway of approach to study sites that minimizes the number of marine mammals potentially harassed. In general, researchers will stay inshore of pinnipeds whenever possible to allow maximum escape to the ocean. Each visit to a given study site will last for approximately 4–6 hours, after which the site is vacated and can be re-occupied by any marine mammals that may have been disturbed by the presence of researchers. By arriving before low tide, worker presence will tend to encourage pinnipeds to move to other areas for the day before they haul out and settle onto rocks at low tide.

PISCO will suspend sampling and monitoring operations immediately if an injured marine mammal is found in the vicinity of the project area and the monitoring activities could aggravate its condition.

Mitigation Conclusions

NMFS has carefully reviewed PISCO's proposed mitigation measures to ensure these measures would have the least practicable impact on the affected marine mammal species and stocks and their habitat. Our evaluation of potential 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 measure is 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 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 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 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 proposed measures, NMFS has preliminarily determined that the proposed mitigation measures provide the means of effecting the least practicable impact on marine mammal species or stocks and their habitat, paying particular attention to rookeries, mating grounds, and areas of similar significance.

Proposed Monitoring and Reporting

In order to issue an ITA for an activity, section 101(a)(5)(D) of the MMPA states that NMFS must, where applicable, set forth ''requirements pertaining to the monitoring and reporting of such taking''. The MMPA implementing regulations at 50 CFR 216.104(a)(13) indicate that requests for ITAs must include the suggested means of accomplishing the necessary monitoring and reporting that will result in increased knowledge of the species and of the level of taking or impacts on populations of marine mammals that are expected to be present in the proposed action area. PISCO has described their long-standing monitoring actions in Section 13 of the Application. The plan may be modified or supplemented based on comments or new information received from the public during the public comment period.

Monitoring measures proposed by the applicant or prescribed by NMFS should accomplish one or more of the following top-level goals:

1. An increase in our understanding of the likely occurrence of marine mammal species in the vicinity of the action, *i.e.,* presence, abundance, distribution, and/or density of species.

2. An increase in our understanding of the nature, scope, or context of the likely exposure of marine mammal species to any of the potential stressor(s) associated with the action (*e.g.,* sound or visual stimuli), through better understanding of one or more of the following: The action itself and its environment (*e.g.,* sound source characterization, propagation, and ambient noise levels); the affected species (*e.g.,* life history or dive pattern); the likely co-occurrence of marine mammal species with the action (in whole or part) associated with specific adverse effects; and/or the likely biological or behavioral context of exposure to the stressor for the marine mammal (*e.g.,* age class of exposed animals or known pupping, calving or feeding areas).

3. An increase in our understanding of how individual marine mammals respond (behaviorally or physiologically) to the specific stressors associated with the action (in specific contexts, where possible, *e.g.,* at what distance or received level).

4. An increase in our understanding of how anticipated individual responses, to individual stressors or anticipated combinations of stressors, may impact either: The long-term fitness and survival of an individual; or the population, species, or stock (*e.g.,* through effects on annual rates of recruitment or survival).

5. An increase in our understanding of how the activity affects marine mammal habitat, such as through effects on prey sources or acoustic habitat (*e.g.,* through characterization of longer-term contributions of multiple sound sources to rising ambient noise levels and assessment of the potential chronic effects on marine mammals).

6. An increase in understanding of the impacts of the activity on marine mammals in combination with the impacts of other anthropogenic activities or natural factors occurring in the region.

7. An increase in our understanding of the effectiveness of mitigation and monitoring measures.

8. An increase in the probability of detecting marine mammals (through improved technology or methodology), both specifically within the safety zone (thus allowing for more effective implementation of the mitigation) and in general, to better achieve the above goals.

PISCO will contribute to the knowledge of pinnipeds in California and Oregon by noting observations of: (1) Unusual behaviors, numbers, or distributions of pinnipeds, such that any potential follow-up research can be conducted by the appropriate personnel; (2) tag-bearing carcasses of pinnipeds, allowing transmittal of the information to appropriate agencies and personnel; and (3) rare or unusual species of marine mammals for agency follow-up.

Proposed monitoring requirements in relation to PISCO's rocky intertidal monitoring will include observations made by the applicant. Information recorded will include species counts (with numbers of pups/juveniles when possible) of animals present before approaching, numbers of observed disturbances, and descriptions of the disturbance behaviors during the monitoring surveys, including location, date, and time of the event. Disturbances will be recorded according to a three-point scale of intensity including: (1) Head orientation in response to disturbance, which may include turning head towards the disturbance, craning head and neck while holding the body rigid in a u-shaped position, or changing from a lying to a sitting position and/or slight movement of less than 1 m; ''alert''; (2) Movements in response to or away from disturbance, over short distances (typically two times its body length) and including dramatic changes in direction or speed of locomotion for animals already in motion; ''movement''; and (3) All flushes to the water as well as lengthier retreats (>3 m); ''flight''. Observations regarding the number and species of any marine mammals observed, either in the water or hauled out, at or adjacent to the site, will be recorded as part of field observations during research activities. Observations of unusual behaviors, numbers, or distributions of pinnipeds will be reported to NMFS so that any potential follow-up observations can be conducted by the appropriate personnel. In addition, observations of tag-bearing pinniped carcasses as well as any rare or unusual species of marine mammals will be reported to NMFS. Information regarding physical and biological conditions pertaining to a site, as well as the date and time that research was conducted will also be noted.

If at any time injury, serious injury, or mortality of the species for which take is authorized should occur, or if take of any kind of any other marine mammal occurs, and such action may be a result of the proposed research, PISCO will suspend research activities and contact NMFS immediately to determine how best to proceed to ensure that another injury or death does not occur and to ensure that the applicant remains in compliance with the MMPA.

A draft final report must be submitted to NMFS Office of Protected Resources within 60 days after the conclusion of the 2015–2016 field season or 60 days prior to the start of the next field season

if a new IHA will be requested. The report will include a summary of the information gathered pursuant to the monitoring requirements set forth in the IHA. A final report must be submitted to the Director of the NMFS Office of Protected Resources and to the NMFS West Coast Regional Administrator within 30 days after receiving comments from NMFS on the draft final report. If no comments are received from NMFS, the draft final report will be considered to be the final report.

Monitoring Results From Previously Authorized Activities

PISCO complied with the mitigation and monitoring that we required under the IHA issued in December 2014. In compliance with the IHA, PISCO submitted a report detailing the activities and marine mammal monitoring they conducted. The IHA required PISCO to conduct counts of pinnipeds present at study sites prior to approaching the sites and to record species counts and any observed reactions to the presence of the researchers.

From December 17, 2014, through September 30, 2015, PISCO researchers conducted rocky intertidal sampling at 61 sites over 48 days (see Table 6 in PISCO's 2014–2015 report). During this time period, no injured, stranded, or dead pinnipeds were observed. Tables 7, 8, and 9 in PISCO's monitoring report (see **ADDRESSES**) outline marine mammal observations and reactions. During this period there were 37 takes of harbor seals, 19 takes of California sea lions, and four takes of northern elephant seals. NMFS had authorized the take of 183 harbor seals, 60 California sea lions, and 30 Northern Elephant seals under the IHA. These takes are authorized to occur during 72 separate visits to all 47 Community Structure Monitoring sites and individual visits to five Biodiversity sites.

Based on the results from the monitoring report, we conclude that these results support our original findings that the mitigation measures set forth in the 2014–2015 IHA effected the least practicable impact on the species or stocks. There were no stampede events this year and most disturbances were level 1 and 2—meaning the animal did not fully flush but observed or moved slightly in response to researchers. Those that did fully flush to the water did so slowly. Flushing events have only occurred with harbor seals. Most of these animals tended to observe researchers from the water and then re-haulout farther upcoast or downcoast of the site within 30 minutes or so.

Estimated Take by Incidental Harassment

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].

All anticipated takes would be by Level B harassment, involving temporary changes in behavior. The proposed mitigation and monitoring measures are expected to minimize the possibility of injurious or lethal takes such that take by injury, serious injury, or mortality is considered remote. Animals hauled out close to the actual survey sites may be disturbed by the presence of biologists and may alter their behavior or attempt to move away from the researchers.

As discussed earlier, NMFS considers an animal to have been harassed if it moved greater than 2 times its body length in response to the researcher's presence or if the animal was already moving and changed direction and/or speed, or if the animal flushed into the water. Animals that became alert without such movements were not considered harassed.

For the purpose of this proposed IHA, only Oregon and California sites that are frequently sampled and have a marine mammal presence during sampling were included in generating take estimates. Sites where only Biodiversity Surveys are conducted did not provide enough data to confidently estimate takes since they are sampled infrequently (once very 3–5 years). A small number of harbor seal, northern elephant seal and California sea lion pup takes are anticipated as pups may be present at several sites during spring and summer sampling.

Take estimates are based on marine mammal observations from each site. Marine mammal observations are done as part of PISCO site observations, which include notes on physical and biological conditions at the site. The maximum number of marine mammals, by species, seen at any given time throughout the sampling day is recorded at the conclusion of sampling. A marine mammal is counted if it is seen on access ways to the site, at the site, or immediately up-coast or down-coast of the site. Marine mammals in the water immediately offshore are also recorded. Any other relevant information, including the location of a marine mammal relevant to the site, any unusual behavior, and the presence of pups is also noted.

These observations formed the basis from which researchers with extensive knowledge and experience at each site estimated the actual number of marine mammals that may be subject to take. In most cases the number of takes is based on the maximum number of marine mammals that have been observed at a site throughout the history of the site (1–3 observation per year for 5–10 years or more). Section 6 in PISCO's application outlines the number of visits per year for each sampling site and the potential number of pinnipeds anticipated to be encountered at each site. Tables 3, 4, 5 in PISCO's application outlines the number of potential takes per site (see **ADDRESSES**).

Harbor seals are expected to occur at 15 locations in numbers ranging from 30 per visit (25 adults and 5 pups) at the Pebble Beach site to 5 per visit (all adults) at the Shelter Cove, Kibesillah Hill, Sea Ranch and Franklin Point sites (Table 3 in Application). These numbers are based on past observations at each site as well as input from researchers with extensive knowledge of individual sites. NMFS took the number of takes estimated at each site, based on past observations as well as input from researchers with extensive site knowledge, and multiplied by the number of site visits scheduled during the authorization period. Nine sites were scheduled for one visit while six sites were projected to have 2 sites. A total of 190 adults and 13 pups were anticipated for take. Therefore, NMFS proposed the take of 203 harbor seals.

Due to the potentially significant effect of El Niño on California sea lions NMFS is proposing to increase the number of California sea lion takes beyond what PISCO requested. Changes in sea surface temperature associated with El Niño can have significant impacts throughout the food web. Historically, El Niño years have resulted in high numbers of marine mammal strandings, likely due to changes in prey availability and increased physiologic stress on the animals. NOAA fisheries west coast region office has reported elevated strandings at locations in central and southern California. For a five-month period from January to May 2015, strandings were over ten times higher than the average stranding level for the same 5 month period during 2004–2012. PISCO plans to conduct 8 visits under this authorization at 5 different sites during the one-year

authorization period (see Table 2 in Application). PISCO had requested 90 takes for these 8 visits at five sites. However, given the increased numbers of California Sea lions recorded earlier in 2015 during the current El Niño event, NMFS proposes to authorize 8 times that number for a total of 720 authorized takes. While all of the five sites may not experience numbers that are ten times greater than is typical it is likely that observations will be significantly elevated. As such, NMFS has elected to increase the total number of takes originally anticipated by PISCO by a factor of eight resulting in a proposed authorization of 720 California sea lion takes.

Northern elephant seals are only expected to occur at one site this year, Piedras Blancs, which will experience two separate visits. Up to twenty takes are expected during each visit for a total of 40 authorized takes.

Previously, PISCO researchers had voluntarily re-scheduled any surveys when Steller sea lions were present. Stellers were listed under the Endangered Species Act (ESA) and PISCO did not want to disturb any threatened or endangered species or enter into a formal ESA section 7 consultation with NMFS on an annual basis. However, Eastern Steller sea lions have been de-listed and, therefore, PISCO will continue with surveys when they are present. PISCO researchers report that they have very rarely observed Stellers at any of their research sites and none have been seen the last several years. Four or five years ago researchers did observe five Stellers at the Cape Arago, OR site. Therefore, NMFS has conservatively authorized the take of up to 10 Steller sea lions.

NMFS proposes to authorize the take, by Level B harassment only, of 720 California sea lions, 203 harbor seals, 40 northern elephant seals and 10 Steller sea lions. These numbers are considered to be maximum take estimates; therefore, actual take may be less if animals decide to haul out at a different location for the day or animals are out foraging at the time of the survey activities.

Analysis and Preliminary Determinations

Negligible Impact

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.

No injuries or mortalities are anticipated to occur as a result of PISCO's rocky intertidal monitoring, and none are proposed to be authorized. The risk of marine mammal injury, serious injury, or mortality associated with rocky intertidal monitoring increases somewhat if disturbances occur during breeding season. These situations present increased potential for mothers and dependent pups to become separated and, if separated pairs do not quickly reunite, the risk of mortality to pups (through starvation) may increase. Separately, adult male elephant seals may trample elephant seal pups if disturbed, which could potentially result in the injury, serious injury, or mortality of the pups. The risk of either of these situations is greater in the event of a stampede.

Very few pups are anticipated to be encountered during the proposed monitoring surveys. However, a small number of harbor seal, northern elephant seal and California sea lion pups have been observed at several of the proposed monitoring sites during past years. Harbor seals are very precocious with only a short period of time in which separation of a mother from a pup cold occur. Though elephant seal pups are occasionally present when researchers visit survey sites, risk of pup mortalities is very low because elephant seals are far less reactive to researcher presence than the other two species. Furthermore, pups are typically found on sand beaches, while study sites are located in the rocky intertidal zone, meaning that there is typically a buffer between researchers and pups. Finally, the caution used by researchers in approaching sites generally precludes the possibility of behavior, such as stampeding, that could result in extended separation of mothers and dependent pups or trampling of pups. No research would occur where separation of mother and her nursing pup or crushing of pups can become a concern.

Typically, even those reactions constituting Level B harassment would result at most in temporary, short-term disturbance. In any given study season, researchers will visit sites one to two times per year for a total of 4–6 hours per visit. Therefore, disturbance of pinnipeds resulting from the presence of researchers lasts only for short periods of time and is separated by significant amounts of time in which no disturbance occurs.

Some of the pinniped species may use some of the sites during certain times of year to conduct pupping and/or breeding. However, some of these species prefer to use the offshore islands for these activities. At the sites where pups may be present, PISCO has proposed to implement certain mitigation measures, such as no intentional flushing if dependent pups are present, which will avoid mother/pup separation and trampling of pups.

Of the four marine mammal species anticipated to occur in the proposed activity areas, none are listed under the ESA. Taking into account the mitigation measures that are planned, effects to marine mammals are generally expected to be restricted to short-term changes in behavior or temporary abandonment of haulout sites. Pinnipeds are not expected to permanently abandon any area that is surveyed by researchers, as is evidenced by continued presence of pinnipeds at the sites during annual monitoring counts. 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 proposed mitigation and monitoring measures, NMFS preliminarily finds that the total marine mammal take from PISCO's rocky intertidal monitoring program will not adversely affect annual rates of recruitment or survival and therefore will have a negligible impact on the affected species or stocks.

Small Numbers

Table 1 in this document presents the abundance of each species or stock, the proposed take estimates, the percentage of the affected populations or stocks that may be taken by harassment, and the species or stock trends. According to these estimates, PISCO would take less than 0.8% of each species or stock. Because these are maximum estimates, actual take numbers are likely to be lower, as some animals may select other haulout sites the day the researchers are present.

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 mitigation and monitoring measures, which are expected to reduce the number of marine mammals potentially affected by the proposed action, NMFS preliminarily finds that small numbers of marine mammals will be taken relative to the populations of the affected species or stocks.

TABLE 1—POPULATION ABUNDANCE ESTIMATES, TOTAL PROPOSED LEVEL B TAKE, AND PERCENTAGE OF POPULATION THAT MAY BE TAKEN FOR THE POTENTIALLY AFFECTED SPECIES DURING THE PROPOSED ROCKY INTERTIDAL MONITORING PROGRAM

Species	Abundance *	Total proposed Level B take	Percentage of stock or population
Harbor seal	[1] 30,968, [2] 24,732	203	<0.01–0.8
California sea lion	296,750	720	0.2
Northern elephant seal	179,000	40	<0.01
Steller sea lion	59,968	10	<0.01

*Abundance estimates are taken from the 2014 U.S. Pacific Marine Mammal Stock Assessments (Carretta *et al.,* 2014).
[1] California stock abundance estimate.
[2] Oregon/Washington stock abundance estimate from 1999—Most recent surveys.

Impact on Availability of Affected Species or Stock for Taking for Subsistence Uses

There are no relevant subsistence uses of marine mammals implicated by this action. Therefore, NMFS has determined that the total taking of affected species or stocks would not have an unmitigable adverse impact on the availability of such species or stocks for taking for subsistence purposes.

Endangered Species Act (ESA)

None of the marine mammals for which incidental take is proposed are listed as threatened or endangered under the ESA. Therefore, NMFS has determined that issuance of the proposed IHA to PISCO under section 101(a)(5)(D) of the MMPA will have no effect on species listed as threatened or endangered under the ESA.

National Environmental Policy Act (NEPA)

In 2012, we prepared an EA analyzing the potential effects to the human environment from conducting rocky intertidal surveys along the California and Oregon coasts and issued a Finding of No Significant Impact (FONSI) on the issuance of an IHA for PISCO's rocky intertidal surveys in accordance with section 6.01 of the NOAA Administrative Order 216–6 (Environmental Review Procedures for Implementing the National Environmental Policy Act, May 20, 1999). We have reviewed the application for a renewed IHA for ongoing monitoring activities for 2015–16 and the 2014–15 monitoring report. Based on that review, we have determined that the proposed action is very similar to that considered in the previous IHA. In addition, no significant new circumstances or information relevant to environmental concerns have been identified. Thus, we have determined preliminarily that the preparation of a new or supplemental NEPA document is not necessary, and will, after review of public comments determine whether or not to reaffirm our 2012 FONSI. The 2012 NEPA documents are available for review at *www.nmfs.noaa.gov/pr/permits/incidental/construction.htm.*

Proposed Authorization

As a result of these preliminary determinations, NMFS proposes to issue an IHA to PISCO for the take of marine mammals incidental to conducting rocky intertidal monitoring research activities, provided the previously mentioned mitigation, monitoring, and reporting requirements are incorporated. The proposed IHA language is provided next.

This section contains a draft of the IHA itself. The wording contained in this section is proposed for inclusion in the IHA (if issued).

1. This IHA is valid from January 1, 2016, through, December 31, 2016.

2. This IHA is valid only for specified activities associated with rocky intertidal monitoring surveys at specific sites along the U.S. California and Oregon coasts.

3. General Conditions

a. A copy of this IHA must be in the possession of personnel operating under the authority of this authorization.

b. The incidental taking of marine mammals, by Level B harassment only, is limited to the following species along the Oregon and California coasts:

i. 203 harbor seal (*Phoca vitulina richardii*);

ii. 720 California sea lion (*Zalophus californianus*);

iii. 40 northern elephant seal (*Mirounga angustirostris*); and

iv. 10 Steller Sea lion (*Eumetopias jubatus*)

c. The taking by injury (Level A harassment), serious injury, or death of any of the species listed in condition 3(b) of the IHA or any taking of any other species of marine mammal is prohibited and may result in the modification, suspension, or revocation of this IHA.

4. Mitigation Measures: The holder of this IHA is required to implement the following mitigation measures:

a. Field biologists must approach study sites cautiously and quietly, such that any disturbance of pinnipeds is minimized. The pathway and rate of approach must be chosen judiciously, avoiding to the extent possible any approach of hauled-out pinnipeds. If approach is unavoidable, field biologists must approach gradually such that stampeding of pinnipeds is avoided. Specific care must be taken to avoid any disturbance that may place pinniped pups at risk. Site visits should be limited to no more than 6 hours in the absence of extenuating circumstances, and personnel shall vacate the area as soon as sampling of the site is completed.

b. Staff shall use binoculars to detect pinnipeds before close approach to avoid being seen by the animals.

c. Staff shall monitor the offshore area for predators (such as killer whales and white sharks) and avoid flushing of pinnipeds when predators are observed in nearshore waters.

d. Staff shall reschedule work at sites where pups are present, unless other means to accomplishing the work can be

done without causing disturbance to mothers and dependent pups.

e. Staff shall approach pinnipeds when located in the sampling plots only if there are no other means to accomplish the survey and there are no pups present (however, approach must be slow and quiet so as not to minimize potential for stampede).

5. Monitoring: The holder of this IHA is required to conduct monitoring of marine mammals present at study sites prior to approaching the sites.

a. Information to be recorded shall include the following:

i. Species counts (with numbers of pups/juveniles); and

ii. Numbers of disturbances, by species and age, according to a three-point scale of intensity including (1) Head orientation in response to disturbance, which may include turning head towards the disturbance, craning head and neck while holding the body rigid in a u-shaped position, or changing from a lying to a sitting position and/or slight movement of less than 1 m; ''alert''; (2) Movements in response to or away from disturbance, over short distances (typically two times its body length) and including dramatic changes in direction or speed of locomotion for animals already in motion; ''movement''; and (3) All flushes to the water as well as lengthier retreats (>3 m); ''flight''.

6. Reporting: The holder of this IHA is required to:

a. Report observations of unusual behaviors, numbers, or distributions of pinnipeds, or of tag-bearing carcasses, to NMFS Southwest Fisheries Science Center (SWFSC).

b. Submit a draft monitoring report to NMFS Office of Protected Resources within 60 days after the conclusion of the 2015–2016 field season or 60 days prior to the start of the next field season if a new IHA will be requested. A final report shall be prepared and submitted within 30 days following resolution of any comments on the draft report from NMFS. This report must contain the informational elements described above, at minimum.

c. Reporting injured or dead marine mammals:

i. In the event that the specified activity clearly causes the take of a marine mammal in a manner prohibited by this IHA, such as an injury (Level A harassment), serious injury, or mortality, PISCO shall immediately cease the specified activities and report the incident to the Office of Protected Resources, NMFS, and the Southwest Regional Stranding Coordinator, NMFS. The report must include the following information:

1. Time and date of the incident;

2. Description of the incident;

3. Environmental conditions (*e.g.,* wind speed and direction, Beaufort sea state, cloud cover, and visibility);

4. Description of all marine mammal observations in the 24 hours preceding the incident;

5. Species identification or description of the animal(s) involved;

6. Fate of the animal(s); and

7. Photographs or video footage of the animal(s).

Activities shall not resume until NMFS is able to review the circumstances of the prohibited take. NMFS will work with PISCO to determine what measures are necessary to minimize the likelihood of further prohibited take and ensure MMPA compliance. PISCO may not resume the activities until notified by NMFS.

ii. In the event that an injured or dead marine mammal is discovered and it is determined that the cause of the injury or death is unknown and the death is relatively recent (*e.g.,* in less than a moderate state of decomposition), PISCO shall immediately report the incident to the Office of Protected Resources, NMFS, and the Southwest Regional Stranding Coordinator, NMFS. The report must include the same information identified in 6(c)(i) of this IHA. Activities may continue while NMFS reviews the circumstances of the incident. NMFS will work with PISCO to determine whether additional mitigation measures or modifications to the activities are appropriate.

iii. In the event that an injured or dead marine mammal is discovered and it is determined that the injury or death is not associated with or related to the activities authorized in the IHA (*e.g.,* previously wounded animal, carcass with moderate to advanced decomposition, or scavenger damage), PISCO shall report the incident to the Office of Protected Resources, NMFS, and the Southwest Regional Stranding Coordinator, NMFS, within 24 hours of the discovery. PISCO shall provide photographs or video footage or other documentation of the stranded animal sighting to NMFS. Activities may continue while NMFS reviews the circumstances of the incident.

7. This IHA may be modified, suspended or withdrawn if the holder fails to abide by the conditions prescribed herein or if NMFS determines the authorized taking is having more than a negligible impact on the species or stock of affected marine mammals.

Request for Public Comments

NMFS requests comment on our analysis, the draft authorization, and any other aspect of the Notice of Proposed IHA for PISCO's proposed rocky intertidal monitoring program. Please include with your comments any supporting data or literature citations to help inform our final decision on PISCO's request for an MMPA authorization.

Dated: December 4, 2015.

Perry Gayaldo,

Deputy Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2015–31036 Filed 12–8–15; 8:45 am]

BILLING CODE 3510–22–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

RIN 0648-XE231

Endangered and Threatened Species; Recovery Plans

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

ACTION: Notice of availability; extension of public comment period.

SUMMARY: We, NMFS, announce the extension of the comment period for the *Proposed Endangered Species Act (ESA) Recovery Plan for Oregon Coast Coho Salmon* (Proposed Plan) published on October 13, 2015. The Proposed Plan addresses the Oregon Coast Coho Salmon (*Oncorhynchus kisutch*) evolutionarily significant unit (ESU) listed as threatened under the ESA. The geographic area covered by the Proposed Plan is the Pacific Ocean and freshwater habitat (rivers, streams and lakes) from the Necanicum River near Seaside, Oregon, on the northern end to the Sixes River near Port Orford, Oregon on the south. As required under the ESA, the Proposed Plan contains objective, measurable delisting criteria, site-specific management actions necessary to achieve the Proposed Plan's goals, and estimates of the time and costs required to implement recovery actions. We are soliciting review and comment from the public and all interested parties on the Proposed Plan. The comment period is being extended—from December 14, 2015, to December 31, 2015—to provide additional opportunity for public comment.

DATES: The deadline for receipt of comments on the Public Draft Recovery

Plan published on October 13, 2015 (80 FR 61379), is extended to close of business on December 31, 2015.

ADDRESSES: You may submit comments on the Public Draft Recovery Plan by the following methods:

• *Electronic Submissions*: Submit all electronic public comments via: *2015CohoPlan.WCR@noaa.gov* Please include ''Comments on Oregon Coast Coho Salmon Recovery Plan'' in the subject line of the email.

• *Facsimile*: (503) 872–2737.

• *Mail:* Robert Walton, National Marine Fisheries Service, 1201 NE. Lloyd Boulevard, Suite 1100, Portland, OR 97232.

Instructions: Comments must be submitted by one of the above methods to ensure comments are received, documented, and considered by NMFS. Comments sent by any other method, to any other address or individual, or received after the end of the comment period, may not be considered. Attachments to electronic comments will be accepted in Microsoft Word, Excel, or Adobe PDF file formats only.

Electronic copies of the Proposed Plan are available electronically at *http://www.westcoast.fisheries.noaa.gov/protected_species/salmon_steelhead/recovery_planning_and_implementation/oregon_coast/oregon_coast_recovery_plan.html.*

Persons wishing to obtain an electronic copy on CD ROM of the Proposed Plan may do so by calling Nancy Johnson at (503) 230–5442 or by emailing a request to *nancy.johnson@noaa.gov* with the subject line ''CD ROM Request for Oregon Coast Coho Salmon Recovery Plan.''

FOR FURTHER INFORMATION CONTACT: Robert Walton, NMFS Oregon Coast Coho Salmon Recovery Coordinator, at (503) 231–2285, or *rob.walton@noaa.gov.*

SUPPLEMENTARY INFORMATION:

Extension of Comment Period

On October 13, 2015 (80 FR 61379) we (NMFS published in the **Federal Register** a request for public comment on the notice of availability of the Proposed Plan for the Oregon Coast Coho salmon. The public comment period for this action is set to end on December 14, 2015. The comment period is being extended through December 31, 2015, to provide additional opportunity for public comment.

Background

We are responsible for developing and implementing recovery plans for Pacific salmon and steelhead listed under the ESA of 1973, as amended (16 U.S.C. 1531 *et seq.*). Recovery means that the listed species and their ecosystems are sufficiently restored, and their future secured, to the point that the protections of the ESA are no longer necessary. Section 4(f)(1) of the ESA requires that recovery plans include, to the maximum extent practicable: (1) Objective, measurable criteria which, when met, would result in a determination that the species is no longer threatened or endangered; (2) site-specific management actions necessary to achieve the plan's goals; and (3) estimates of the time required and costs to implement recovery actions. The ESA requires the development of recovery plans for each listed species unless such a plan would not promote its recovery.

We believe it is essential to have local support of recovery plans by those whose activities directly affect the listed species and whose continued commitment and leadership will be needed to implement the necessary recovery actions. We therefore support and participate in locally led, collaborative efforts to develop recovery plans that involve state, tribal, and Federal entities, local communities, and other stakeholders. We have determined that this *Proposed ESA Recovery Plan for Oregon Coast Coho Salmon* meets the statutory requirements for a recovery plan and are proposing to adopt it as the ESA recovery plan for this threatened species. Section 4(f) of the ESA, as amended in 1988, requires that public notice and an opportunity for public review and comment be provided prior to final approval of a recovery plan. This notice solicits comments on this Proposed Plan.

Development of the Proposed Plan

For the purpose of recovery planning for the ESA-listed species of Pacific salmon and steelhead in Idaho, Oregon and Washington, NMFS designated five geographically based ''recovery domains.'' The Oregon Coast Coho Salmon ESU spawning range is in the Oregon Coast domain. For each domain, NMFS appointed a team of scientists, nominated for their geographic and species expertise, to provide a solid scientific foundation for recovery plans. The Oregon and Northern California Coasts Technical Recovery Team (TRT) included scientists from NMFS, other Federal agencies, the state of Oregon, and the private sector.

A primary task for the Oregon and Northern California Coasts Technical Recovery Team was to recommend criteria for determining when the ESU should be considered viable (*i.e.*, when they are have a low risk of extinction over a 100-year period) and when the ESU would have a risk of extinction consistent with no longer needing the protections of the ESA. All Technical Recovery Teams used the same biological principles for developing their recommendations; these principles are described in the NOAA technical memorandum *Viable Salmonid Populations and the Recovery of Evolutionarily Significant Units* (McElhany et al., 2000). Viable salmonid populations (VSP) are defined in terms of four parameters: Abundance, productivity or growth rate, spatial structure, and diversity.

For this Proposed Plan, we collaborated with state, tribal and Federal scientists and resource managers and stakeholders to provide technical information that NMFS used to write the Proposed Plan which is built upon locally-led recovery efforts.

The Proposed Plan, including the recovery plan modules, is now available for public review and comment.

Contents of Proposed Plan

The Proposed Plan contains biological background and contextual information that includes description of the ESU, the planning area, and the context of the plan's development. It presents relevant information on ESU structure, biological status and proposed biological viability criteria and threats criteria for delisting.

The Proposed Plan also describes specific information on the following: Current status of Oregon Coast Coho Salmon; limiting factors and threats for the full life cycle that contributed to the species decline; recovery strategies and actions addressing these limiting factors and threats; key information needs, and a proposed research, monitoring, and evaluation program for adaptive management. For recovery strategies and actions, Chapter 6 in the Proposed Plan includes proposed actions at the ESU and strata levels. Population level information will be posted on the recovery plan Web site (see below). The plan also describes how implementation, prioritization of actions, and adaptive management will proceed at the population, strata, and ESU scales. The Proposed Plan also summarizes time and costs (Chapter 7) required to implement recovery actions. In addition to the information in the Proposed Plan, readers are referred to the recovery plan Web site for more information on all these topics. (*http://www.westcoast.fisheries.noaa.gov/protected_species/salmon_steelhead/recovery_planning_and_implementation/oregon_coast/oregon_*

coast__salmon__recovery__domain.html)

How NMFS and Others Expect To Use the Plan

With approval of the final Plan, we will commit to implement the actions in the Plan for which we have authority and funding; encourage other Federal and state agencies and tribal governments to implement recovery actions for which they have responsibility, authority and funding; and work cooperatively with the public and local stakeholders on implementation of other actions. We expect the Plan to guide us and other Federal agencies in evaluating Federal actions under ESA section 7, as well as in implementing other provisions of the ESA and other statutes. For example, the Plan will provide greater biological context for evaluating the effects that a proposed action may have on a species by providing delisting criteria, information on priority areas for addressing specific limiting factors, and information on how future populations within the ESU can tolerate varying levels of risk.

When we are considering a species for delisting, the agency will examine whether the section 4(a)(1) listing factors have been addressed. To assist in this examination, we will use the delisting criteria described in Chapter 4 of the Plan, which includes both biological criteria and criteria addressing each of the ESA section 4(a)(1) listing factors, as well as any other relevant data and policy considerations.

We will also work with the Oregon Coast Coho Conservation Plan Implementation Team described in the Proposed Plan to develop implementation schedules that provide greater specificity for recovery actions to be implemented over three-to five-year periods. This Team will also help promote implementation of recovery actions and subsequent implementation schedules, and will track and report on implementation progress.

Conclusion

Section 4(f)(1)(B) of the ESA requires that recovery plans incorporate, to the maximum extent practicable, (1) objective, measurable criteria which, when met, would result in a determination that the species is no longer threatened or endangered; (2) site-specific management actions necessary to achieve the plan's goals; and (3) estimates of the time required and costs to implement recovery actions. We conclude that the Proposed Plan meets the requirements of ESA section 4(f) and are proposing to adopt it as the *ESA Recovery Plan for Oregon Coast Coho Salmon.*

Public Comments Solicited

We are soliciting written comments on the Proposed Plan. All substantive comments received by the date specified above will be considered and incorporated, as appropriate, prior to our decision whether to approve the plan. We will issue a news release announcing the adoption and availability of the final plan. We will post on the NMFS West Coast Region Web site (*www.wcr.noaa.gov*) a summary of, and responses to, the comments received, along with electronic copies of the final plan and its appendices.

Literature Cited

McElhany, P., M.H. Ruckelshaus, M.J. Ford, T.C. Wainwright, and E.P. Bjorkstedt. 2000. Viable salmon populations and the recovery of evolutionarily significant units. U.S. Dept. of Commerce, NOAA Tech. Memo., NMFS NWFSC 42, 156 p.

Authority: 16 U.S.C. 1531 *et seq.*

Dated: December 3, 2015.

Perry F. Gayaldo,

Deputy Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 2015–30956 Filed 12–8–15; 8:45 am]

BILLING CODE 3510–22–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

[Docket No: CFPB–2015–0054]

Agency Information Collection Activities: Comment Request

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice and request for comment.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (PRA), the Consumer Financial Protection Bureau (Bureau) is requesting to renew the Office of Management and Budget (OMB) approval for an existing information collection, titled, ''Loan Originator Compensation Amendment (Regulation Z).''

DATES: Written comments are encouraged and must be received on or before February 8, 2016 to be assured of consideration.

ADDRESSES: You may submit comments, identified by the title of the information collection, OMB Control Number (see below), and docket number (see above), by any of the following methods:

- *Electronic: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Consumer Financial Protection Bureau (Attention: PRA Office), 1700 G Street NW., Washington, DC 20552.
- *Hand Delivery/Courier:* Consumer Financial Protection Bureau (Attention: PRA Office), 1275 First Street NE., Washington, DC 20002.

Please note that comments submitted after the comment period will not be accepted. In general, all comments received will become public records, including any personal information provided. Sensitive personal information, such as account numbers or social security numbers, should not be included.

FOR FURTHER INFORMATION CONTACT: Documentation prepared in support of this information collection request is available at *www.regulations.gov.* Requests for additional information should be directed to the Consumer Financial Protection Bureau, (Attention: PRA Office), 1700 G Street NW., Washington, DC 20552, (202) 435–9575, or email: *PRA@cfpb.gov. Please do not submit comments to this mailbox.*

SUPPLEMENTARY INFORMATION:

Title of Collection: Loan Originator Compensation Amendment (Regulation Z).

OMB Control Number: 3170–0031.

Type of Review: Extension without change of a currently approved collection.

Affected Public: Private sector.

Estimated Number of Respondents: 8,254.

Estimated Total Annual Burden Hours: 94,635.

Abstract: The Truth in Lending Act (TILA), 15 U.S.C. 1601 *et seq.*, was enacted to foster comparison credit shopping and informed credit decision making by requiring accurate disclosure of the costs and terms of credit to consumers. The Dodd-Frank Act then amended TILA to include, among other things, provisions about the qualifications and compensation of mortgage loan officers, in order to ensure consumers are getting a fair deal on their loans.

Request for Comments: Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Bureau, including whether the information will have practical utility; (b) The accuracy of the Bureau's estimate of the burden of the collection of information, including the validity of the methods and the assumptions used; (c) Ways to enhance the quality, utility,

and clarity of the information to be collected; and (d) Ways to minimize the burden of the collection of information on 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. All comments will become a matter of public record.

Dated: December 3, 2015.

Darrin A. King,

Paperwork Reduction Act Officer, Bureau of Consumer Financial Protection.

[FR Doc. 2015–31025 Filed 12–8–15; 8:45 am]

BILLING CODE 4810–AM–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Proposed Information Collection; Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (CNCS), as part of its continuing effort to reduce paperwork and respondent burden, conducts a pre-clearance 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 (PRA95) (44 U.S.C. Sec. 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 requirement on respondents can be properly assessed.

Currently, CNCS is soliciting comments concerning its proposed Employers of National Service Annual Survey. The Employers of National Service program seeks to connect employers from all sectors with AmeriCorps and Peace Corps alumni. Organizations that have signed up to participate in the Employers of National Service program will be filling out this form on an annual basis. Through this survey, CNCS will collect information that will enable the agency to improve the program. Information provided is purely voluntary and will not be used for any grant or funding support.

Copies of the information collection request can be obtained by contacting the office listed in the **ADDRESSES** section of this Notice.

DATES: Written comments must be submitted to the individual and office listed in the **ADDRESSES** section by February 8, 2016.

ADDRESSES: You may submit comments, identified by the title of the information collection activity, by any of the following methods:

(1) By mail sent to: Corporation for National and Community Service, Office of the CPO; Attention: Erin Dahlin, Deputy Chief of Program Operations, Rm 9309; 1201 New York Avenue NW., Washington, DC 20525.

(2) By hand delivery or by courier to the CNCS mailroom at Room 8100 at the mail address given in paragraph (1) above, between 9:00 a.m. and 4:00 p.m. Eastern Time, Monday through Friday, except Federal holidays.

(3) Electronically through *www.regulations.gov.*

Individuals who use a telecommunications device for the deaf (TTY–TDD) may call 1–800–833–3722 between 8:00 a.m. and 8:00 p.m. Eastern Time, Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Erin Dahlin, 202–606–6931, or by email at *edahlin@cns.gov.*

SUPPLEMENTARY INFORMATION: CNCS is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of CNCS, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- 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 expected to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology (*e.g.,* permitting electronic submissions of responses).

Background

Organizations from all sectors who are Employers of National Service will be filling out this form, including businesses, nonprofits, institutions of higher education, school districts, state/local governments, and federal agencies. The purpose of the form is to track what actions an employer has taken in the past year, gather stories of success or impact, collect quantitative hiring data relating to AmeriCorps and Peace Corps alumni, and provide organizations with an opportunity to update their contact and location data. The information will be collected electronically via our Web site.

Current Action

This is a new information collection request. The items on the form are: Employer name; fields to share notable hiring experiences and future plans/goals; human resources policy changes as an Employer of National Service; a section on recruiting and hiring, including applicants, candidates hired, and overall workforce information; a section to update contact and location information.

Type of Review: New.

Agency: Corporation for National and Community Service.

Title: Employers of National Service Annual Survey.

OMB Number: New.

Agency Number: None.

Affected Public: Any organization that is an Employer of National Service program, including businesses, nonprofits, institutions of higher education, school districts, state/local governments, and federal agencies.

Total Respondents: 500.

Frequency: Annually.

Average Time per Response: 30 minutes.

Estimated Total Burden Hours: 250.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintenance): None.

Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval of the information collection request; they will also become a matter of public record.

Dated: December 3, 2015.

Erin Dahlin,

Deputy Chief of Program Operations.

[FR Doc. 2015–31018 Filed 12–8–15; 8:45 am]

BILLING CODE 6050–28–P

CORPORATION FOR NATIONAL AND COMMUNITY SERVICE

Information Collection; Submission for OMB Review, Comment Request

AGENCY: Corporation for National and Community Service.

ACTION: Notice.

SUMMARY: The Corporation for National and Community Service (CNCS) has submitted a public information

collection request (ICR) entitled Employers of National Service Enrollment Form for review and approval in accordance with the Paperwork Reduction Act of 1995, Public Law 104–13, (44 U.S.C. Chapter 35). Copies of this ICR, with applicable supporting documentation, may be obtained by calling the Corporation for National and Community Service, Erin Dahlin, at 202–606–6931 or email to *edahlin@cns.gov.* Individuals who use a telecommunications device for the deaf (TTY–TDD) may call 1–800–833–3722 between 8:00 a.m. and 8:00 p.m. Eastern Time, Monday through Friday.

DATES: Comments may be submitted, identified by the title of the information collection activity, within January 8, 2016.

ADDRESSES: Comments may be submitted, identified by the title of the information collection activity, to the Office of Information and Regulatory Affairs, Attn: Ms. Sharon Mar, OMB Desk Officer for the Corporation for National and Community Service, by any of the following two methods within 30 days from the date of publication in the **Federal Register**:

(1) By fax to: 202–395–6974, Attention: Ms. Sharon Mar, OMB Desk Officer for the Corporation for National and Community Service; or

(2) By email to: *smar@omb.eop.gov.*

SUPPLEMENTARY INFORMATION: The OMB is particularly interested in comments which:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of CNCS, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Propose ways to enhance the quality, utility, and clarity of the information to be collected; and
- Propose ways to minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Comments

A 60-day Notice requesting public comment was published in the **Federal Register** on August 20, 2015 at 80 FR 50610. This comment period ended October 19, 2015. No public comments were received from this Notice.

Description: CNCS is soliciting comments concerning its proposed Employers of National Service Enrollment Form. The Employers of National Service program is administered by CNCS (in conjunction with the Peace Corps, the National Peace Corps Association, the Points of Light Foundation and the Aspen Institute), and seeks to connect employers from all sectors with AmeriCorps and Peace Corps alumni. Organizations that are looking to join the initiative will be filling out this form in order to document their participation. Information provided is purely voluntary and will not be used for any grant or funding support.

Type of Review: Renewal.

Agency: Corporation for National and Community Service.

Title: Employers of National Service Enrollment Form.

OMB Number: None.

Agency Number: None.

Affected Public: Any organization seeking to join the Employers of National Service program.

Total Respondents: 300.

Frequency: Ongoing.

Average Time per Response: 15 minutes.

Estimated Total Burden Hours: 75 hours.

Total Burden Cost (capital/startup): None.

Total Burden Cost (operating/maintenance): None.

Dated: December 3, 2015.

Erin Dahlin,

Deputy Chief of Program Operations.

[FR Doc. 2015–31020 Filed 12–8–15; 8:45 am]

BILLING CODE 6050–28–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency & Renewable Energy

Notice of Public Release of Stewardship of the National Training and Education Resource (NTER)®

AGENCY: Office of Energy Efficiency & Renewable Energy, Department of Energy (DOE)

ACTION: Notice.

SUMMARY: The Department of Energy (DOE) today gives notice to inform any interested parties that:

- DOE will no longer provide financial support for development and web hosting of the National Training and Education Resource (NTER)®.
- DOE is releasing stewardship of the learning management system (LMS) and content management system (CMS) of NTER® to the open source community, consistent with the original development strategy.
- Parties interested in the LMS and the CMS should follow the guidance in the **SUPPLEMENTARY INFORMATION** Section below.

DATES: Public release will occur on November 30, 2015.

ADDRESSES: U.S. Department of Energy, Forrestal Building, 1000 Independence Ave. SW., Washington, DC 20585–1615, Attn: John Lushetsky.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to: The Office of Strategic Programs, U.S. Department of Energy, Mailstop EE–61T, 1000 Independence Avenue SW., Washington, DC 20585, Attn: John Lushetsky or by email at *nwtp.Webmaster@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: The U.S. Department of Energy (DOE)'s mission is to ensure America's security and prosperity by addressing its energy, environmental, and nuclear challenges through transformative science and technology solutions. DOE developed the National Training and Education Resource (NTER)® to provide an open source platform for multimedia self-paced training courses designed to build skills in clean energy vocations at lower costs than proprietary packages. NTER® primarily consists of a learning management system (LMS) and a content management system (CMS) that streamlines the delivery of training and content to stakeholders. The LMS and the CMS were designed to leverage open source code and open data, enabling educators to create content and students to take courses easily. These systems have offered DOE and other organizations a unified platform to provide state-of-the-art training. NTER® users have earned certifications and demonstrated competencies that translate directly into on-the-job performance. The highly modular design has allowed NTER® to be used as a stand-alone open-source toolkit or to be combined with proprietary third-party materials.

Over the last several years, the open source community has demonstrated the ability to assume stewardship and development of the LMS and the CMS of NTER® to maximize the use and market adoption of these educational tools. Multiple organizations, with expertise in open source development of educational content, have incorporated and adapted the NTER® elements and are offering services based on it. DOE believes that these organizations and the open source community are most

qualified to maintain and build upon the success of the LMS and CMS of NTER® and will continue to provide state-of-the-art training platforms for educators and students.

The LMS and CMS of NTER® can be found at the NTER® URL (*www.nterlearning.org).* The software and data are available to the public under an open source license and an open data license. DOE willno longer maintain and support the NTER® URL after April 1, 2016. Therefore, parties interested in the LMS and CMS should visit the NTER® URL as soon as possible in order to download the necessary software and data.

NTER® is a registered trademark of DOE. Any party who uses or builds upon the LMS and CMS of NTER® may disclose that its training platform is based upon or a derivative to the LMS and the CMS of NTER®. No party shall use the NTER® trademark or identify DOE in any manner that would cause a reasonable person to believe that its training platform is being offered, supported, or endorsed by NTER® or DOE.

Issued in Golden, CO, on: November 30, 2015.

Stephanie Carabajal,

Contracting Officer.

[FR Doc. 2015–30997 Filed 12–8–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

[Docket Number EERE–2013–BT–NOC–0005]

Appliance Standards and Rulemaking Federal Advisory Committee: Notice of Open Meetings

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of open meetings.

SUMMARY: The Department of Energy (DOE) announces public meetings and webinars for the Appliance Standards and Rulemaking Federal Advisory Committee (ASRAC). The Federal Advisory Committee Act requires that agencies publish notice of an advisory committee meeting in the **Federal Register**.

DATES: DOE will host public meetings on the following dates:

- December 18, 2015 (webinar only); 3:00 p.m.–5:00 p.m.
- January 20, 2016; 9:30 a.m.–5:00 p.m.

ADDRESSES: Unless otherwise stated, the meetings will be held at: U.S. Department of Energy, Forrestal Building, Room 8E–089, 1000 Independence Avenue SW., Washington, DC 20585.

To register for the webinar and receive call-in information, please register for the appropriate meeting date at *https://attendee.gotowebinar.com/register/7335166795746629122.*

FOR FURTHER INFORMATION CONTACT: John Cymbalsky, ASRAC Designated Federal Officer, U.S. Department of Energy (DOE), Office of Energy Efficiency and Renewable Energy, 950 L'Enfant Plaza SW., Washington, DC 20024. Email: *asrac@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: DOE announces public meetings and webinars for the ASRAC. Members of the public are welcome to observe the business of the meeting and, if time allows, may make oral statements during the specified period for public comment. To attend the meeting and/or to make oral statements regarding any of the items on the agenda, email *asrac@ee.doe.gov*. In the email, please indicate your name, organization (if appropriate), citizenship, and contact information. Please note that foreign nationals participating in the public meeting are subject to advance security screening procedures which require advance notice prior to attendance at the public meeting. If a foreign national wishes to participate in the public meeting, please inform DOE as soon as possible by contacting Ms. Regina Washington at (202) 586–1214 or by email: *Regina.Washington@ee.doe.gov* so that the necessary procedures can be completed. Anyone attending the meeting will be required to present a government photo identification, such as a passport, driver's license, or government identification. Due to the required security screening upon entry, individuals attending should arrive early to allow for the extra time needed.

Due to the REAL ID Act implemented by the Department of Homeland Security (DHS) recent changes have been made regarding ID requirements for individuals wishing to enter Federal buildings from specific states and U.S. territories. Driver's licenses from the following states or territory will not be accepted for building entry and 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, Louisiana, New York, American Samoa, Maine, Oklahoma, Arizona, Massachusetts, Washington, and Minnesota.

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.

Docket: The docket is available for review at *www.regulations.gov*, including **Federal Register** notices, public meeting attendee lists and transcripts, 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.

Issued in Washington, DC, on December 1, 2015.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

[FR Doc. 2015–30998 Filed 12–8–15; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP16–19–000]

Sabine Pass Liquefaction, LLC; Notice of Application

Take notice that on November 18, 2015, Sabine Pass Liquefaction, LLC (Sabine Pass) filed in Docket No. CP16–19–000 an application pursuant to section 3(a) of the Natural Gas Act (NGA) for authorization to site, construct, and operate liquefied natural gas (LNG) transport carrier loading facilities at its LNG terminal in Cameron Parish, Louisiana. Specifically, Sabine Pass seeks authorization to construct: (i) Conventional cold, insulated piping, (ii) cryogenic hoses for filling and vapor return, (iii) two LNG loading stations, each having two bays capable of loading LNG transport carriers or International Standards Organization containers, and (iv) appurtenances, 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 TYY, (202) 502–8659.

Any questions concerning this application may be directed to Lisa M. Tonery, Norton Rose Fulbright US LLP, 666 Fifth Avenue, New York, New York 10103, by telephone at (212) 318–3009 or by email at *lisa.tonery@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 final environmental impact statement (FEIS) or EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's FEIS or EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below file with the Federal Energy Regulatory Commission, 888 First Street, NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit 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: 5:00 p.m. Eastern Time on December 24, 2015.

Dated: December 3, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–30962 Filed 12–8–15; 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: ER15–522–003.

Applicants: Arizona Public Service Company.

Description: Compliance filing: Market Based Rate Tariff Compliance Filing to be effective 2/2/2015.

Filed Date: 12/3/15.

Accession Number: 20151203–5057.

Comments Due: 5 p.m. ET 12/24/15.

Docket Numbers: ER15–2376–002; ER10–2020–003; ER10–2018–004; ER10–2019–005.

Applicants: Energy Power Investment Company, LLC, EPP Renewable Energy, LLC, EPP New Jersey Biogas, LLC, EPP New Jersey Solar, LLC.

Description: Notice of Change in Status of the EPP Sellers.

Filed Date: 12/2/15.

Accession Number: 20151202–5245.

Comments Due: 5 p.m. ET 12/23/15.

Docket Numbers: ER15–2728–002.

Applicants: Maricopa West Solar PV, LLC.

Description: Tariff Amendment: Amdmt to Pending Tariff Filing—Maricopa Removal Affiliate Waiver 120215 to be effective 11/1/2015.

Filed Date: 12/2/15.

Accession Number: 20151202–5171.

Comments Due: 5 p.m. ET 12/23/15.

Docket Numbers: ER16–160–001.

Applicants: New-Indy Ontario LLC.

Description: Tariff Amendment: Amendment to MBR to be effective 1/1/2016.

Filed Date: 12/3/15.

Accession Number: 20151203–5033.

Comments Due: 5 p.m. ET 12/17/15.

Docket Numbers: ER16–161–001.

Applicants: New-Indy Oxnard LLC.

Description: Tariff Amendment: Amendment to MBR to be effective 1/1/2016.

Filed Date: 12/3/15.

Accession Number: 20151203–5036.

Comments Due: 5 p.m. ET 12/17/15.

Docket Numbers: ER16–452–001.

Applicants: RE Tranquillity LLC.

Description: Tariff Amendment: Amendment to Application and Initial Baseline Tariff Filing to be effective 12/3/2015.

Filed Date: 12/3/15.

Accession Number: 20151203–5095.

Comments Due: 5 p.m. ET 12/24/15.

Docket Numbers: ER16–454–000.

Applicants: Seward Generation, LLC.

Description: Baseline eTariff Filing: Seward Generation, LLC Market Based Rate Tariff to be effective 1/1/2016.

Filed Date: 12/3/15.

Accession Number: 20151203–5000.

Comments Due: 5 p.m. ET 12/24/15.

Docket Numbers: ER16–455–000.

Applicants: PacifiCorp.

Description: PacifiCorp submits Notice of Cancellation of multiple Inactive Rate Schedules and Service Agreements.

Filed Date: 12/2/15.
Accession Number: 20151202–5243.
Comments Due: 5 p.m. ET 12/23/15.

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: December 3, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–30958 Filed 12–8–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. ER16–454–000]

Seward Generation, 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 Seward Generation, LLC's application for market-based rate authority, with an accompanying rate tariff, noting that such application includes a request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability.

Any person desiring to intervene or to protest should file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). Anyone filing a motion to intervene or protest must serve a copy of that document on the Applicant.

Notice is hereby given that the deadline for filing protests with regard to the applicant's request for blanket authorization, under 18 CFR part 34, of future issuances of securities and assumptions of liability, is December 23, 2015.

The Commission encourages electronic submission of protests and interventions in lieu of paper, using the FERC Online links at *http://www.ferc.gov.* To facilitate electronic service, persons with Internet access who will eFile a document and/or be listed as a contact for an intervenor must create and validate an eRegistration account using the eRegistration link. Select the eFiling link to log on and submit the intervention or protests.

Persons unable to file electronically should submit an original and 5 copies of the intervention or protest to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

The filings in the above-referenced proceeding are accessible in the Commission's eLibrary system by clicking on the appropriate link in the above list. They are also available for electronic review in the Commission's Public Reference Room in Washington, DC. There is an eSubscription link on the Web site that enables subscribers to receive email notification when a document is added to a subscribed docket(s). For assistance with any FERC Online service, please email *FERCOnlineSupport@ferc.gov.* or call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: December 3, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–30961 Filed 12–8–15; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. CP16–4–000]

Tennessee Gas Pipeline Company, L.L.C.; Supplemental Notice of Intent To Prepare an Environmental Assessment for the Proposed Orion 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 Orion Project involving construction and operation of facilities by Tennessee Gas Pipeline Company, L.L.C. (TGP) in Wayne and Pike Counties, Pennsylvania. The Commission will use this EA in its decision-making process to determine whether the project is in the public convenience and necessity.

This supplemental notice announces the extension of the scoping period and describes the process the Commission will use to gather input from the public and interested agencies on the project. The extension is to allow all recipients adequate time to submit comments 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 January 4, 2016.

If you sent comments on this project to the Commission before the opening of this docket on October 9, 2015, you will need to file those comments in Docket No. CP16–4–000 to ensure they are considered as part of this proceeding.

This supplemental 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.

TGP 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 No. (CP16–4–000) 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

TGP proposes to construct and operate pipeline facilities, to modify existing aboveground facilities, and add new tie-in facilities in Wayne and Pike Counties, Pennsylvania. The Orion Project would provide about 135,000 dekatherms per day of natural gas. According to TGP, its project would meet market needs of the Middle Atlantic and New England regions of the United States, and to a lesser extent Canada.

The Orion Project would consist of the following facilities:

- Approximately 12.9 miles of new 36-inch-diameter looping [1] pipeline in Wayne and Pike Counties, Pennsylvania;
- a new internal pipeline inspection (''pig'') launcher, crossover, and connecting facilities at the beginning of the proposed pipeline loop in Wayne County, Pennsylvania;
- a new ''pig'' receiver, crossover, and connecting facilities at the end of the proposed pipeline loop in Pike County, Pennsylvania;
- modifications at the existing Compressor Station 323, including rewheeling/restaging of an existing compressor and other piping and appurtenant modifications.

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 248 acres of land for the pipeline and aboveground facilities, 62 acres of which are associated with existing permanent TGP rights-of-way. Following construction, TGP would maintain about 79 acres for permanent operation of the project's facilities, 34 acres of which are associated with existing permanent TGP rights-of-way; the remaining acreage would be restored and revert to former uses. The majority of the proposed pipeline route parallels TGP's existing 300 Line rights-of-way. The majority of the aboveground facilities would be constructed within existing facility boundaries or existing permanent easement; however, an additional 0.1 acre of new operational right-of-way would be needed for the proposed aboveground 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 a Certificate of Public Convenience and Necessity. NEPA also requires us [3] 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. We will 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 Pennsylvania 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.[5] 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

[1] A pipeline loop is a segment of pipe constructed parallel to an existing pipeline to increase capacity.

[2] 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 page 6 of this notice.

[3] ''We,'' ''us,'' and ''our'' refer to the environmental staff of the Commission's Office of Energy Projects.

[4] The Council on Environmental Quality regulations addressing cooperating agency responsibilities are at Title 40, Code of Federal Regulations, Part 1501.6.

[5] The Advisory Council on Historic Preservation's regulations are at Title 36, Code of Federal Regulations, Part 800. Those regulations define historic properties as any prehistoric or historic district, site, building, structure, or object included in or eligible for inclusion in the National Register of Historic Places.

encompasses all areas subject to ground disturbance (examples include construction right-of-way, contractor/pipe storage yards, compressor stations, and access roads). Our EA for this project will document our findings on the impacts on historic properties and summarize the status of consultations under section 106.

Environmental Mailing List

The environmental mailing list includes federal, state, and local government representatives and agencies; elected officials; environmental and public interest groups; Native American tribes; other interested parties; and local libraries and newspapers. This list also includes all affected landowners (as defined in the Commission's regulations) who are potential right-of-way grantors, whose property may be used temporarily for project purposes, or who own homes within certain distances of aboveground facilities, and anyone who submits comments on the project. We will update the environmental mailing list as the analysis proceeds to ensure that we send the information related to this environmental review to all individuals, organizations, and government entities interested in and/or potentially affected by the proposed project.

Copies of the EA will be sent to the environmental mailing list for public review and comment. If you would prefer to receive a paper copy of the document instead of the CD version or would like to remove your name from the mailing list, please return the attached Information Request (appendix 2).

Becoming an Intervenor

In addition to involvement in the EA scoping process, you may want to become an ''intervenor'' which is an official party to the Commission's proceeding. Intervenors play a more formal role in the process and are able to file briefs, appear at hearings, and be heard by the courts if they choose to appeal the Commission's final ruling. An intervenor formally participates in the proceeding by filing a request to intervene. Instructions for becoming an intervenor are 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.,* CP16–4). 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: December 3, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–30960 Filed 12–8–15; 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: ER10–1959–005*;* ER15–2014–002; ER15–2015–002; ER15–2018–002; ER15–2026–002; ER15–2016–002; ER15–2013–002; ER15–2020–002; ER12–2510–006; ER12–2512–006; ER12–2513–006; ER10–2432–009; ER10–2435–009; ER10–2440–009; ER10–2444–009; ER10–2446–009; ER13–2308–004; ER10–2499–002; ER12–2511–006; ER10–2442–009; ER10–3310–010; ER10–3286–010; ER10–3299–009; ER11–2489–007; ER12–726–006; ER12–2639–005; ER11–3620–009; ER11–2882–010; ER12–1431–007; ER12–1434–007; ER12–1432–007; ER12–1435–007; ER13–2102–005; ER14–1439–004; ER15–1019–003; ER10–2628–004; ER11–3959–006; *ER15–2022–002.*

Applicants: Lower Mount Bethel Energy, LLC, Brunner Island, LLC, Holtwood, LLC, Martins Creek, LLC, Montour, LLC, Susquehanna Nuclear, LLC, Talen Ironwood, LLC, Talen Energy Marketing, LLC, Talen Montana, LLC, Brandon Shores LLC, H.A. Wagner LLC, Raven Power Marketing LLC, Bayonne Plant Holding, L.L.C., Camden Plant Holding, L.L.C., Dartmouth Power Associates Limited Partnership, Newark Bay Cogeneration Partnership, L.P., Pedricktown Cogeneration Company LP, Sapphire Power Marketing LLC, York Generation Company LLC, C.P. Crane LLC, Elmwood Park Power, LLC, New Harquahala Generating Company, LLC, Millennium Power Partners, L.P., New Athens Generating Company, LLC, Hatchet Ridge Wind, LLC, Spring Valley Wind LLC, Ocotillo Express LLC, Lyonsdale Biomass, LLC, ReEnergy Sterling CT Limited Partnership, ReEnergy Ashland LLC, ReEnergy Fort Fairfield LLC, ReEnergy Livermore Falls LLC, ReEnergy Stratton LLC, ReEnergy Black River LLC, TrailStone Power, LLC, Fowler Ridge IV Wind Farm LLC, Lost Creek Wind, LLC, Post Rock Wind Power Project, LLC.

Description: Notice of Change in Status of the Talen Sellers and Riverstone MBR Entities.

Filed Date: 12/2/15.

Accession Numbers: 20151202–5247, 20151203–5195.

Comments Due: 5 p.m. ET 12/23/15.

Docket Numbers: ER12–2065–003; ER14–2472–003; ER15–1721–002.

Applicants: Agera Energy LLC, Agera Energy LLC, energy.me midwest llc.

Description: Notice of Non-Material Change in Status of Agera Energy LLC, et. al.

Filed Date: 12/3/15.

Accession Number: 20151203–5145.

Comments Due: 5 p.m. ET 12/24/15.

Docket Numbers: ER15–1925–002.

Applicants: Breckinridge Wind Project, LLC.

Description: Breckinridge Wind Project, LLC Notice of Non-material Change in Status.

Filed Date: 12/3/15.

Accession Number: 20151203–5144.

Comments Due: 5 p.m. ET 12/24/15.

Docket Numbers: ER16–456–000.

Applicants: PJM Interconnection, L.L.C., Baltimore Gas and Electric Company, Delmarva Power & Light Company, Atlantic City Electric Company, Potomac Electric Power Company.

Description: Compliance filing: BGE, Delmarva, Pepco & Atlantic City submit compliance filing per 11/3/15 order to be effective 12/3/2015.

Filed Date: 12/3/15.

Accession Number: 20151203–5133.

Comments Due: 5 p.m. ET 12/24/15

Docket Numbers: ER16–457–000.

Applicants: California Independent System Operator Corporation.

Description: § 205(d) Rate Filing: Certificate of Concurrence-Svc Agmt 3480 to be effective 12/2/2015.

Filed Date: 12/3/15.

Accession Number: 20151203–5142.

Comments Due: 5 p.m. ET 12/24/15.

Docket Numbers: ER16–458–000

Applicants: Midcontinent Independent System Operator, Inc.

Description: § 205(d) Rate Filing: 2015–12–03_SA 2078 Notice of Termination G587 GIA to be effective 11/24/2015.

Filed Date: 12/3/15.

Accession Number: 20151203–5169.

Comments Due: 5 p.m. ET 12/24/15.

Docket Numbers: ER16–459–000.

Applicants: Southern California Edison Company.

Description: § 205(d) Rate Filing: GIA and Distribution Service Agmt Windustries Project to be effective 11/24/2015.

Filed Date: 12/3/15.

Accession Number: 20151203–5188.

Comments Due: 5 p.m. ET 12/24/15

Take notice that the Commission received the following electric securities filings:

Docket Numbers: ES16–7–000.

Applicants: PECO Energy Company.

Description: Supplement to October 30, 2015 Application of PECO Energy Company Under Section 204 of the Federal Power Act for Authorization of the Issuance Securities.

Filed Date: 12/3/15.

Accession Number: 20151203–5123.

Comments Due: 5 p.m. ET 12/14/15.

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: December 3, 2015.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2015–30959 Filed 12–8–15; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL_9931–92–OEI]

Cross-Media Electronic Reporting: Authorized Program Revision Approval, State of Illinois

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's approval of the State of Illinois's request to revise/modify its EPA Administered Permit Programs: The National Pollutant Discharge Elimination System EPA-authorized program to allow electronic reporting.

DATES: EPA's approval is effective December 9, 2015.

FOR FURTHER INFORMATION CONTACT: Karen Seeh, U.S. Environmental Protection Agency, Office of Environmental Information, Mail Stop 2823T, 1200 Pennsylvania Avenue NW., Washington, DC 20460, (202) 566–1175, *seeh.karen@epa.gov.*

SUPPLEMENTARY INFORMATION: On October 13, 2005, the final Cross-Media Electronic Reporting Rule (CROMERR) was published in the **Federal Register** (70 FR 59848) and codified as part 3 of title 40 of the CFR. CROMERR establishes electronic reporting as an acceptable regulatory alternative to paper reporting and establishes requirements to assure that electronic documents are as legally dependable as their paper counterparts. Subpart D of CROMERR requires that state, tribal or local government agencies that receive, or wish to begin receiving, electronic reports under their EPA-authorized programs must apply to EPA for a revision or modification of those programs and obtain EPA approval. Subpart D provides standards for such approvals based on consideration of the electronic document receiving systems that the state, tribe, or local government will use to implement the electronic reporting. Additionally, § 3.1000(b) through (e) of 40 CFR part 3, subpart D provides special procedures for program revisions and modifications to allow electronic reporting, to be used at the option of the state, tribe or local government in place of procedures available under existing program-specific authorization regulations. An application submitted under the subpart D procedures must show that the state, tribe or local government has sufficient legal authority to implement the electronic reporting components of the programs covered by the application and will use electronic document receiving systems that meet the applicable subpart D requirements.

On September 15, 2015, the Illinois Environmental Protection Agency (IEPA) submitted an application titled ''National Network Discharge Monitoring Report System'' for revision/modification its EPA-approved Part 123 program under title 40 CFR to allow new electronic reporting. EPA reviewed IEPA's request to revise/modify its EPA-authorized Part 123—EPA Administered Permit Programs: The National Pollutant Discharge Elimination System program and, based on this review, EPA determined that the application met the standards for approval of authorized program revision/modification set out in 40 CFR part 3, subpart D. In accordance with 40 CFR 3.1000(d), this notice of EPA's decision to approve Illinois's request to revise/modify its Part 123—EPA Administered Permit Programs: The National Pollutant Discharge Elimination System program to allow electronic reporting if discharge monitoring report information under 40 CFR part 122 is being published in the **Federal Register**.

IEPA was notified of EPA's determination to approve its application with respect to the authorized program listed above.

Matthew Leopard,

Director, Office of Information Collection.

[FR Doc. 2015–30914 Filed 12–8–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–RCRA–2015–0731, FRL–9939–96–OSWER]

Agency Information Collection Activities; Proposed Collection; Comment Request; Generator Standards Applicable to Laboratories Owned by Eligible Academic Entities

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), Generator Standards Applicable To Laboratories Owned By Eligible Academic Entities (EPA ICR No. 2317.03, OMB Control No. 2050–0204 to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*). Before doing so, the EPA is soliciting public comments on specific aspects of the proposed information

collection as described below. This is a proposed extension of the ICR, which is currently approved through March 31, 2016. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Comments must be submitted on or before February 8, 2016.

ADDRESSES: Submit your comments, referencing by Docket ID No. EPA–HQ–RCRA–2015–0731, online using *www.regulations.gov* (our preferred method), by email to *rcra-docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Josh Smeraldi, Office of Resource Conservation and Recovery (mail code 5304P), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: 703–308–0441; fax number: 703–308–0514; email address: *Smeraldi.josh@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, the EPA is soliciting comments and information to enable it to: (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. The EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, the EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: The U.S. Environmental Protection Agency (EPA) has finalized an alternative set of generator requirements applicable to laboratories owned by eligible academic entities, as defined in the final rule. The rule, which establishes a Subpart K within 40 CFR Part 262, provides a flexible and protective set of regulations that address the specific nature of hazardous waste generation and accumulation in laboratories owned by colleges and universities, and teaching hospitals and non-profit research institutes that are either owned by or formally affiliated with a college or university. In addition, the rule allows colleges and universities and these other eligible academic entities formally affiliated with a college or university the discretion to determine the most appropriate and effective method of compliance with these requirements by allowing them the choice of managing their hazardous wastes in accordance with the alternative regulations as set forth in Subpart K or remaining subject to the existing generator regulations.

Form Numbers: None.

Respondents/affected entities: Entities potentially affected by this action are private sector as well as State, Local, or Tribal Governments.

Respondent's obligation to respond: required to obtain or retain a benefit (Sections 2002, 3001, 3002, 3004 of RCRA).

Estimated number of respondents: 99.

Frequency of response: On occasion.

Total estimated burden: 27,719 hours Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: Estimated Total Annual Cost: $1,322,414, which includes $1,218,693 annualized labor costs and $103,720 annualized capital or O&M costs.

Changes in Estimates: The burden hours are likely to stay substantially the same.

Dated: November 23, 2015.

Barnes Johnson,

Director, Office of Resource Conservation and Recovery.

[FR Doc. 2015–31045 Filed 12–8–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2014–0533; FRL–9939–91–OAR]

California State Nonroad Engine Pollution Control Standards; Large Spark-Ignition (LSI) Engines; New Emission Standards and In-Use Fleet Requirements; Notice of Decision

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of decision.

SUMMARY: The Environmental Protection Agency (EPA) is granting the California Air Resources Board's (CARB's) request for authorization of California's 2008 amendments to its new large spark-ignition nonroad engines regulation (2008 LSI Amendments). EPA is also confirming that CARB's 2010 amendments to its in-use fleet average emission requirements (2010 LSI Fleet Amendments) are within the scope of EPA's prior authorization. This decision is issued under the authority of the Clean Air Act (''CAA'' or ''Act'').

DATES: Petitions for review must be filed by February 8, 2016.

ADDRESSES: EPA has established a docket for this action under Docket ID EPA–HQ–OAR–2014–0533. All documents relied upon in making this decision, including those submitted to EPA by CARB, are contained in the public docket. Publicly available docket materials are available either electronically through *www.regulations.gov* or in hard copy at the Air and Radiation Docket in the EPA Headquarters Library, EPA West Building, Room 3334, located at 1301 Constitution Avenue NW, Washington, DC. The Public Reading Room is open to the public on all federal government working days from 8:30 a.m. to 4:30 p.m.; generally, it is open Monday through Friday, excluding holidays. The telephone number for the Reading Room is (202) 566–1744. The Air and Radiation Docket and Information Center's Web site is *http://www.epa.gov/oar/docket.html.* The electronic mail (email) address for the Air and Radiation Docket is: *a-and-r-Docket@epa.gov,* the telephone number is (202) 566–1742, and the fax number is (202) 566–9744. An electronic version of the

public docket is available through the federal government's electronic public docket and comment system. You may access EPA dockets at *http://www.regulations.gov.* After opening the *www.regulations.gov* Web site, enter EPA–HQ–OAR–2014–0533 in the ''Enter Keyword or ID'' fill-in box to view documents in the record. Although a part of the official docket, the public docket does not include Confidential Business Information (''CBI'') or other information whose disclosure is restricted by statute.

EPA's Office of Transportation and Air Quality (''OTAQ'') maintains a Web page that contains general information on its review of California waiver requests. Included on that page are links to prior waiver **Federal Register** notices, some of which are cited in today's notice; the page can be accessed at *http://www.epa.gov/otaq/cafr.htm.*

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SUPPLEMENTARY INFORMATION:

I. Background

A. California's LSI Regulations

CARB promulgated its first LSI regulations in 1999, applicable to new LSI engines (1999 LSI regulations).[1] The 1999 LSI regulations established exhaust emission standards and associated test procedures for LSI engines based upon engine displacement. The exhaust emission standards applicable to 2002 and subsequent model years (MYs) with displacements up to one liter were identical to the emission standards applicable to California small off-road engines (SORE) with engines greater than or equal to 225 cubic centimeters. CARB subsequently adopted more stringent exhaust emission standards for engines greater than 225 cubic centimeters.[2] CARB adopted is initial off-road LSI fleet operator regulations on May 25, 2006.[3] The fleet operator regulations are designed to address the hydrocarbon and nitrogen oxide emissions from the existing LSI engines operating in California and require fleets to meet certain fleet average emission level (FAEL) standards.[4]

By letter dated June 2, 2014, CARB submitted to EPA its request pursuant to section 209(e) of the CAA, regarding its 2008 LSI Amendments which create two new subcategories of LSI engines: LSI engines with an engine displacement less than or equal to 825 cubic centimeters (cc) (LSI ≤ 825 cc), and LSI engines with an engine displacement greater than 825 cc but less than or equal to one liter (825cc ≤1.0 L). The 2008 LSI Amendments establish exhaust emission standards for new 2011 and subsequent model year (MY) LSI engines in each of these new subcategories and additionally establish more stringent exhaust emission standards for 2015 and subsequent MY LSI engines with engine displacements 825cc ≤1.0 L. The 2008 LSI Amendments also establish evaporative emission standards for 2011 and subsequent MY LSI engines within the two new subcategories, and the amendments provide manufacturers of LSI engines used in vehicles that are similar to off-highway recreational vehicles (OHRVs) the option to use the OHRV test and certification procedures.[5]

CARB also submitted its 2010 LSI Fleet Amendments for confirmation from EPA that such amendments are within the scope of a previous EPA authorization. These amendments are designed to enhance the compliance flexibility provisions of the existing LSI Fleet regulation. They amend the existing limited hours of use (LHU) provisions to exempt equipment that operates no more than 200 hours per year subsequent to January 1, 2011 from the fleet average emission standard requirements of the LSI Fleet regulation. The 2010 LSI Fleet Amendments also extend the existing compliance extension period that is available if CARB has not verified a retrofit emission control system, or if one is not commercially available, from one year to two years and allow for an additional two year extension if a retrofit emission control system remains unavailable. The 2010 LSI Fleet Amendments also include additional provisions that largely clarify existing regulatory provisions or provide additional compliance flexibility (*e.g.* revising the definitions of ''baseline inventory,'' ''operator,'' and ''airport ground support equipment''; providing an exclusion for certain inoperable equipment from the FAEL requirements; and providing a clarification of the record keeping requirements and of the FAEL definition).[6]

B. Clean Air Act Nonroad Engine and Vehicle Authorizations

Section 209(e)(1) of the Act permanently preempts any State, or political subdivision thereof, from adopting or attempting to enforce any standard or other requirement relating to the control of emissions for new nonroad engines or vehicles. States are also preempted from adopting and enforcing standards and other requirements related to the control of emissions from non-new nonroad engines or vehicles. Section 209(e)(2) requires the Administrator, after notice and opportunity for public hearing, to authorize California to enforce such standards and other requirements, unless EPA makes one of three findings. In addition, other states with attainment plans may adopt and enforce such regulations if the standards, and implementation and enforcement procedures, are identical to California's standards. On July 20, 1994, EPA promulgated a rule that sets forth, among other things, regulations providing the criteria, as found in section 209(e)(2), which EPA must consider before granting any California authorization request for new nonroad engine or vehicle emission standards.[7] EPA later revised these regulations in 1997.[8] As stated in the preamble to the 1994 rule, EPA has historically interpreted the section 209(e)(2)(iii)

[1] EPA granted an authorization for these LSI regulations at 71 FR 29623 (May 15, 2006).

[2] EPA granted an authorization for these LSI regulations at 71 FR 75536 (December 15, 2006).

[3] The term ''off-road'' is used interchangeably with ''nonroad'' within this decision.

[4] EPA granted an authorization for these LSI regulations at 77 FR 20388 (April 12, 2012).

[5] CARB adopted the 2008 LSI Amendments on November 21, 2008 (see Resolution 08–42 at EPA–HQ–OAR–2014–0533–0008).

[6] CARB adopted the 2010 LSI Fleet Amendments on December 17, 2010 (see Resolution 10–48 at EPA–HQ–OAR–2014–0533–0024).

[7] 59 FR 36969 (July 20, 1994).

[8] *See* 62 FR 67733 (December 30, 1997). The applicable regulations, now in 40 CFR part 1074, subpart B, § 1074.105, provide:

(a) The Administrator will grant the authorization if California determines that its standards will be, in the aggregate, at least as protective of public health and welfare as otherwise applicable federal standards.

(b) The authorization will not be granted if the Administrator finds that any of the following are true:

(1) California's determination is arbitrary and capricious.

(2) California does not need such standards to meet compelling and extraordinary conditions.

(3) The California standards and accompanying enforcement procedures are not consistent with section 209 of the Act.

(c) In considering any request from California to authorize the state to adopt or enforce standards or other requirements relating to the control of emissions from new nonroad spark-ignition engines smaller than 50 horsepower, the Administrator will give appropriate consideration to safety factors (including the potential increased risk of burn or fire) associated with compliance with the California standard.

''consistency'' inquiry to require, at minimum, that California standards and enforcement procedures be consistent with section 209(a), section 209(e)(1), and section 209(b)(1)(C) (as EPA has interpreted that subsection in the context of section 209(b) motor vehicle waivers).[9]

In order to be consistent with section 209(a), California's nonroad standards and enforcement procedures must not apply to new motor vehicles or new motor vehicle engines. To be consistent with section 209(e)(1), California's nonroad standards and enforcement procedures must not attempt to regulate engine categories that are permanently preempted from state regulation. To determine consistency with section 209(b)(1)(C), EPA typically reviews nonroad authorization requests under the same ''consistency'' criteria that are applied to motor vehicle waiver requests. Pursuant to section 209(b)(1)(C), the Administrator shall not grant California a motor vehicle waiver if she finds that California ''standards and accompanying enforcement procedures are not consistent with section 202(a)'' of the Act. Previous decisions granting waivers and authorizations have noted that state standards and enforcement procedures are inconsistent with section 202(a) if: (1) There is inadequate lead time to permit the development of the necessary technology giving appropriate consideration to the cost of compliance within that time, or (2) the federal and state testing procedures impose inconsistent certification requirements.

In light of the similar language of sections 209(b) and 209(e)(2)(A), EPA has reviewed California's requests for authorization of nonroad vehicle or engine standards under section 209(e)(2)(A) using the same principles that it has historically applied in reviewing requests for waivers of preemption for new motor vehicle or new motor vehicle engine standards under section 209(b).[10] These principles include, among other things, that EPA should limit its inquiry to the three specific authorization criteria identified in section 209(e)(2)(A),[11] and that EPA should give substantial deference to the policy judgments California has made in adopting its regulations. In previous waiver decisions, EPA has stated that Congress intended EPA's review of California's decision-making be narrow. EPA has rejected arguments that are not specified in the statute as grounds for denying a waiver:

> The law makes it clear that the waiver requests cannot be denied unless the specific findings designated in the statute can properly be made. The issue of whether a proposed California requirement is likely to result in only marginal improvement in California air quality not commensurate with its costs or is otherwise an arguably unwise exercise of regulatory power is not legally pertinent to my decision under section 209, so long as the California requirement is consistent with section 202(a) and is more stringent than applicable Federal requirements in the sense that it may result in some further reduction in air pollution in California.[12]

This principle of narrow EPA review has been upheld by the U.S. Court of Appeals for the District of Columbia Circuit.[13] Thus, EPA's consideration of all the evidence submitted concerning an authorization decision is circumscribed by its relevance to those questions that may be considered under section 209(e)(2)(A).

C. Within-the-Scope Determinations

If California amends regulations that were previously authorized by EPA, California may ask EPA to determine that the amendments are within the scope of the earlier authorization. A within-the-scope determination for such amendments is permissible without a full authorization review if three conditions are met. First, the amended regulations must not undermine California's previous determination that its standards, in the aggregate, are as protective of public health and welfare as applicable federal standards. Second, the amended regulations must not affect consistency with section 209 of the Act, following the same criteria discussed above in the context of full authorizations. Third, the amended regulations must not raise any ''new issues'' affecting EPA's prior authorizations.[14]

D. Deference to California

In previous waiver decisions, EPA has recognized that the intent of Congress in creating a limited review based on the section 209(b)(1) criteria was to ensure that the federal government did not second-guess state policy choices. This has led EPA to state:

> It is worth noting. . . . I would feel constrained to approve a California approach to the problem which I might also feel unable to adopt at the federal level in my own capacity as a regulator. The whole approach of the Clean Air Act is to force the development of new types of emission control technology where that is needed by compelling the industry to ''catch up'' to some degree with newly promulgated standards. Such an approach . . . may be attended with costs, in the shape of reduced product offering, or price or fuel economy penalties, and by risks that a wider number of vehicle classes may not be able to complete their development work in time. Since a balancing of these risks and costs against the potential benefits from reduced emissions is a central policy decision for any regulatory agency under the statutory scheme outlined above, I believe I am required to give very substantial deference to California's judgments on this score.[15]

EPA has stated that the text, structure, and history of the California waiver provision clearly indicate both a congressional intent and appropriate EPA practice of leaving the decision on ''ambiguous and controversial matters of public policy'' to California's judgment.[16]

The House Committee Report explained as part of the 1977 amendments to the Clean Air Act, where Congress had the opportunity to restrict the waiver provision, it elected instead to explain California's flexibility to adopt a complete program of motor vehicle emission controls. The amendment is intended to ratify and strengthen the California waiver provision and to affirm the underlying intent of that provision, *i.e.,* to afford California the broadest possible discretion in selecting the best means to protect the health of its citizens and the public welfare.[17]

E. Burden and Standard of Proof

As the U.S. Court of Appeals for the D.C. Circuit has made clear in *MEMA I,* opponents of a waiver request by California bear the burden of showing that the statutory criteria for a denial of the request have been met:

[9] *See* 59 FR 36969 (July 20, 1994).

[10] *See Engine Manufacturers Association* v. *EPA,* 88 F.3d 1075, 1087 (D.C. Cir. 1996): ''. . . EPA was within the bounds of permissible construction in analogizing § 209(e) on nonroad sources to § 209(a) on motor vehicles.''

[11] *See supra* note 12, at 36983.

[12] ''Waiver of Application of Clean Air Act to California State Standards,'' 36 FR 17458 (August 31, 1971). Note that the more stringent standard expressed here, in 1971, was superseded by the 1977 amendments to section 209, which established that California must determine that its standards are, in the aggregate, at least as protective of public health and welfare as applicable Federal standards. In the 1990 amendments to section 209, Congress established section 209(e) and similar language in section 209(e)(1)(i) pertaining to California's nonroad emission standards which California must determine to be, in the aggregate, at least as protective of public health and welfare as applicable federal standards.

[13] *See, e.g., Motor and Equip. Mfrs Assoc.* v. *EPA,* 627 F.2d 1095 (D.C. Cir. 1979) (''*MEMA I*'').

[14] *See* ''California State Motor Vehicle Pollution Control Standards; Amendments Within the Scope of Previous Waiver of Federal Preemption,'' 46 FR 36742 (July 15, 1981).

[15] 40 FR 23103–23104 (May 28, 1975); *see also* LEV I Decision Document at 64 (58 FR 4166 (January 13, 1993)).

[16] 40 FR 23104; 58 FR 4166.

[17] *MEMA I,* 627 F.2d at 1110 (citing H.R.Rep. No. 294, 95 Cong., 1st Sess. 301–02 (1977).

> [T]he language of the statute and its legislative history indicate that California's regulations, and California's determinations that they must comply with the statute, when presented to the Administrator are presumed to satisfy the waiver requirements and that the burden of proving otherwise is on whoever attacks them. California must present its regulations and findings at the hearing and thereafter the parties opposing the waiver request bear the burden of persuading the Administrator that the waiver request should be denied.[18]

The Administrator's burden, on the other hand, is to make a reasonable evaluation of the information in the record in coming to the waiver decision. As the court in *MEMA I* stated: ''here, too, if the Administrator ignores evidence demonstrating that the waiver should not be granted, or if he seeks to overcome that evidence with unsupported assumptions of his own, he runs the risk of having his waiver decision set aside as 'arbitrary and capricious.' '' [19] Therefore, the Administrator's burden is to act ''reasonably.'' [20]

With regard to the standard of proof, the court in *MEMA I* explained that the Administrator's role in a section 209 proceeding is to:

> [. . .] consider all evidence that passes the threshold test of materiality and * * * thereafter assess such material evidence against a standard of proof to determine whether the parties favoring a denial of the waiver have shown that the factual circumstances exist in which Congress intended a denial of the waiver.[21]

In that decision, the court considered the standards of proof under section 209 for the two findings related to granting a waiver for an ''accompanying enforcement procedure.'' Those findings involve: (1) Whether the enforcement procedures impact California's prior protectiveness determination for the associated standards, and (2) whether the procedures are consistent with section 202(a). The principles set forth by the court, however, are similarly applicable to an EPA review of a request for a waiver of preemption for a standard. The court instructed that ''the standard of proof must take account of the nature of the risk of error involved in any given decision, and it therefore varies with the finding involved. We need not decide how this standard operates in every waiver decision.'' [22]

With regard to the protectiveness finding, the court upheld the Administrator's position that, to deny a waiver, there must be ''clear and compelling evidence'' to show that proposed enforcement procedures undermine the protectiveness of California's standards.[23] The court noted that this standard of proof also accords with the congressional intent to provide California with the broadest possible discretion in setting regulations it finds protective of the public health and welfare.[24]

With respect to the consistency finding, the court did not articulate a standard of proof applicable to all proceedings, but found that the opponents of the waiver were unable to meet their burden of proof even if the standard were a mere preponderance of the evidence. Although *MEMA I* did not explicitly consider the standards of proof under section 209 concerning a waiver request for ''standards,'' as compared to a waiver request for accompanying enforcement procedures, there is nothing in the opinion to suggest that the court's analysis would not apply with equal force to such determinations. EPA's past waiver decisions have consistently made clear that: ''[E]ven in the two areas concededly reserved for Federal judgment by this legislation—the existence of 'compelling and extraordinary' conditions and whether the standards are technologically feasible—Congress intended that the standards of EPA review of the State decision to be a narrow one.'' [25]

F. EPA's Administrative Process in Consideration of California's LSI Regulations

On November 24, 2014, EPA published a **Federal Register** notice announcing its receipt of California's authorization request. In that notice, EPA invited public comment on the 2008 LSI Amendments and the 2010 LSI Fleet Amendments and provided an opportunity to request a public hearing.[26]

EPA requested comment on the amendments, as follows: (1) Should California's amendments be considered under the within-the-scope analysis, or should they be considered under the full authorization criteria?; (2) If those amendments should be considered as a within-the-scope request, do they meet the criteria for EPA to grant a within-the-scope confirmation?; and (3) If the amendments should not be considered under the within-the-scope analysis, or in the event that EPA determines they are not within the scope of the previous authorization, do they meet the criteria for making a full authorization determination?

EPA received no written comments. Additionally, EPA received no requests for a public hearing. Consequently, EPA did not hold a public hearing.

II. Discussion

California requested that the Administrator grant a full authorization for its 2008 LSI Amendments and that such amendments meet the three authorization criteria found in section 209(e)(2)(A) of the CAA. We received no adverse comment or evidence suggesting that these amendments fail to meet any of the full authorization criteria.

California also requested that the Administrator confirm that the 2010 LSI Fleet Amendments detailed above are within the scope of a previously granted full authorization. California asserted that the 2010 LSI Fleet Amendments met all three within-the-scope criteria, *i.e.* that the amendments: (1) Do not undermine the original protectiveness determination underlying California's regulations; (2) do not affect the consistency of the regulations with section 202(a); and (3) do not raise any new issues affecting the prior authorizations. We received no adverse comments or evidence suggesting a within-the-scope analysis is inappropriate, or that the 2010 LSI Amendments fail to meet any of the three criteria for within-the-scope confirmation.

Our analysis of the 2008 LSI Amendments in the context of the full authorization criteria, and our analysis of the 2010 LSI Fleet Amendments in the context of the within-the-scope criteria, is set forth below.

A. California's Protectiveness Determination

Section 209(e)(2)(A)(i) of the CAA instructs that EPA cannot grant a full authorization if the agency finds that California was arbitrary and capricious in its determination that its standards are, in the aggregate, at least as protective of public health and welfare as applicable federal standards. CARB's Board made a protectiveness determination in Resolution 08–42, finding that California's 2008 LSI

[18] *MEMA I, supra* note 19, at 1121.

[19] *Id.* at 1126.

[20] *Id.* at 1126.

[21] *Id.* at 1122.

[22] *Id.*

[23] *Id.*

[24] *Id.*

[25] *See, e.g.,* ''California State Motor Vehicle Pollution Control Standards; Waiver of Federal Preemption,'' 40 FR 23102 (May 28, 1975), at 23103.

[26] *See* ''California State Nonroad Engine Pollution Control Standards; Small Off-Road Engines Regulations; Tier 4 Off-Road Compression-Ignition Regulations; Exhaust Emission Certification Test Fuel for Off-Road Spark-Ignition Engines, Equipment, and Vehicles Regulations; Request for Within-the-Scope and Full Authorization; Opportunity for Public Hearing and Comment,'' 79 FR 27801 (November 24, 2014).

Amendments will not cause the California emission standards, in the aggregate, to be less protective of public health and welfare than applicable federal standards.[27] CARB presents that California's exhaust emission standards applicable to LSI ≤ 825 cc and 825 cc ≤ LSI≤ 1.0 L are at least as protective of public health and welfare as applicable federal exhaust emission standards. Similarly CARB's Executive Officer found that California's evaporative emission requirements applicable to 2011 and subsequent MY engines less than or equal to one liter are, in the aggregate, at least as protective as applicable federal standards.[28]

EPA did not receive any comments challenging California's protectiveness determination. Therefore, based on the record before us, EPA finds no evidence in the record that demonstrates California was arbitrary and capricious in its determination that its 2008 LSI Amendments are, in the aggregate, at least as protective of public health and welfare as applicable federal standards.

Similarly, CARB's 2010 LSI Fleet Amendments must not undermine California's previous determination that its standards, in the aggregate, are as protective of public health and welfare as applicable federal standards. In adopting the 2010 LSI Fleet Amendments CARB made a protectiveness determination in Resolution 10–48, finding that California's 2010 LSI Fleet Amendments do not undermine the Board's previous determination that the California emission standards, other emission related requirements, and associated enforcement procedures are, in the aggregate, at least as protective of public health and welfare than applicable federal standards.[29]

EPA did not receive any comments challenging California's determination that its 2010 LSI Fleet Amendments do not undermine California's prior protectiveness determination. Therefore, based on the record before us, EPA finds no evidence in the record that demonstrates California was arbitrary and capricious in its determination that its 2010 LSI Fleet Amendments do not undermine California's prior protectiveness determination.

B. Need for California Standards To Meet Compelling and Extraordinary Conditions

Section 209(e)(2)(A)(ii) of the Act instructs that EPA cannot grant a full authorization if the agency finds that California ''does not need such California standards to meet compelling and extraordinary conditions.'' This criterion restricts EPA's inquiry to whether California needs its own mobile source pollution program to meet compelling and extraordinary conditions, and not whether any given standards are necessary to meet such conditions.[30] In its Resolution 08–42, CARB affirmed its longstanding position that California continues to need its own nonroad engine program to meet its serious air pollution problems. Likewise, EPA has consistently recognized that California continues to have the same ''geographical and climatic conditions that, when combined with the large numbers and high concentrations of automobiles, create serious pollution problems.''[31] Furthermore, no commenter has presented any argument or evidence to suggest that California no longer needs a separate nonroad engine emissions program to address compelling and extraordinary conditions in California. Therefore, EPA has determined that we cannot deny California an authorization for its 2008 LSI Amendments under section 209(e)(2)(A)(ii). EPA's within-the-scope determinations, applicable in this instance to CARB's request for its 2010 LSI Fleet Amendments, does not require an EPA analysis under section 209(e)(2)(A)(ii).

C. Consistency With Section 209 of the Clean Air Act

Section 209(e)(2)(A)(iii) of the Act instructs that EPA cannot grant an authorization if California's standards and enforcement procedures are not consistent with section 209. As described above, EPA has historically evaluated this criterion for consistency with sections 209(a), 209(e)(1), and 209(b)(1)(C). Similarly, EPA's analysis for within-the-scope determinations includes an assessment of whether the amendments are consistent with section 209.

1. Consistency With Section 209(a)

To be consistent with section 209(a) of the Clean Air Act, California's 2008 LSI Amendments and 2010 LSI Fleet Amendments must not apply to new motor vehicles or new motor vehicle engines. California's LSI regulations expressly apply only to off-road vehicles and do not apply to engines used in motor vehicles as defined by section 216(2) of the Clean Air Act.[32] No commenter presented otherwise. Therefore, EPA cannot deny California's request on the basis that California's 2008 LSI Amendments and 2010 LSI Fleet Amendments are not consistent with section 209(a).

2. Consistency With Section 209(e)(1)

To be consistent with section 209(e)(1) of the Clean Air Act, California's 2008 LSI Amendments and 2010 LSI Fleet Amendments must not affect new farming or construction vehicles or engines that are below 175 horsepower, or new locomotives or their engines. CARB notes that its LSI regulations do not affect such permanently preempted vehicles or engines.[33] Therefore, EPA cannot deny California's request on the basis that California's LSI amendments are not consistent with section 209(e)(1).

3. Consistency With Section 209(b)(1)(C)

The requirement that California's standards be consistent with section 209(b)(1)(C) of the Clean Air Act effectively requires consistency with section 202(a) of the Act. California standards are inconsistent with section 202(a) of the Act if there is inadequate lead-time to permit the development of technology necessary to meet those requirements, giving appropriate consideration to the cost of compliance within that timeframe. California's accompanying enforcement procedures would also be inconsistent with section 202(a) if federal and California test procedures conflicted. The scope of EPA's review of whether California's action is consistent with section 202(a) is narrow. The determination is limited to whether those opposed to the authorization or waiver have met their burden of establishing that California's standards are technologically infeasible, or that California's test procedures impose requirements inconsistent with the federal test procedures.[34]

[27] ''BE IT FURTHER RESOLVED that the Board hereby determines, pursuant to section 209(e)(2) of the federal Clean Air Act that the emission standards and other requirements related to the control of emissions adopted as part of these regulations are, in the aggregate, at least as protective of public health and welfare as applicable federal standards, that California needs the adopted standards to meet compelling and extraordinary conditions, and that the adopted standards and accompanying enforcement procedures are consistent with the provisions in section 209.'' CARB, Resolution 06–11. This Resolution also extends to CARB's amendment requiring LSI engines used in vehicles similar to OHRVs to utilize OHRV test procedures. EPA–HQ–OAR–2014–0533–0008.

[28] CARB Executive Order G–14–014, EPA–HQ–OAR–2014–0533–0033.

[29] CARB Resolution 10–48, EP–HQ–OAR–2014–0533–0024.

[30] *See* 74 FR 32744, 32761 (July 8, 2009); 49 FR 18887, 18889–18890 (May 3, 1984).

[31] 49 FR 18887, 18890 (May 3, 1984); *see also* 76 FR 34693 (June 14, 2011), 74 FR 32744, 32763 (July 8, 2009), and 73 FR 52042 (September 8, 2008).

[32] CARB, Request for Authorization at 16, and 23. EPA–HQ–OAR–2014–0533–0003.

[33] *Id.*

[34] *MEMA I,* 627, F.2d at 1126.

a. Technological Feasibility

Congress has stated that the consistency requirement of section 202(a) relates to technological feasibility.[35] Section 202(a)(2) states, in part, that any regulation promulgated under its authority ''shall take effect after such period as the Administrator finds necessary to permit the development and application of the requisite technology, giving appropriate consideration to the cost of compliance within such period.'' Section 202(a) thus requires the Administrator to first determine whether adequate technology already exists; or if it does not, whether there is adequate time to develop and apply the technology before the standards go into effect. The latter scenario also requires the Administrator to decide whether the cost of developing and applying the technology within that time is feasible. Previous EPA waivers are in accord with this position.[36] For example, a previous EPA waiver decision considered California's standards and enforcement procedures to be consistent with section 202(a) because adequate technology existed as well as adequate lead-time to implement that technology.[37] Subsequently, Congress has stated that, generally, EPA's construction of the waiver provision has been consistent with congressional intent.[38]

CARB presents that the technology required to comply with its LSI regulations is feasible, and that it has provided sufficient lead-time, giving consideration to the cost of compliance.[39]

EPA did not receive any comments suggesting that CARB's standards and test procedures are technologically infeasible. Consequently, based on the record, EPA cannot deny California's full authorization (for the 2008 LSI Amendments) based on technological infeasibility. Also, EPA cannot deny California's within-the-scope request for the 2010 LSI Fleet Amendments based on technological infeasibility.

b. Consistency of Certification Procedures

California's standards and accompanying enforcement procedures would also be inconsistent with section 202(a) if the California test procedures were to impose certification requirements inconsistent with the federal certification requirements. Such inconsistency means that manufacturers would be unable to meet both the California and federal testing requirements using the same test vehicle or engine.[40] CARB presents that there is no issue regarding test procedure inconsistency for new LSI engines as California's test procedures were not modified since EPA's prior waiver.[41] CARB also presents that its 2010 LSI Fleet Amendments do not include any test procedures and thus do not create an inconsistency issue.

EPA received no comments suggesting that CARB's LSI regulations pose any test procedure consistency problem. Therefore, based on the record, EPA cannot find that CARB's testing procedures are inconsistent with section 202(a). Consequently, EPA cannot deny CARB's request based on the criterion of consistency with section 209.

4. New Issues

In the context of the 2010 LSI Fleet Amendments, CARB states that it is not aware of any new issues affecting the previously granted authorization for CARB's LSI Fleet regulations. ''The Amendments do not create new, more stringent emission standards or requirements, nor force any change in technology to warrant revisiting conclusions in granting the existing authorization.''[42] EPA received no comment on this issue. We therefore do not find any new issues raised by the 2010 LSI Fleet Amendments.

E. Authorization Determinations for California's LSI Amendments

After a review of the information submitted by CARB, EPA finds no basis for denying CARB's full authorization request for the 2008 LSI Fleet Amendments and EPA finds no basis for denying CARB's request that EPA confirm the 2010 LSI Fleet Amendments are within the scope of a prior EPA full authorization. For these reasons, EPA finds that a full authorization for California's 2008 LSI Amendments should be granted and a within-the-scope determination should be granted for California's 2010 LSI Fleet Amendments.

III. Decision

The Administrator has delegated the authority to grant California section 209(e) authorizations to the Assistant Administrator for Air and Radiation. After evaluating California's LSI amendments, CARB's submissions, and the lack of any comment or adverse comment, EPA is granting a full authorization to California for its 2008 LSI Amendments and a within-the-scope determination for its 2010 LSI Fleet Amendments.

This decision will affect persons in California and those manufacturers and/or owners/operators nationwide who must comply with California's requirements. In addition, because other states may adopt California's standards for which a section 209(e)(2)(A) authorization has been granted if certain criteria are met, this decision would also affect those states and those persons in such states. See CAA section 209(e)(2)(B). For these reasons, EPA determines and finds that this is a final action of national applicability, and also a final action of nationwide scope or effect for purposes of section 307(b)(1) of the Act. Pursuant to section 307(b)(1) of the Act, judicial review of this final action may be sought only in the United States Court of Appeals for the District of Columbia Circuit. Petitions for review must be filed by February 8, 2016. Judicial review of this final action may not be obtained in subsequent enforcement proceedings, pursuant to section 307(b)(2) of the Act.

IV. Statutory and Executive Order Reviews

As with past authorization and waiver decisions, this action is not a rule as defined by Executive Order 12866. Therefore, it is exempt from review by the Office of Management and Budget as required for rules and regulations by Executive Order 12866.

In addition, this action is not a rule as defined in the Regulatory Flexibility Act, 5 U.S.C. 601(2). Therefore, EPA has not prepared a supporting regulatory flexibility analysis addressing the impact of this action on small business entities.

Further, the Congressional Review Act, 5 U.S.C. 801, *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, does not apply because this action is not a rule for purposes of 5 U.S.C. 804(3).

Dated: December 1, 2015.

Janet G. McCabe,

Acting Assistant Administrator, Office of Air and Radiation.

[FR Doc. 2015–31049 Filed 12–8–15; 8:45 am]

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[35] H.R. Rep. No. 95–294, 95th Cong., 1st Sess. 301 (1977).

[36] *See, e.g.,* 49 FR 1887, 1895 (May 3, 1984); 43 FR 32182, 32183 (July 25, 1978); 41 FR 44209, 44213 (October 7, 1976).

[37] 41 FR 44209 (October 7, 1976).

[38] H.R. Rep. No. 95–294, 95th Cong., 1st Sess. 301 (1977).

[39] CARB, Request for Authorization at 17–21, 23.

[40] *See, e.g.,* 43 FR 32182 (July 25, 1978).

[41] 79 FR 29623 (May 23, 2006). *See also* CARB, Request for Authorization at 21.

[42] CARB, Request for Authorization at 23.

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9931–88–OEI]

Cross-Media Electronic Reporting: Authorized Program Revision Approval, State of Iowa

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: This notice announces EPA's approval of the State of Iowa's request to revise certain of its EPA-authorized programs to allow electronic reporting.

DATES: EPA's approval is effective December 9, 2015.

FOR FURTHER INFORMATION CONTACT: Karen Seeh, U.S. Environmental Protection Agency, Office of Environmental Information, Mail Stop 2823T, 1200 Pennsylvania Avenue NW., Washington, DC 20460, (202) 566–1175, *seeh.karen@epa.gov.*

SUPPLEMENTARY INFORMATION: On October 13, 2005, the final Cross-Media Electronic Reporting Rule (CROMERR) was published in the **Federal Register** (70 FR 59848) and codified as part 3 of title 40 of the CFR. CROMERR establishes electronic reporting as an acceptable regulatory alternative to paper reporting and establishes requirements to assure that electronic documents are as legally dependable as their paper counterparts. Subpart D of CROMERR requires that state, tribal or local government agencies that receive, or wish to begin receiving, electronic reports under their EPA-authorized programs must apply to EPA for a revision or modification of those programs and obtain EPA approval. Subpart D provides standards for such approvals based on consideration of the electronic document receiving systems that the state, tribe, or local government will use to implement the electronic reporting. Additionally, § 3.1000(b) through (e) of 40 CFR part 3, subpart D provides special procedures for program revisions and modifications to allow electronic reporting, to be used at the option of the state, tribe or local government in place of procedures available under existing program-specific authorization regulations. An application submitted under the subpart D procedures must show that the state, tribe or local government has sufficient legal authority to implement the electronic reporting components of the programs covered by the application and will use electronic document receiving systems that meet the applicable subpart D requirements.

On September 22, 2015, the Iowa Department of Natural Resources (IDNR) submitted an amended application titled ''State and Local Emissions Inventory System (SLEIS)'' for revisions to its EPA-approved programs under title 40 CFR to allow for electronic reporting. EPA reviewed IDNR's request to revise its EPA-authorized programs and, based on this review, EPA determined that the application met the standards for approval of authorized program revisions set out in 40 CFR part 3, subpart D. In accordance with 40 CFR 3.1000(d), this notice of EPA's decision to approve Iowa's request to revise its following EPA-authorized programs to allow electronic reporting under 40 CFR parts 51 and 70, is being published in the **Federal Register**: Part 52—Approval and Promulgation of Implementation Plans; and Part 70—State Operating Permit Programs.

IDNR was notified of EPA's determination to approve its application with respect to the authorized programs listed above.

Matt Leopard,

Director, Office of Information Collection.

[FR Doc. 2015–30913 Filed 12–8–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OAR–2003–0039; FRL–9939–90–OAR]

Proposed Information Collection Request; Comment Request; Reporting and Recordkeeping Requirements of the HCFC Allowance System

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency is planning to submit an information collection request (ICR), Reporting and Recordkeeping Requirements of the HCFC Allowance System (EPA ICR No. 2014.06, OMB Control No. 2060–0498) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Before doing so, EPA is soliciting public comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through April 30, 2016. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Comments must be submitted on or before February 8, 2016.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–HQ–OAR–2003–0039 online using *www.regulations.gov* (our preferred method), by email to *a-and-r-Docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Robert Burchard, Stratospheric Protection Division, Office of Atmospheric Programs (6205T), Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (202) 343–9126; fax number: (202) 343–2338; email address: *burchard.robert@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, EPA is soliciting comments and information to enable it to: (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology,

e.g., permitting electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: The international treaty *The Montreal Protocol on Substances that Deplete the Ozone Layer* (Protocol) and Title VI of the Clean Air Act Amendments (CAAA) established limits on total U.S. production, import, and export of class I and class II controlled ozone depleting substances (referred to hereinafter as ''controlled substances'').

Under its Protocol commitments, the United States was obligated to cease production and import of class I controlled substances (*e.g.,* chlorofluorocarbons or CFCs) with exemptions for essential uses, critical uses, previously-used material, and material that is transformed, destroyed, or exported to developing countries. The Protocol also establishes limits and reduction schedules leading to the eventual phaseout of class II controlled substances (*i.e.,* hydrochlorofluorocarbons or HCFCs).

The U.S. is obligated to limit HCFC consumption (defined by the Protocol as production plus imports, minus exports). The schedule called for a 35 percent reduction on January 1, 2004, followed by a 75 percent reduction on January 1, 2010, a 90 percent reduction on January 1, 2015, a 99.5 percent reduction on January 1, 2020, and a total phaseout on January 1, 2030. EPA is responsible for administering the phaseout.

To ensure U.S. compliance with these limits and restrictions, EPA established an allowance system to control U.S. production and import of HCFCs by granting control measures referred to as baseline and calendar-year allowances. Baseline allowances are based on the historical activity of individual companies. Calendar-year allowances allow holders to produce and/or import controlled substances in a given year and are allocated as a percentage of baseline.

There are two types of baseline and calendar-year allowances: Consumption and production allowances. Since each allowance is equal to 1 kilogram of HCFC, EPA is able to monitor the quantity of HCFCs being produced, imported and exported. Transfers of production and consumption allowances among producers and importers are allowed and are tracked by EPA.

The above-described limits and restrictions are monitored by EPA through the recordkeeping and reporting requirements established in the regulations in *40 CFR part 82,* subpart A. To submit required information, regulated entities can download reporting forms from EPA's Web site (*http://www.epa.gov/ozone/record*), complete them, and send them to EPA electronically, via mail, courier, or fax.

Upon receipt of the reports, the data is entered into the ODS Tracking System. The ODS Tracking System is a secure database that maintains the data submitted to EPA and helps the agency: (1) Maintain oversight over total production and consumption of controlled substances; (2) monitor compliance with limits and restrictions on production, imports, and trades and specific exemptions from the phaseout for individual U.S. companies; and (3) assess, and report on, compliance with U.S. obligations under the Montreal Protocol.

EPA has implemented an electronic reporting system that allows regulated entities to prepare and submit data electronically. Coupled with the widespread use of the standardized forms, electronic reporting has improved data quality and made the reporting process efficient for both reporting companies and EPA. Most reporting is done electronically.

Pursuant to regulations in *40 CFR part 2,* subpart B, reporting businesses are entitled to assert a business confidentiality claim covering any part of the submitted business information as defined in *40 CFR 2.201*(c). EPA's practice is to manage the reported information as confidential business information.

Form numbers: Forms associated with this ICR are: Quarterly Reports, Second Party Transformation Report, Second Party Destruction Report, Transmission Verification Report, Destruction Efficiency Report, Destruction Verification Report, Semi-annual Report, International Transfer of Allowances Report, and the Domestic Transfer of Allowances Report. All are under OMB Control Number 2060–0498.

Respondents/affected entities: 40.

Respondent's obligation to respond: Mandatory (Title VI of the Clean Air Act Amendments).

Estimated number of respondents: 40.

Frequency of response: Annually, quarterly, or as needed.

Total estimated burden: 1,434 hours (per year). Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $153,264 (per year), includes $1,155 annualized capital or operation & maintenance costs.

Changes in estimates: The respondent numbers changed because the reporting community continues to change as ODS are phased out in the US. Specifically, we estimate fewer companies reporting on imports and exports of Class II ODS. We also assume fewer companies reporting on the destruction and transformation of this material. These updates are based on 2014 reporting activity whereas our previous estimates were based on 2010–2011 reporting activity.

Dated: November 23, 2015.

Drusilla Hufford,

Director, Stratospheric Protection Division.

[FR Doc. 2015–31051 Filed 12–8–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9939–84–OW]

Notice of Open Meeting of the Environmental Financial Advisory Board

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The EPA's Environmental Financial Advisory Board (EFAB) will hold a public meeting on January 12–13, 2016. EFAB is an EPA advisory committee chartered under the Federal Advisory Committee Act to provide advice and recommendations to EPA on creative approaches to funding environmental programs, projects, and activities.

The purpose of this meeting is to hear from informed speakers on environmental finance issues, proposed legislation, and EPA priorities; to discuss activities, progress, and preliminary recommendations with regard current EFAB work projects; and to consider requests for assistance from EPA offices. Environmental finance discussions and presentations are expected on, but not limited to, the following topics: Financing operations and maintenance costs at green infrastructure sites; financing stormwater and green infrastructure programs; public-private partnerships for water infrastructure projects; financing pre-development activities in communities; affordability challenges in the water sector; and financial capacity development for small drinking/wastewater systems. The meeting is open to the public; however, seating is limited. All members of the public who

wish to attend the meeting must register, in advance, no later than Monday, December 28, 2015. Registration is required for all members of the public to ensure an expeditious security process.

DATES: The full board meeting will be held on Tuesday, January 12, 2016 from 1:00 p.m. to 5 p.m., EST and Wednesday, January 13, 2015 from 9:00 a.m. to 5 p.m., EST.

ADDRESSES: Hamilton Crowne Plaza Hotel, 1001 14th St. NW., Washington, DC 20005.

FOR FURTHER INFORMATION CONTACT: For information on access or services for individuals with disabilities, or to request accommodations for a person with a disability, please contact Sandra Williams at (202) 564–4999 or *williams.sandra@epa.gov,* at least 10 days prior to the meeting, to allow as much time as possible to process your request.

Dated: December 2, 2015.

Andrew D. Sawyers,

Director, Office of Wastewater Management, Office of Water.

[FR Doc. 2015–31044 Filed 12–8–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9939–69–OECA]

Notice of eDisclosure Portal Launch: Modernizing Implementation of EPA's Self-Policing Incentive Policies

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is modernizing implementation of its self-disclosure policies by creating a centralized web-based ''eDisclosure'' portal to receive and automatically process self-disclosed civil violations of environmental law. Under the automated eDisclosure system, large and small businesses will quickly be able to get some of their more routine types of disclosures resolved.

EPA is launching the eDisclosure system because it continues to believe strongly in the benefits of its self-disclosure policies: To provide penalty mitigation and other incentives for companies that self-police, disclose, correct and prevent violations. EPA believes that the implementation changes announced today will make the processing of disclosures faster and more efficient, and will save time and resources for regulated entities and EPA.

DATES: These modifications to the implementation of EPA's Audit Policy and Small Business Compliance Policy, and the launch of the eDisclosure portal, are effective immediately, December 9, 2015.

FOR FURTHER INFORMATION CONTACT: Philip Milton of EPA's Office of Enforcement and Compliance Assurance, Office of Civil Enforcement, at *milton.philip@epa.gov* or (202) 564–5029. For general information on the eDisclosure portal please visit *http://www2.epa.gov/compliance/epas-edisclosure.*

SUPPLEMENTARY INFORMATION: Over the past several years, EPA has been evaluating how best to realize the benefits of the self-disclosure policies. Most recently, EPA held two webinars in June 2015 to share its plan for eDisclosure and allow the nearly 350 people who participated to share their views and ask questions.

Companies have suggested that EPA could streamline implementation of the self-disclosure policies for more routine disclosures to make the process faster, more efficient, and to save time and resources for regulated entities and EPA, while still retaining the incentives to self-police environmental problems. The regulated community also emphasized that a key time to encourage self-auditing and self-disclosure is when companies are purchased or acquired, because that is a point in time when companies typically are assessing operations and management systems. EPA agrees with those suggestions from the regulated community and welcomes input, on an ongoing basis, as to how the eDisclosure system is working.

I. Explanation of Modification to the Implementation of the Policies

A. Introduction

On April 11, 2000, EPA issued its policy on ''Incentives for Self-Policing: Discovery, Disclosure, Correction and Prevention of Violations'' (Audit Policy). 65 FR 19618. The purpose of the Audit Policy is to enhance protection of human health and the environment by encouraging regulated entities to voluntarily discover, promptly disclose, expeditiously correct and prevent the recurrence of violations of federal environmental law. Benefits available to entities that make disclosures under the terms of the Audit Policy include reductions in, and in some cases the elimination of, civil penalties, and an EPA determination not to recommend criminal prosecution of disclosing entities. (Ultimate prosecutorial discretion resides with the U.S. Department of Justice.) More information on the Audit Policy is available at *http://www2.epa.gov/compliance/epas-audit-policy.*

On August 1, 2008, EPA issued the ''Interim Approach to Applying the Audit Policy to New Owners'' (New Owner Policy). 73 FR 44991. The purpose of the New Owner Policy is to tailor Audit Policy incentives for new owners that want to make a ''clean start'' at recently acquired facilities by addressing environmental noncompliance that began prior to acquisition. The New Owner Policy is designed to motivate new owners to audit newly acquired facilities and to encourage self-disclosures of violations that will, once corrected, yield significant pollutant reductions and benefits to the environment. The incentives tailored for new owners include clearly defined penalty mitigation beyond what is offered by the Audit Policy, as well as the modification of certain Audit Policy conditions that will allow more violations to be eligible for penalty mitigation under the Audit Policy. More information on the New Owner Policy is available at *http://www2.epa.gov/compliance/epas-interim-approach-applying-audit-policy-new-owners.*

EPA's Small Business Compliance Policy (65 FR 19630, April 11, 2000) is an additional voluntary disclosure policy that provides incentives for small businesses (with 100 or fewer employees) that voluntarily discover, promptly disclose, and expeditiously correct environmental violations. More information on the Small Business Compliance Policy is available at *http://www2.epa.gov/compliance/small-business-compliance.*

B. Background on Today's Modifications

The penalty mitigation available under EPA's self-disclosure policies has provided an incentive for regulated entities to detect, promptly disclose, expeditiously correct and prevent violations of federal environmental requirements. Since 1995, the regulated community has increasingly adopted environmental auditing and environmental management practices as key components of sound business practices. Thousands of entities have disclosed violations to EPA pursuant to the Agency's voluntary disclosure policies, and EPA continues to receive hundreds of new disclosures every year. Enforcement also has contributed to the dramatic expansion of environmental auditing, as many regulated entities who conducted audits have told EPA that one of the primary reasons for doing so

was to identify and correct violations before government inspectors discover noncompliance. Regulated entities have realized cost savings through auditing, not only by limiting their enforcement liability but also by reducing the amount of pollutants that they generate (*e.g.,* by adopting lower-cost production methods or energy-saving process changes).

C. Summary of Modifications to Audit Policy and Small Business Policy Implementation

The large number of violations self-disclosed to EPA has taxed the Agency's ability to promptly resolve all pending disclosures. Although EPA is not modifying the substantive conditions in its Audit Policy or Small Business Compliance Policy, the eDisclosure portal launched today streamlines and modernizes EPA's approach to handling disclosures under these two policies. Today's changes will result in faster and more efficient resolution of self-disclosures, while saving considerable time and resources for regulated entities and EPA. At the same time, EPA will continue to accept and process outside the automated eDisclosure system any new owner self-disclosures and any potential criminal violations disclosed to the Voluntary Disclosure Board (VDB).

In summary, entities that disclose potential violations through the new eDisclosure portal may qualify for one of two types of automated treatment, Category 1 or Category 2. In the June 2015 webinars and Information Sheet summarizing its plan for eDisclosure, EPA referred to these two types of treatment as Tier 1 and Tier 2. Because commenters expressed concern about possible confusion with Tier II Reports under the Emergency Planning and Community Right-to-Know Act (EPCRA), EPA has changed these description to Category 1 and Category 2.

Category 1. Category 1 disclosures include: (1) EPCRA violations that meet all Audit Policy conditions; and (2) EPCRA violations that meet all Small Business Compliance Policy conditions. It does not, however, include Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) section 103/EPCRA section 304 chemical release reporting violations or EPCRA violations with significant economic benefit as defined by EPA.

For disclosures that qualify for Category 1 treatment, the eDisclosure system automatically will issue an electronic Notice of Determination (eNOD) confirming that the violations are resolved with no assessment of civil penalties, conditioned on the accuracy and completeness of the submitter's disclosure. EPA will spot check Category 1 disclosures to ensure conformance with EPCRA, the Audit Policy, the Small Business Compliance Policy, and eDisclosure requirements.

EPA is currently limiting Category 1 resolutions to the above-described violations because: (a) The Agency has significant experience with providing NODs for these self-disclosed EPCRA violations (about half the disclosures EPA receives involve EPCRA reporting violations); (b) it is easy to confirm compliance with EPCRA reporting requirements; and (c) the regulated community suggested such violations for streamlined Audit Policy treatment. As the Agency gains experience with the eDisclosure system, it will evaluate whether to expand the types of violations that can qualify for Category 1 treatment.

Category 2. Category 2 disclosures include: (1) All non-EPCRA violations; (2) EPCRA violations where the discloser can only certify compliance with Audit Policy Conditions 2–9 (*i.e.,* discovery was not systematic); and (3) EPCRA/CERCLA violations excluded from Category 1 above.

For disclosures that qualify for Category 2 treatment, the eDisclosure system automatically will issue an Acknowledgement Letter (AL) noting EPA's receipt of the disclosure and promising that EPA will make a determination as to eligibility for penalty mitigation if and when it considers taking enforcement action for environmental violations. EPA will screen Category 2 disclosures for significant concerns such as criminal conduct and potential imminent hazards.

D. Summary of the eDisclosure Process

Entities wishing to disclose potential violations through the eDisclosure system must follow a three-step process:

1. *Register to File with the Centralized Web-Based Portal.* This step requires entities to register with EPA's Central Data Exchange (CDX) system. See *http://www.epa.gov/cdx/.* Existing CDX registrants who are already identity-proofed under the Cross Media Electronic Reporting and Recordkeeping Rule (CROMERR) would not be required to re-register with CDX. Also, paper identity proofing is available if electronic ID-proofing fails.

2. *Submit a Violation Disclosure.* In order to be considered ''prompt'' under both the Audit Policy and Small Business Compliance Policy, potential violations must be disclosed online within 21 calendar days of the entity's discovery that such potential violations may have occurred. If the 21st day after discovery falls on a weekend or federal holiday, the eDisclosure system will treat the disclosure as prompt if it is submitted on the next business day. Regulated entities may submit disclosures of potential (but not confirmed) violations to give them time to determine whether a violation actually occurred and to more specifically identify the particular violation(s).

eDisclosure is not designed to receive or process any information claimed as Confidential Business Information (CBI), so disclosers must submit sanitized (non-CBI) information through the online system. Any follow-up CBI required to be submitted must be done manually according to EPA procedures and the requirements of 40 CFR part 2.

3. *Certify Compliance.* Within 60 days of submitting an Audit Policy disclosure (or within 90 days of submitting a Small Business Compliance Policy disclosure), the discloser must submit a Compliance Certification in the eDisclosure system. Such Compliance Certifications must identify the specific violations, and certify that the violations have been corrected and that the Audit Policy or Small Business Compliance Policy conditions have been met. The 60-day and 90-day Compliance Certification deadlines are subject to limited extensions, as discussed further in this Notice.

Disclosed violations will be considered withdrawn from Audit Policy or Small Business Compliance Policy consideration where the disclosing entity: (1) Voluntarily withdraws its disclosure before submitting its Compliance Certification (*e.g.,* where it determines after disclosure that no violations actually occurred); (2) does not timely submit its Compliance Certification; or (3) submits a Compliance Certification that does not meet the conditions of the Audit Policy or Small Business Compliance Policy.

Whenever there is a withdrawal, the eDisclosure system automatically will record the entity's attempt to disclose potential violations, notify it that EPA will retain such records, and send the discloser a notice that the disclosure does not qualify for Audit Policy or Small Business Compliance Policy penalty mitigation through the eDisclosure system.

E. Implementation Details

1. *Violation Correction and Compliance Certification Deadlines.* Under the Audit Policy and Small Business Compliance Policy, disclosed

violations must be corrected as expeditiously as feasible and ordinarily within 60 or 90 days, respectively, from the date that the potential violations are discovered. Prior to today's launch of the automated eDisclosure system, EPA and regulated entities would communicate directly with regulated entities or their counsel to resolve their requests to extend the deadlines for correcting disclosed violations. Today's adoption of an automated eDisclosure system includes an automated process for handling requests for extension of such deadlines. Below is a discussion of the possible extensions in eDisclosure and how the eDisclosure system will process extension requests, followed by a timeline that summarizes the violation correction deadlines for new disclosures submitted after today's launch.

a. *Category 1 Disclosures.* To obtain an electronic Notice of Determination (eNOD), disclosers must correct their violations: (a) Within 60 days of the date of discovery for those seeking penalty mitigation under the Audit Policy; or (b) within 90 days of the date of discovery for those seeking penalty mitigation under the Small Business Compliance Policy. Since all self-disclosures must be made within 21 days of discovery in order to be prompt, a Category 1 Audit Policy Compliance Certification, therefore, will be due no later than 81 (*i.e.,* 60+21) days after violation discovery and a Category 1 Small Business Compliance Policy Compliance Certification will be due no later than 111 (*i.e.,* 90+21) days after violation discovery.

Extensions of the violation correction deadline and corresponding compliance certification deadline are not allowed for Category 1 disclosures. If an entity requests an extension of the violation correction deadline for an EPCRA disclosure that is potentially eligible for Category 1 treatment (*i.e.,* it meets all of the Audit Policy or Small Business Compliance Policy conditions and does not involve EPCRA section 304 chemical release reporting violations or EPCRA violations with significant economic benefit as defined by EPA), the disclosure will be potentially eligible only for Category 2 (Acknowledgement Letter) treatment.

b. *Category 2 Disclosures Pursuant to the Audit Policy.* Category 2 disclosers seeking penalty mitigation under the Audit Policy can make an online request for up to 30 additional days (beyond the 60 days already allowed under the policy) to correct their violations, with no explanation required. Such extensions will be considered granted at the time of the request, and the eDisclosure system automatically will extend the Compliance Certification due date by an amount equal to the violation correction period extension (*e.g.,* an entity that gets 30 extra days to correct violations also gets 30 extra days to certify compliance).

Category 2 disclosers seeking penalty mitigation under the Audit Policy can make an online request for more than 30 additional days to correct their violations, provided the violation correction date does not extend beyond 180 days after the date of discovery. To make such a request for an extension of more than 30 days, disclosers must include in the eDisclosure system a justification for such extension. Upon such request, the eDisclosure system automatically will extend the Compliance Certification due date by an amount equal to the correction period extension, but the request is not considered granted or denied at the time of the request. Note also that EPA is more likely to scrutinize requests for extension beyond 30 additional days and ultimately may decide that correction was not prompt, if and when it considers taking an enforcement action for environmental violations.

c. *Category 2 Disclosures Pursuant to the Small Business Compliance Policy.* Category 2 disclosers seeking penalty mitigation under the Small Business Compliance Policy can make an online request for up to 90 additional days (beyond the 90 days already allowed under the policy) to correct their violations, with no explanation required. Such extensions are considered granted at the time of the request and the eDisclosure system automatically will extend the Compliance Certification due date by an amount equal to the correction period extension (*e.g.,* an entity that gets 90 extra days to correct violations also gets 90 extra days to certify compliance).

Category 2 disclosers seeking penalty mitigation under the Small Business Compliance Policy can make an online request for more than 90 additional days to correct their violations, provided the violation correction date does not extend beyond 360 days after the date of discovery. To make such a request for an extension of more than 90 days, disclosers must include in the eDisclosure system a justification for such extension. Extensions of more than 180 days after discovery must be based on the time needed to correct the violation(s) by putting into place pollution prevention measures. Upon such request, the eDisclosure system automatically will extend the Compliance Certification due date by an amount equal to the correction period extension, but the request is not considered granted or denied at the time of the request. Note also that EPA is more likely to scrutinize requests for extension beyond 90 additional days and ultimately may decide that correction was not prompt, if and when it considers taking an enforcement action for environmental violations.

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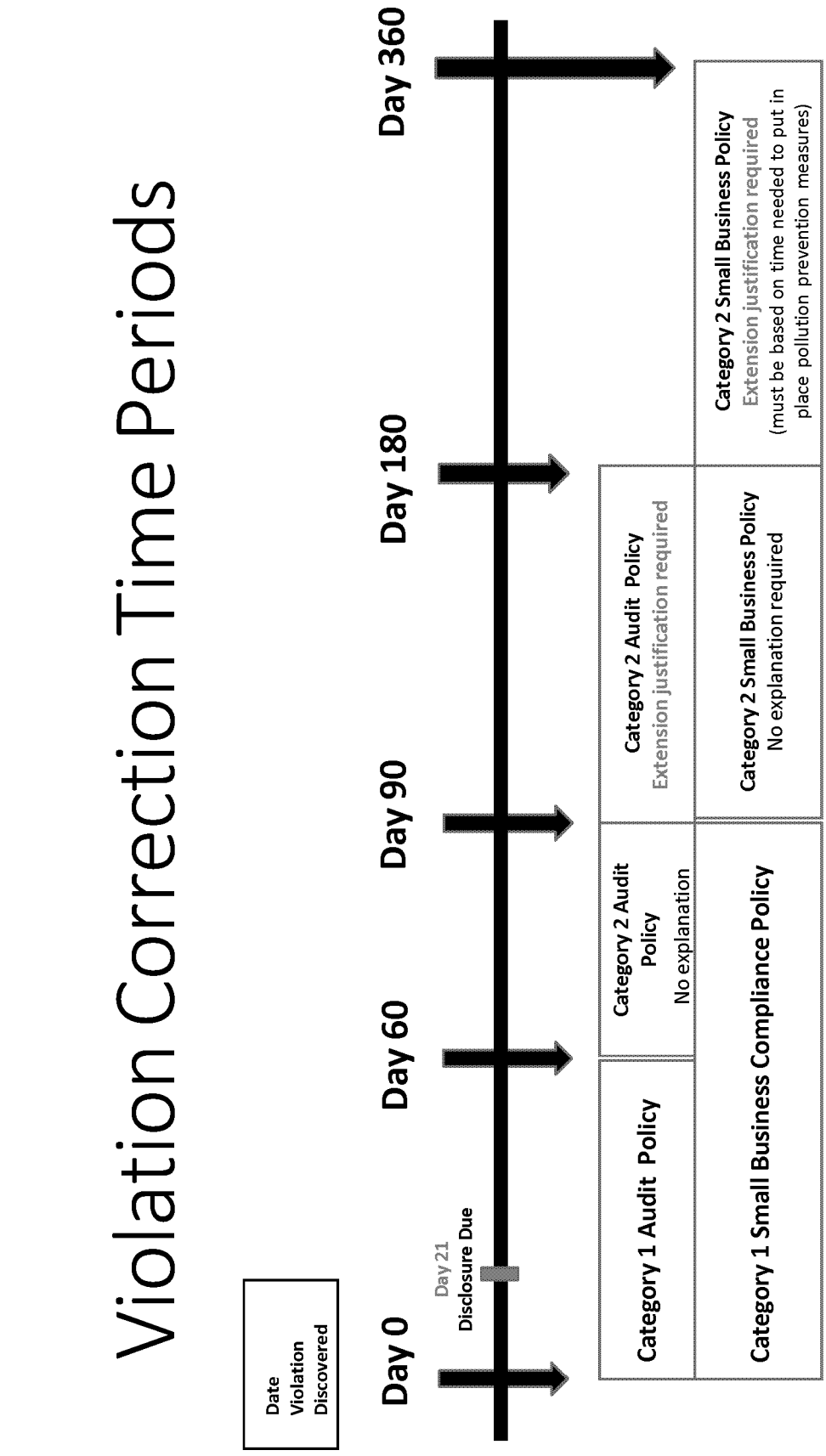

Figure 1

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2. *Processing Unresolved Disclosures That Were Submitted Prior to Today's Launch.* In the June 2015 webinars and Information Sheet, EPA stated its

intention to allow regulated entities with pre-existing unresolved EPCRA disclosures to resubmit such disclosures through the eDisclosure system within 90 days of its launch date. In order to provide for a more orderly transition, EPA is extending this resubmittal opportunity to 120 days after today's launch. If such pre-existing unresolved EPCRA disclosures qualify for Category 1 treatment as outlined in today's Notice, the eDisclosure system automatically will issue an eNOD for such disclosures.

Note that for any such re-submitted disclosure, regulated entities must certify in eDisclosure within 30 days of their re-submittal that they timely corrected their violations. Timely correction is within 60 days of violation discovery for disclosures submitted under the Audit Policy and within 90 days of violation discovery for disclosures submitted pursuant to the Small Business Compliance Policy. No extensions of the 60-day or 90-day violation correction periods are available for such pre-existing EPCRA disclosures.

For pre-existing disclosures subject to an audit agreement or significant settlement negotiations, EPA will resolve such disclosures with a Notice of Determination (NOD), Consent Agreement and Final Order (CAFO), or Consent Decree (CD). All other pre-existing disclosures (*i.e.,* non-EPCRA disclosures and pre-existing EPCRA disclosures that are not resubmitted within 120 days of today's eDisclosure launch) are hereby treated as Category 2 disclosures and this **Federal Register** Notice serves as the Acknowledgement Letter for such disclosures. If and when EPA considers taking enforcement action for environmental violations, it will make a determination as to eligibility for penalty mitigation.

II. Unchanged Aspects of EPA's Self-Disclosure Policies

A. No Changes to Conditions in the Audit Policy and Small Business Compliance Policy

The launch of the eDisclosure system does not modify the substantive conditions in EPA's Audit Policy or Small Business Compliance Policy. Instead, eDisclosure automates implementation of these policies to allow for faster and more efficient processing of self-disclosed civil violations. Moreover, disclosures of criminal violations will continue to be handled by the Voluntary Disclosure Board (VDB), outside the eDisclosure system, pursuant to the process outlined in EPA's Audit Policy at 65 FR 19624.

B. No Changes to EPA New Owner Policy Implementation

This Notice does not change EPA's approach to resolving New Owner disclosures as outlined in the New Owner Policy (73 FR 44991, August 1, 2008). Pre-existing New Owner disclosures will not be resolved through the eDisclosure system, but instead EPA will resolve these manually. New owners may elect to use the eDisclosure system to disclose future violations, but doing so will not provide New Owner treatment. To provide New Owner consideration, EPA will continue to accept and manually process new owner disclosures outside of the eDisclosure system pursuant to EPA's New Owner Policy, and EPA will enter into audit agreements as appropriate with new owners.

C. No Routine Requests for Audit Reports

As discussed in the revised Audit Policy at 65 FR 19620, EPA reaffirms its policy, in effect since 1986, to refrain from routine requests for audit reports. EPA has not requested, and will not routinely request, copies of audit reports to trigger enforcement investigations. In general, an audit that results in expeditious correction will reduce liability, not expand it. If, however, the Agency has independent evidence that there may be violations, it may seek the information it needs to establish the extent and nature of the violation and the degree of culpability.

D. Opposition to Audit Privilege and Immunity

As discussed in the revised Audit Policy at 65 FR 19623, EPA reaffirms its opposition to audit privilege and immunity. EPA remains opposed to state legislation that does not reserve the right to bring independent action against regulated entities for violations of federal law that threaten human health or the environment, reflect criminal conduct, or show repeated noncompliance. EPA also opposes legislation that bars enforcement in a way that allows one company to profit at the expense of its law-abiding competitors. *See* ''Statement of Principles, Effect of State Audit Immunity/Privilege Laws on Enforcement Authority for Federal Programs,'' dated February 14, 1997. The Agency opposes statutory immunity because it diminishes law enforcement's ability to discourage wrongful behavior and interferes with a regulator's ability to enforce against individuals who disregard the law and place others in danger.

III. EPA Approach to FOIA Requests Seeking Disclosures

EPA has always considered resolved Audit Policy disclosures to be publicly releasable under the Freedom of Information Act (FOIA) (see 1997 Memo from Steven A. Herman, ''Confidentiality of Information Received Under Agency's Self-Disclosure Policy,'' available at *http://www2.epa.gov/sites/production/files/documents/sahmemo.pdf*). EPA is continuing such approach. This means that FOIA requests for eNODs generally will be granted, particularly since the eDisclosure system warns users that it is inappropriate to submit in the online portal any confidential business information (CBI) or information that would constitute an unwarranted invasion of any person's privacy (*e.g.,* social security numbers, birth dates, medical records, personal financial information, or other private information).

The 1997 memo also states that EPA generally will withhold unresolved disclosures pursuant to the FOIA ''law enforcement proceeding'' exemption, Exemption 7(A). By this Notice, EPA is effectively revising the 1997 Steve Herman memorandum to eliminate the presumption in favor of withholding unresolved disclosures and to replace it with a presumption in favor of disclosure. This change is consistent with the 2009 open government and transparency memoranda from President Obama and Attorney General Eric Holder. *See http://www.justice.gov/sites/default/files/oip/legacy/2014/07/23/foia-memorandum.pdf.* Therefore, in response to any FOIA requests for individual unresolved disclosures, EPA instead will determine on a case-by-case basis whether it reasonably foresees that release would harm an interest protected by a FOIA exemption. In doing so, EPA will endeavor to be as accommodating as possible in responding to such requests, and EPA generally expects to make Category 1 and Category 2 disclosures publicly available within a relatively short period of time after their receipt.

EPA believes that this change is appropriate in part because it generally expects to spot check Category 1 disclosures and screen Category 2 disclosures within a few months after their submission and will determine at that time whether further investigation or other action is warranted. It is possible that disclosures involving longer requests for a violation correction extension could cause EPA to withhold such disclosures under FOIA, but that would be determined on a case-by-case

basis as noted above. EPA also notes that entities with wholly past violations and no outstanding noncompliance likely face little, if any, risk of citizen suit exposure. Accordingly, regardless whether the disclosed violations are resolved, EPA is optimistic that responsible disclosing entities will not be dissuaded from disclosing violations.

IV. Applicability

The Audit Policy, Small Business Compliance Policy, and New Owner Policy are policies that guide the Agency in the exercise of its enforcement discretion. They are not rules or regulations, and they are not intended, nor can they be relied upon, to create any rights enforceable by any party in litigation with the United States. The policies and how they are implemented may be revised without public notice to reflect changes in EPA's approach to providing incentives for self-policing by regulated entities, or to clarify and update the policies as necessary.

IV. Effective Date

These modifications to the implementation of EPA's Audit Policy and Small Business Compliance Policy are effective on December 9, 2015.

Dated: November 30, 2015.

Cynthia Giles,

Assistant Administrator for Enforcement and Compliance Assurance.

[FR Doc. 2015–30928 Filed 12–8–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2015–0301; FRL–9939–34]

Pesticide Emergency Exemptions; Agency Decisions and State and Federal Agency Crisis Declarations

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA has granted or denied emergency exemptions under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) for use of pesticides as listed in this notice. The exemptions or denials were granted during the period July 1, 2015 to September 30, 2015 to control unforeseen pest outbreaks.

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).

If you have any questions regarding the applicability of this action to a particular entity, consult the person listed at the end of the emergency exemption or denial.

B. How can I get copies of this document and other related information?

The docket for this action, identified by docket identification (ID) number EPA–HQ–OPP–2015–0301 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.*

II. Background

EPA has granted or denied emergency exemptions to the following State and Federal agencies. The emergency exemptions may take the following form: Crisis, public health, quarantine, or specific. EPA has also listed denied emergency exemption requests in this notice.

Under FIFRA section 18 (7 U.S.C. 136p), EPA can authorize the use of a pesticide when emergency conditions exist. Authorizations (commonly called emergency exemptions) are granted to State and Federal agencies and are of four types:

1. A ''specific exemption'' authorizes use of a pesticide against specific pests on a limited acreage in a particular State. Most emergency exemptions are specific exemptions.

2. ''Quarantine'' and ''public health'' exemptions are emergency exemptions issued for quarantine or public health purposes. These are rarely requested.

3. A ''crisis exemption'' is initiated by a State or Federal agency (and is confirmed by EPA) when there is insufficient time to request and obtain EPA permission for use of a pesticide in an emergency.

EPA may deny an emergency exemption: If the State or Federal agency cannot demonstrate that an emergency exists, if the use poses unacceptable risks to the environment, or if EPA cannot reach a conclusion that the proposed pesticide use is likely to result in ''a reasonable certainty of no harm'' to human health, including exposure of residues of the pesticide to infants and children.

If the emergency use of the pesticide on a food or feed commodity would result in pesticide chemical residues, EPA establishes a time-limited tolerance meeting the ''reasonable certainty of no harm standard'' of the Federal Food, Drug, and Cosmetic Act (FFDCA).

In this document: EPA identifies the State or Federal agency granted the exemption or denial, the type of exemption, the pesticide authorized and the pests, the crop or use for which authorized, number of acres (if applicable), and the duration of the exemption. EPA also gives the **Federal Register** citation for the time-limited tolerance, if any.

III. Emergency Exemptions and Denials

A. U.S. States and Territories

California

Department of Environmental Protection

Crisis exemption: On August 27, 2015 the California Department of Environmental Protection declared a crisis for the use of methoxyfenozide on rice to control armyworms.

Delaware

Department of Agriculture

Specific Exemption: EPA authorized the use of dinotefuran on pome fruit and stone fruit to control the brown marmorated stinkbug; July 16, 2015 to October 15, 2015.

Florida

Department of Agriculture and Consumer Services

Specific Exemption: EPA authorized the use of streptomycin sulfate on

grapefruit to control citrus canker; July 1, 2015 to July 1, 2016.

Kentucky

Department of Agriculture

Specific Exemption: EPA authorized the use of sulfoxaflor on sorghum to control sugarcane aphid; August 10, 2015 to November 30, 2015.

Maryland

Department of Agriculture

Specific Exemption: EPA authorized the use of dinotefuran on pome fruit and stone fruit to control the brown marmorated stinkbug; July 16, 2015 to October 15, 2015.

Department of Health and Mental Hygiene

Crisis exemptions: On July 7, 2015 the Maryland Department of Health and Mental Hygiene declared crisis exemptions for the use of ethylene oxide, formaldehyde, hydrogen peroxide, paracetic acid, and sodium hypochlorite to inactivate *Bacillus anthracis* (anthrax) spores in laboratories that processed samples originating from Dugway Proving Ground potentially containing viable anthrax spores.

Michigan

Department of Agriculture and Rural Development

Specific Exemption: EPA authorized the use of dinotefuran on pome fruit and stone fruit to control the brown marmorated stinkbug; July 16, 2015 to November 30, 2015.

Mississippi

Department of Agriculture and Commerce

Denial: On July 27, 2015 EPA denied the use of a pesticide product containing the active ingredient thiamethoxam on sorghum to control sugarcane aphid. This request was denied because the Agency determined the situation did not meet criteria to be considered an urgent and non-routine situation, and a specific exemption under section 18 was not justified.

New Jersey

Department of Environmental Protection

Specific Exemptions: EPA authorized the use of dinotefuran on pome fruit and stone fruit to control the brown marmorated stinkbug; September 15, 2015 to October 15, 2015.

EPA authorized the use of bifenthrin on apple, peach and nectarine to control the brown marmorated stinkbug; September 21, 2015 to October 15, 2015.

New Mexico

Department of Agriculture

Specific Exemption: EPA authorized the use of sulfoxaflor on sorghum to control sugarcane aphid; August 28, 2015 to November 30, 2015.

New York

Department of Environmental Conservation

Specific Exemption: EPA authorized the use of bifenthrin on apple, peach and nectarine to control the brown marmorated stinkbug; July 30, 2015 to October 15, 2015.

North Carolina

Department of Agriculture and Consumer Services

Specific Exemptions: EPA authorized the use of dinotefuran on pome fruit and stone fruit to control the brown marmorated stinkbug; July 16, 2015 to October 15, 2015.

EPA authorized the use of sulfoxaflor on sorghum to control sugarcane aphid; July 16, 2015 to November 30, 2015.

Pennsylvania

Department of Agriculture

Specific Exemption: EPA authorized the use of dinotefuran on pome fruit and stone fruit to control the brown marmorated stinkbug; July 16, 2015 to October 15, 2015.

South Dakota

Department of Agriculture

Specific Exemption: EPA authorized the use of hop beta acids on beehives to control the varroa mite; August 19, 2015 to December 31, 2015.

Tennessee

Health Department

Crisis exemption: On July 29, 2015 the Tennessee Health Department declared a crisis for the use of hydrogen peroxide to inactivate *Bacillus anthracis* (anthrax) spores in laboratories that processed samples originating from Dugway Proving Ground potentially containing viable anthrax spores.

Virginia

Department of Agriculture and Consumer Services

Specific Exemption: EPA authorized the use of dinotefuran on pome fruit and stone fruit to control the brown marmorated stinkbug; July 16, 2015 to October 15, 2015.

West Virginia

Department of Agriculture

Specific Exemption: EPA authorized the use of dinotefuran on pome fruit and stone fruit to control the brown marmorated stinkbug; July 16, 2015 to October 15, 2015.

B. Federal Departments and Agencies

Department of Agriculture

Animal and Plant Health Inspection Service

Quarantine Exemptions: EPA authorized the use of sodium chlorite to produce chlorine dioxide gas for decontamination of poultry facilities from avian influenza virus; August 4, 2015 to August 4, 2018.

EPA authorized the use of sodium hypochlorite on surfaces to decontaminate from foot and mouth disease, African swine flu and classical swine flu; September 17, 2015 to September 17, 2018.

EPA authorized the uses of sodium hypochlorite and sodium hydroxide to decontaminate surfaces potentially exposed to prions, the causal agents of transmissible spongiform encephalitic diseases in livestock; September 25, 2015 to September 25, 2018.

Authority: 7 U.S.C. 136 *et seq.*

Dated: December 2, 2015.

Susan Lewis,

Director, Registration Division, Office of Pesticide Programs.

[FR Doc. 2015–31055 Filed 12–8–15; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–RCRA–2015–0732, FRL–9939–97–OSWER]

Agency Information Collection Activities; Proposed Collection; Comment Request; Identification of Non-Hazardous Secondary Materials That Are Solid Waste (Renewal)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: The Environmental Protection Agency (EPA) is planning to submit an information collection request (ICR), Identification of Non-Hazardous Secondary Materials That Are Solid Waste (Renewal) (EPA ICR No. 2382.04, OMB Control No. 2050–0205) to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Before doing so, EPA is soliciting public

comments on specific aspects of the proposed information collection as described below. This is a proposed extension of the ICR, which is currently approved through March 31, 2016. An Agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number.

DATES: Comments must be submitted on or before February 8, 2016.

ADDRESSES: Submit your comments, referencing Docket ID No. EPA–RCRA–2015–0732, online using *www.regulations.gov* (our preferred method), by email to *rcra-docket@epa.gov,* or by mail to: EPA Docket Center, Environmental Protection Agency, Mail Code 28221T, 1200 Pennsylvania Ave. NW., Washington, DC 20460.

EPA's policy is that all comments received will be included in the public docket without change including any personal information provided, unless the comment includes profanity, threats, information claimed to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

FOR FURTHER INFORMATION CONTACT: Jesse Miller, Office of Resource Conservation and Recovery, Materials Recovery and Waste Management Division, MC 5302P, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460; telephone number: (703) 308–1180; fax number: (703) 308–0522; email address: *miller.jesse@epa.gov.*

SUPPLEMENTARY INFORMATION: Supporting documents which explain in detail the information that the EPA will be collecting are available in the public docket for this ICR. The docket can be viewed online at *www.regulations.gov* or in person at the EPA Docket Center, WJC West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The telephone number for the Docket Center is 202–566–1744. For additional information about EPA's public docket, visit *http://www.epa.gov/dockets.*

Pursuant to section 3506(c)(2)(A) of the PRA, the EPA is soliciting comments and information to enable it to: (i) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the Agency, including whether the information will have practical utility; (ii) evaluate the accuracy of the Agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (iii) enhance the quality, utility, and clarity of the information to be collected; and (iv) minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses. EPA will consider the comments received and amend the ICR as appropriate. The final ICR package will then be submitted to OMB for review and approval. At that time, EPA will issue another **Federal Register** notice to announce the submission of the ICR to OMB and the opportunity to submit additional comments to OMB.

Abstract: On March 21, 2011, EPA finalized standards and procedures to be used to identify whether non-hazardous secondary materials are solid wastes when used as fuels or ingredients in combustion units. ''Secondary material'' is defined as any material that is not the primary product of a manufacturing or commercial process, and can include post-consumer material, off-specification commercial chemical products or manufacturing chemical intermediates, post-industrial material, and scrap (codified in § 241.2). ''Non-hazardous secondary material'' is a secondary material that, when discarded, would not be identified as a hazardous waste under 40 CFR part 261 (codified in § 241.2). This RCRA solid waste definition determines whether a combustion unit is required to meet the emissions standards for solid waste incineration units issued under section 129 of the Clean Air Act (CAA) or the emissions standards for commercial, industrial, and institutional boilers issued under section 112 of the CAA. In this rule, EPA also finalized a definition of traditional fuels.

Form Numbers: None.

Respondents/affected entities: Entities potentially affected by this action are private sector.

Respondent's obligation to respond: required to obtain benefit (Sections 1004 and 2002 of RCRA).

Estimated number of respondents: 1,461.

Frequency of response: One-time.

Total estimated burden: 2,951 hours. Burden is defined at 5 CFR 1320.03(b).

Total estimated cost: $320,200, which includes $320,200 annualized labor costs and $0 annualized capital or O&M costs.

Changes in Estimates: There is a decrease of 23,542 hours in the total estimated respondent burden and $1.4 million in the total labor costs compared with the ICR currently approved by OMB. These decreases are not due to any program changes, but rather a revised estimate of the number of petitions expected to be submitted by the respondents. Only two petitions were submitted over the last three year period, versus the original estimate of 168 petitions. The number of petitions anticipated to be filed over the next three year period has therefore been reduced to 10, which EPA believes is still a conservative estimate. The change in labor costs also incorporates updated labors rates available from the Bureau of Labor Statistics.

Dated: November 23, 2015.

Barnes Johnson,

Director, Office of Resource Conservation and Recovery.

[FR Doc. 2015–31046 Filed 12–8–15; 8:45 am]

BILLING CODE 6560–50–P

EXPORT-IMPORT BANK

[Public Notice 2015–6014]

Agency Information Collection Activities: Comment Request

AGENCY: Export-Import Bank of the U.S.

ACTION: Submission for OMB Review and Comments Request.

Form Title: EIB 95–10, Application for Long Term Loan or Guarantee.

SUMMARY: The Export-Import Bank of the United States (Ex-Im Bank), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal Agencies to comment on the proposed information collection, as required by the paperwork Reduction Act of 1995.

By neutralizing the effect of export credit insurance and guarantees offered by foreign governments and by absorbing credit risks that the private section will not accept, Ex-Im Bank enables U.S. exporters to compete fairly in foreign markets on the basis of price and product. This collection of information is necessary, pursuant to 12 U.S.C. 635(a)(1), to determine eligibility of the applicant for Ex-Im Bank support.

The Export-Import Bank has made a change to the report to have the financial institution provide specific information (industry code, number of employees and annual sales volume) needed to make a determination as to whether or not the exporter meets the SBA's definition of a small business. The financial institution already provides the exporter's name and address. These additional pieces of information will allow Ex-Im Bank to

better track the extent to which its support assists U.S. small businesses.

The other change that Ex-Im Bank has made is to require the financial institution to indicate whether the exporter is a minority-owned business, women-owned business and/or veteran-owned business. Although answers to the questions are mandatory, the company may choose any one of the three answers: Yes/No/Decline to Answer. The option of ''Decline to Answer'' allows a company to consciously decline to answer the specific question should they not wish to provide that information.

The application can be viewed at *http://www.exim.gov/sites/default/files/pub/pending/eib95-10all.pdf.*

DATES: Comments should be received on or before February 8, 2016 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *WWW.REGULATIONS.GOV* or by mail to Michele Kuester, Export Import Bank of the United States, 811 Vermont Ave. NW., Washington, DC 20571.

SUPPLEMENTARY INFORMATION:

Titles and Form Number: EIB 95–10 Application for Long Term Loan or Guarantee.

OMB Number: 3048–0013.

Type of Review: Regular.

Need and Use: The information collected will provide information needed to determine compliance and creditworthiness for transaction requests submitted to the Export Import Bank under its long term guarantee and direct loan programs.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 84.

Estimated Time per Respondent: 1.75 hours.

Annual Burden Hours: 147 hours.

Frequency of Reporting or Use: As needed.

Government Expenses:

Reviewing Time per Year: 147 hours.

Average Wages per Hour: $42.50.

Average Cost per Year: $6,248 (time*wages).

Benefits and Overhead: 20%.

Total Government Cost: $7,498.

Bonita Jones-McNeil,

Agency Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2015–30982 Filed 12–8–15; 8:45 am]

BILLING CODE 6690–01–P

EXPORT-IMPORT BANK OF THE U.S.

[Public Notice 2015–3002]

Agency Information Collection Activities: Comment Request

AGENCY: Export-Import Bank of the U.S.

ACTION: Submission for OMB review and comments request.

Form Title: EIB 11–08, Application for Global Credit Express Revolving Line of Credit

SUMMARY: The Export-Import Bank of the United States (Ex-Im Bank), as a part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal Agencies to comment on the proposed information collection, as required by the Paperwork Reduction Act of 1995.

The Application for Global Credit Express Revolving Line of Credit is used to determine the eligibility of the applicant and the transaction for Export-Import Bank assistance under its Working Capital Guarantee and Direct Loan Program. This form is used by small U.S. businesses with limited export experience. This program relies to a large extent on the exporter's qualifying score on the FICO (Fair Isaac Corporation) SBSS (Small Business Scoring Service). Therefore the financial and credit information needs are minimized. This is a request to renew an existing form. The only change is to enhance a question about company ownership so as to improve the quality of information derived from the question.

The form can be viewed at: *http://www.exim.gov/pub/pending/EIB11-08-Final.pdf*

DATES: Comments should be received on or before January 8, 2016, 2015 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *http://www.regulations.gov* (EIB:11–08) or by mail to Office of Information and Regulatory Affairs, 725 17th Street, NW., Washington, DC 20038 Attn: OMB Number 3048–0038.

SUPPLEMENTARY INFORMATION:

Titles and Form Number: EIB 11–08, Application for Global Credit Express Revolving Line of Credit.

OMB Number: 3048–0038.

Type of Review: Regular.

Need and Use: The Application for Global Credit Express Revolving Line of Credit is used to determine the eligibility of the applicant and the transaction for Export-Import Bank assistance under its Working Capital Guarantee and Direct Loan Program.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 130.

Estimated Time per Respondent: 1.5 hours.

Annual Burden Hours: 195 hours.

Frequency of Reporting or Use: As needed.

Government Expenses:

Reviewing Time per Year: 195 hours.

Average Wages per Hour: $42.50.

Average Cost per Year: $8,287.5 (time*wages).

Benefits and Overhead: 20%.

Total Government Cost: $9,945.

Bonita Jones-McNeil,

Records Management Division, Office of the Chief Information Officer.

[FR Doc. 2015–31000 Filed 12–8–15; 8:45 am]

BILLING CODE 6690–01–P

EXPORT-IMPORT BANK

[Public Notice: 2015–3010]

Agency Information Collection Activities: Comment Request

AGENCY: Export-Import Bank of the United States.

ACTION: Submission for OMB review and comments request.

Form Title: EIB 92–64 Application for Exporter Short Term Single Buyer Insurance.

SUMMARY: The Export-Import Bank of the United States (Ex-Im Bank), as a part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal Agencies to comment on the proposed information collection, as required by the Paperwork Reduction Act of 1995.

The ''Application for Exporter Short Term Single Buyer Insurance'' form will be used by entities involved in the export of U.S. goods and services, to provide Ex-Im Bank with the information necessary to obtain legislatively required assurance of repayment and fulfills other statutory requirements. Export-Import Bank customers will be able to submit this form on paper or electronically.

The Export-Import Bank has made a change to the report to have the applicant provide the number of employees or annual sales volume. That information is needed to determine whether or not they meet the SBA's definition of a small business. The applicant already provides their name, address and industry code (NAICS). These additional pieces of information will allow Ex-Im Bank to better track the

extent to which its support assists U.S. small businesses.

The other change that Ex-Im Bank has made is to require the applicant to indicate whether it is a minority-owned business, women-owned business and/or veteran-owned business. Although answers to the questions are mandatory, the company may choose any one of the three answers: Yes/No/Decline to Answer. The option of ''Decline to Answer'' allows a company to consciously decline to answer the specific question should they not wish to provide that information.

The application can be reviewed at: *www.exim.gov/pub/pending/EIB92-64.pdf*

DATES: Comments must be received on or before January 8, 2016 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *WWW.REGULATIONS.GOV* or by mail to Office of Information and Regulatory Affairs, 725 17th Street NW., Washington, DC 20038, Attn: OMB 3048–0018.

SUPPLEMENTARY INFORMATION:

Title and Form Number: EIB 92–64 Application for Exporter Short Term Single Buyer Insurance.

OMB Number: 3048–0018.

Type of Review: Regular.

Need and Use: The information requested enables the applicant to provide Ex-Im Bank with the information necessary to obtain legislatively required assurance of repayment and fulfills other statutory requirements.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 310.

Estimated Time per Respondent: 1.5 hours.

Annual Burden Hours: 465 hours.

Frequency of Reporting of Use: As needed.

Government Costs:

Reviewing time per year: 465 hours.

Average Wages per Hour: $42.50.

Average Cost per Year: $19,762.5.

(time*wages)

Benefits and Overhead: 20%.

Total Government Cost: $23,715.

Bonita Jones-McNeil,

Program Analyst, Agency Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2015–31022 Filed 12–8–15; 8:45 am]

BILLING CODE 6690–01–P

EXPORT-IMPORT BANK

[Public Notice: 2015–3013]

Agency Information Collection Activities: Comment Request: Form Title: EIB 03–02, Application for Medium Term Insurance or Guarantee

AGENCY: Export-Import Bank of the U.S.

ACTION: Submission for OMB review and comments request.

SUMMARY: The Export-Import Bank of the United States (Ex-Im Bank), as a part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal Agencies to comment on the proposed information collection, as required by the Paperwork Reduction Act of 1995.

The purpose of this collection is to gather information necessary to make a determination of eligibility of a transaction for Ex-Im Bank assistance under its medium-term guarantee and insurance program.

The Export-Import Bank has made a change to the report to have the financial institution provide specific information (industry code, number of employees and annual sales volume) needed to make a determination as to whether or not the exporter meets the SBA's definition of a small business. The financial institution already provides the exporter's name and address. These additional pieces of information will allow Ex-Im Bank to better track the extent to which its support assists U.S. small businesses.

The other change that Ex-Im Bank has made is to require the financial institution to indicate whether the exporter is a minority-owned business, women-owned business and/or veteran-owned business. Although answers to the questions are mandatory, the company may choose any one of the three answers: Yes/No/Decline to Answer. The option of ''Decline to Answer'' allows a company to consciously decline to answer the specific question should they not wish to provide that information.

The form can be viewed at: *http://www.exim.gov/sites/default/files/pub/pending/eib03-02_0.pdf.*

DATES: Comments should be received on or before January 8, 2016, 2016 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *http://www.regulations.gov* (EIB:03–02) or by mail to Office of Information and Regulatory Affairs, 725 17th Street NW., Washington, DC 20038, Attn: OMB 3048–0014.

SUPPLEMENTARY INFORMATION:

Titles and Form Number: EIB 03–02, Application for Medium Term Insurance or Guarantee.

OMB Number: 3048–0014.

Type of Review: Regular.

Need and Use: The purpose of this collection is to gather information necessary to make a determination of eligibility of a transaction for Ex-Im Bank assistance under its medium-term guarantee and insurance program.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 400.

Estimated Time per Respondent: 1.2 hour.

Annual Burden Hours: 480 hours.

Frequency of Reporting or Use: As needed.

Government Expenses:

Reviewing Time per Year: 700 hours.

Average Wages per Hour: $42.50.

Average Cost per Year: $29,750 (time*wages).

Benefits and Overhead: 20%.

Total Government Cost: $35,700.

Bonita Jones-McNeil,

Program Analyst, Records Management Division, Office of the Chief Information Officer.

[FR Doc. 2015–31014 Filed 12–8–15; 8:45 am]

BILLING CODE 6690–01–P

EXPORT-IMPORT BANK

[Public Notice: 2015–3007]

Agency Information Collection Activities: Comment Request: Form Title: EIB 92–36 Application for Issuing Bank Credit Limit (IBCL) Under Lender or Exporter-Held Policies

AGENCY: Export-Import Bank of the United States .

ACTION: Submission for OMB review and comments request.

SUMMARY: The Export-Import Banks of the United States (Ex-Im Bank), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal Agencies to comment on the proposed information collection, as required by the Paperwork Reduction Act of 1995.

This collection of information is necessary, pursuant to 12 U.S.C. Sec. 635(a)(1), to determine eligibility of the applicant for Ex-Im Bank assistance.

The Export-Import Bank has made a change to the report to have the financial institution provide specific information (industry code, number of employees and annual sales volume)

needed to make a determination as to whether or not the exporter meets the SBA's definition of a small business. The financial institution already provides the exporter's name and address. These additional pieces of information will allow Ex-Im Bank to better track the extent to which its support assists U.S. small businesses.

The other change that Ex-Im Bank has made is to require the financial institution to indicate whether the exporter is a minority-owned business, women-owned business and/or veteran-owned business. Although answers to the questions are mandatory, the company may choose any one of the three answers: Yes/No/Decline to Answer. The option of ''Decline to Answer'' allows a company to consciously decline to answer the specific question should they not wish to provide that information.

The application tool can be reviewed at: *http://www.exim.gov/pub/pending/eib92-36.pdf*

DATES: Comments must be received on or before January 8, 2016, to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *WWW.REGULATIONS.GOV* or by mail to Office of Information and Regulatory Affairs, 725 17th Street NW., Washington, DC 20038, Attn: OMB 3048–0016.

SUPPLEMENTARY INFORMATION:

Title and Form Number: EIB 92–36 Application for Issuing Bank Credit Limit (IBCL) Under Lender or Exporter-Held Policies.

OMB Number: 3048–0016.

Type of Review: Regular.

Need and Use: This form is used by an insured exporter or lender (or broker acting on its behalf) in order to obtain approval for coverage of the repayment risk of an overseas bank. The information received allows Ex-Im Bank staff to make a determination of the creditworthiness of the foreign bank and the underlying export sale for Ex-Im Bank assistance under its programs.

This form has been updated to include a new Certification and Notices section as well as a new statement explaining Ex-Im Bank's limitation on support for goods subject to trade measures or sanctions.

Affected Public:

This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 480.

Estimated Time per Respondent: 1.2 hours.

Annual Burden Hours: 576 hours.

Frequency of Reporting of Use: As needed.

Government Expenses:

*Reviewing time per year:*480 hours.

Average Wages per Hour: $42.50.

Average Cost per Year: $20,400. (time*wages)

Benefits and Overhead: 20%.

Total Government Cost: $24,480.

Bonita Jones-McNeil,

Program Analyst, Agency Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2015–31012 Filed 12–8–15; 8:45 am]

BILLING CODE 6690–01–P

EXPORT-IMPORT BANK

[Public Notice: 2015–3005]

Agency Information Collection Activities: Comment Request: Form Title: EIB 92–41 Application for Financial Institution Short-Term, Single-Buyer Insurance

AGENCY: Export-Import Bank of the United States

ACTION: Submission for OMB review and comments request.

SUMMARY: The Export-Import Banks of the United States (Ex-Im Bank), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal Agencies to comment on the proposed information collection, as required by the Paperwork Reduction Act of 1995.

This collection of information is necessary, pursuant to 12 U.S.C. Sec. 635(a)(1), to determine eligibility of the underlying export transaction for Ex-Im Bank insurance coverage.

The Export-Import Bank has made a change to the report to have the insured financial institution provide specific information (industry code, number of employees and annual sales volume) needed to make a determination as to whether or not the exporter meets the SBA's definition of a small business. The insured financial institution already provides a short description of the goods and/or services being exported and the name and address of the exporter. These additional pieces of information will allow Ex-Im Bank to better track the extent to which its support assists U.S. small businesses.

The other change that Ex-Im Bank has made is to require the insured financial institution to indicate whether the exporter is a minority-owned business, women-owned business and/or veteran-owned business. Although answers to the questions are mandatory, the company may choose any one of the three answers: Yes/No/Decline to Answer. The option of ''Decline to Answer'' allows a company to consciously decline to answer the specific question should they not wish to answer.

The information collection tool can be reviewed at: *http://www.exim.gov/pub/pending/EIB92-41.pdf.*

DATES: Comments must be received on or before January 8, 2016 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *WWW.REGULATIONS.GOV* or by mail to Office of Information and Regulatory Affairs, 725 17th Street NW., Washington, DC 20038, Attn: OMB 3048–0019.

SUPPLEMENTARY INFORMATION:

Title and Form Number: EIB 92–41 Application for Financial Institution Short-Term, Single-Buyer Insurance.

OMB Number: 3048–0019.

Type of Review: Regular.

Need and Use: The ''Application for Financial Institution Short-term Single-Buyer Insurance'' form will be used by financial institution applicants to provide Ex-Im Bank with the information necessary to determine if the subject transaction is eligible for Ex-Im Bank insurance coverage.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 215.

Estimated Time per Respondent: 1.6 hours.

Annual Burden Hours: 344.

Frequency of Reporting of Use: Annual.

Government Expenses:

Reviewing time per year: 1,290 hours.

Average Wages per Hour: $42.50.

Average Cost per Year: (time*wages) $54,825.

Benefits and Overhead: 20%.

Total Government Cost: $ 70,176.

Bonita Jones-McNeil,

Program Analyst, Agency Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2015–31015 Filed 12–8–15; 8:45 am]

BILLING CODE 6690–01–P

EXPORT-IMPORT BANK

[Public Notice: 2015–3008]

Agency Information Collection Activities: Comment Request: Form Title: EIB 92–50 Short-Term Multi-Buyer Export Credit Insurance Policy Applications (ST Multi-Buyer)

AGENCY: Export-Import Bank of the United States.

ACTION: Submission for OMB review and comments request.

SUMMARY: The Export-Import Banks of the United States (Ex-Im Bank), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal Agencies to comment on the proposed information collection, as required by the Paperwork Reduction Act of 1995.

This collection of information is necessary, pursuant to 12 U.S.C. Sec. 635(a)(1), to determine eligibility of the applicant for Ex-Im Bank assistance.

The Application for Short-Term Multi-Buyer Export Credit Insurance Policy will be used to determine the eligibility of the applicant and the transaction for Export-Import Bank assistance under its insurance program. Export-Import Bank customers will be able to submit this form on paper or electronically.

The Export-Import Bank has made a change to the report to have the applicant provide their number of employees or annual sales volume. That information is needed to determine whether or not they meet the SBA's definition of a small business. The applicant already provides their name, address and industry code (NAICS). These additional pieces of information will allow Ex-Im Bank to better track the extent to which its support assists U.S. small businesses.

The other change that Ex-Im Bank has made is to require the applicant to indicate whether it is a minority-owned business, women-owned business and/or veteran-owned business. Although answers to the questions are mandatory, the company may choose any one of the three answers: Yes/No/Decline to Answer. The option of ''Decline to Answer'' allows a company to consciously decline to answer the specific question should they not wish to provide that information.

The application tool can be reviewed at: *http://www.exim.gov/sites/default/files/pub/pending/eib92-50.pdf.*

DATES: Comments must be received on or before January 8, 2016 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *WWW.REGULATIONS.GOV* or by mail to Office of Information and Regulatory Affairs, 725 17th Street NW., Washington, DC 20038, Attn: OMB 3048–0023.

SUPPLEMENTARY INFORMATION:

Title and Form Number: EIB 92–50 Export-Import Bank of the United States Short-Term Multi-Buyer Export Credit Insurance Policy Applications (ST Multi-Buyer).

OMB Number: 3048–0023.

Type of Review: Regular.

Need and Use: The Application for Short-Term Multi-Buyer Export Credit Insurance Policy will be used to determine the eligibility of the applicant and the transaction for Export-Import Bank assistance under its insurance program.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 285.

Estimated Time per Respondent: 0.5 hours.

Annual Burden Hours: 143.

Frequency of Reporting of Use: As needed.

Government Reviewing Time per Year:

Reviewing time per year: 285 hours.

Average Wages per Hour: $42.50.

Average Cost per Year: $12,113. (time*wages)

Benefits and Overhead: 20%.

Total Government Cost: $15,504.

Bonita Jones-McNeil,

Program Analyst, Agency Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2015–31021 Filed 12–8–15; 8:45 am]

BILLING CODE 6690–01–P

EXPORT-IMPORT BANK

[Public Notice: 2015 3004]

Agency Information Collection Activities: Comment Request

AGENCY: Export-Import Bank of the United States.

ACTION: Submission for OMB review and comments request.

Form Title: EIB 84–01 Joint Application for Export Working Capital Guarantee

SUMMARY: This is a joint application form for working capital loan guarantees provided by Ex-Im Bank and the Small Business Administration. This collection of information is necessary, pursuant to 12 U.S.C. Sec. 635 (a) (1) and 15 U.S.C. Sec. 636 (a) (14), to determine eligibility of the applicant for Ex-Im Bank or SBA assistance.

The Export-Import Bank has made a change to the report to have the applicant provide the number of employees or annual sales volume. That information is needed to determine whether or not they meet the SBA's definition of a small business. The applicant already provides their name, address and industry code (NAICS). These additional pieces of information will allow Ex-Im Bank to better track the extent to which its support assists U.S. small businesses.

The other change that Ex-Im Bank has made is to require the applicant to indicate whether it is a minority-owned business, women-owned business and/or veteran-owned business. Although answers to the questions are mandatory, the company may choose any one of the three answers: Yes/No/Not Disclosed. The option of ''Not Disclosed'' allows a company to consciously decline to answer the specific question should they not wish to provide that information.

The application tool can be reviewed at: *http://www.exim.gov/sites/default/files/pub/pending/eib84-01.pdf*

DATES: Comments must be received on or before January 8, 2016 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *WWW.REGULATIONS.GOV* or by mail to Office of Information and Regulatory Affairs, 725 17th Street NW., Washington, DC 20038, Attn: OMB 3048–0013

SUPPLEMENTARY INFORMATION:

Title and Form Number: EIB 84–01 Joint Application for Export Working Capital Guarantee.

OMB Number: 3048–0013

Type of Review: Renewal

Need and Use: This form provides Ex-Im Bank and Small Business Administration staff with the information necessary to determine if the application and transaction are eligible for Ex-Im Bank and SBA assistance under their export working capital guarantee programs.

Affected Public:

This form affects entities involved in the export of U.S. goods and services.

	Ex-Im Bank	SBA
Annual Number of Respondents:	475	188.
Estimated Time per Respondent:	2.5 hours	2.5 hours.
Annual Burden Hours:	1,188 hours	470 hours.
Frequency of Reporting of Use:	Annually	Annually.

Government Expenses:

Ex-Im Bank	SBA	
Reviewing time per year:	950 hours	376
Average Wages per Hour:	$42.50	$35.00
Average Cost per Year: (time*wages)	$40,375	$13,160
Benefits and Overhead:	20%	100%
Total Agency Cost:	$48,450	$26,320
Total Government Cost:	$74,770	

Bonita Jones-McNeil,

Program Analyst, Office of the Chief Information Officer.

[FR Doc. 2015–30989 Filed 12–8–15; 8:45 am]

BILLING CODE 6690–01–P

EXPORT-IMPORT BANK

[Public Notice 2015–3009]

Agency Information Collection Activities: Comment Request

AGENCY: Export-Import Bank of the United States

ACTION: Submission for OMB review and comments request.

Form Title: EIB 10–02 Application for Short-Term Express Credit Insurance Policy.

SUMMARY: The Export-Import Banks of the United States (Ex-Im Bank), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal Agencies to comment on the proposed information collection, as required by the Paperwork Reduction Act of 1995.

This collection of information is necessary, pursuant to 12 U.S.C. Sec. 635 (a) (1), to determine eligibility of the applicant for Ex-Im Bank assistance.

The Export-Import Bank has made a change to the report to have the applicant provide the number of employees or annual sales volume. That information is needed to determine whether or not they meet the SBA's definition of a small business. The applicant already provides their name, address and industry code (NAICS). These additional pieces of information will allow Ex-Im Bank to better track the extent to which its support assists U.S. small businesses.

The other change that Ex-Im Bank has made is to require the applicant to indicate whether it is a minority-owned business, women-owned business and/or veteran-owned business. Although answers to the questions are mandatory, the company may choose any one of the three answers: Yes/No/Decline to Answer. The option of ''Decline to Answer'' allows a company to consciously decline to answer the specific question should they not wish to provide that information.

The application tool can be reviewed at: *http://www.exim.gov/sites/default/files/pub/pending/eib10_02.pdf*.

DATES: Comments must be received on or before January 8, 2016, 2016 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *WWW.REGULATIONS.GOV* or by mail to Office of Information and Regulatory Affairs, 725 17th Street NW., Washington, DC 20038, Attn: OMB 3048–0031.

SUPPLEMENTARY INFORMATION:

Title and Form Number: EIB 10–02 Application for Short-Term Express Credit Insurance Policy

OMB Number: 3048–0031.

Type of Review: Regular.

Need and Use: This form is used by an exporter (or broker acting on its behalf) in order to obtain approval for coverage of the repayment risk of export sales. The information received allows Ex-Im Bank staff to make a determination of the eligibility of the applicant and the creditworthiness of one of the applicant's foreign buyers for Ex-Im Bank assistance under its programs.

Affected Public: This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 500.

Estimated Time per Respondent: 0.25 hours.

Annual Burden Hours: 125 hours.

Frequency of Reporting of Use: Once per year.

Government Expenses:

Reviewing time per year: 1,000 hours.

Average Wages per Hour: $42.50.

Average Cost per Year: $42,250. (time*wages)

Benefits and Overhead: 20%.

Total Government Cost: $51,000.

Bonita Jones-McNeil,

Program Analyst, Office of the Chief Information Officer.

[FR Doc. 2015–30999 Filed 12–8–15; 8:45 am]

BILLING CODE 6690–01–P

EXPORT-IMPORT BANK

[Public Notice: 2015–3006]

Agency Information Collection Activities: Comment Request

AGENCY: Export-Import Bank of the United States.

ACTION: Submission for OMB review and comments request.

Form Title: EIB 92–30 Report of Premiums Payable for Financial Institutions Only.

SUMMARY: The Export-Import Bank of the United States (Ex-Im Bank), as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal Agencies to comment on the proposed information collection, as required by the Paperwork Reduction Act of 1995.

This collection of information is necessary, pursuant to 12 U.S.C. Sec. 635(a)(1), to determine eligibility of the export sales for insurance coverage. The Report of Premiums Payable for Financial Institutions Only is used to determine the eligibility of the shipment(s) and to calculate the premium due to Ex-Im Bank for its support of the shipment(s) under its insurance program. Export-Import Bank customers will be able to submit this form on paper or electronically.

The Export-Import Bank has made a change to the report to have the insured financial institution provide the industry code (NAICS) associated with each specific export as well as specific information needed to make a determination as to whether or not the exporter meets the SBA's definition of a small business. The insured financial institution already provides a short description of the goods and/or services being exported and the name and address of the exporter. These additional pieces of information will allow Ex-Im Bank to better track what exports it is covering with its insurance policy and the extent to which its support assists U.S. small businesses.

The other change that Ex-Im Bank has made is to require the insured financial

institution to indicate whether the exporter is a minority-owned business, women-owned business and/or veteran-owned business. Although answers to the question are mandatory, the company may choose any one of the three answers: Yes/No/Decline to Answer. The option of ''Decline to Answer'' allows a company to consciously decline to answer the specific question should they not wish to answer.

The information collection tool can be reviewed at: *http://www.exim.gov/pub/pending/eib92-30.pdf.*

DATES: Comments must be received on or before January 8, 2016 to be assured of consideration.

ADDRESSES: Comments may be submitted electronically on *WWW.REGULATIONS.GOV* or by mail to Office of Information and Regulatory Affairs, 725 17th Street NW., Washington, DC 20038, Attn: OMB 3048–0021.

SUPPLEMENTARY INFORMATION:

Title and Form Number: EIB 92–30 Report of Premiums Payable for Financial Institutions Only.

OMB Number: 3048–0021.

Type of Review: Regular.

Need and Use: This collection of information is necessary, pursuant to 12 U.S.C. Sec. 635(a)(1), to determine eligibility of the applicant for Ex-Im Bank assistance. The information collected enables Ex-Im Bank to determine the eligibility of the shipment(s) for insurance and to calculate the premium due to Ex-Im Bank for its support of the shipment(s) under its insurance program.

Affected Public:

This form affects entities involved in the export of U.S. goods and services.

Annual Number of Respondents: 215.

Estimated Time per Respondent: 30 minutes.

Annual Burden Hours: 1,290 hours.

Frequency of Reporting of Use: Monthly.

Government Expenses:

Reviewing time per year: 860 hours.

Average Wages per Hour: $42.50.

Average Cost per Year: (time*wages) $36,550.

Benefits and Overhead: 20%.

Total Government Cost: $43,860.

Bonita Jones-McNeil,

Agency Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2015–31007 Filed 12–8–15; 8:45 am]

BILLING CODE 6690–01–P

FEDERAL MARITIME COMMISSION

Performance Review Board

AGENCY: Federal Maritime Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given of the names of the members of the Performance Review Board.

FOR FURTHER INFORMATION CONTACT: William ''Todd'' Cole, Director Office of Human Resources, Federal Maritime Commission, 800 North Capitol Street NW., Washington, DC 20573.

SUPPLEMENTARY INFORMATION: Sec. 4314(c) (1) through (5) of title 5, U.S.C., requires each agency to establish, in accordance with regulations prescribed by the Office of Personnel Management, one or more performance review boards. The board shall review and evaluate the initial appraisal of a senior executive's performance by the supervisor, along with any recommendations to the appointing authority relative to the performance of the senior executive.

The Members of the Performance Review Board Are:

1. Michael A. Khouri, Commissioner
2. Richard A. Lidinsky, Jr., Commissioner
3. Rebecca F. Dye, Commissioner
4. William P. Doyle, Commissioner
5. Clay G. Guthridge, Administrative Law Judge
6. Erin M. Wirth, Administrative Law Judge
7. Florence A. Carr, Director, Bureau of Trade Analysis
8. Rebecca A. Fenneman, Director, Office of Consumer Affairs & Dispute Resolution Services
9. Karen V. Gregory, Secretary
10. Vern W. Hill, Director, Managing Director
11. Peter J. King, Director, Bureau of Enforcement
12. Sandra L. Kusumoto, Bureau of Certification and Licensing
13. Mary T. Hoang, Chief of Staff
14. Tyler J. Wood, General Council

Mario Cordero,

Chairman.

[FR Doc. 2015–30938 Filed 12–8–15; 8:45 am]

BILLING CODE 6731–AA–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.: 010979–063.

Title: Caribbean Shipowners Association.

Parties: CMA CGM, S.A.; Crowley Caribbean Services LLC; Hybur Ltd.; King Ocean Services Limited; Seaboard Marine, Ltd.; Tropical Shipping and Construction Company Limited; and Zim Integrated Shipping Services, Ltd.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Connor, 1200 19th Street NW., Washington, DC 20036.

Synopsis: The amendment deletes Seafreight Lines, Ltd. as a party to the Agreement.

Agreement No.: 012267–003.

Title: COSCON/CSCL Vessel Sharing and Slot Exchange Agreement.

Parties: China Shipping Container Lines Co., Ltd. and China Shipping Container Lines (Hong Kong) Co. Ltd. (collectively CSCL); COSCO Container Lines Company Limited.

Filing Party: Patricia M. O'Neill, Esq.; Blank Rome, LLP; Watergate; 600 New Hampshire Avenue NW., Washington, DC 20037.

Synopsis: The amendment updates language concerning operational coordination with third parties using slots provided by COSCON and/or CSCL under the Agreement.

Agreement No.: 012295–002.

Title: Hoegh/Hyundai Glovis Middle East Space Charter Agreement.

Parties: Hoegh Autoliners AS and Hyundai Glovis Co. Ltd.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Connor; 1627 I Street NW., Suite 1100, Washington, DC 20006.

Synopsis: The amendment would add Mozambique, South Africa, Angola, Nigeria, Ghana, Senegal, Kenya and Tanzania to the geographic scope of the agreement, make the agreement bi-directional rather than U.S.-outbound only, and correct the address of Hyundai Glovis.

Agreement No.: 012376.

Title: CMA CGM/COSCON Slot Exchange Agreement Asia—U.S. East Coast.

Parties: CMA CGM S.A. and COSCO Container Lines Company, Limited.

Filing Party: Eric. C. Jeffrey, Esq.; Nixon Peabody LLP; 799 9th Street NW., Suite 500; Washington, DC 20001.

Synopsis: The agreement authorizes the parties to exchange space on vessels they operate or on which they have space in the trade between China, Singapore, Taiwan, Vietnam, and Malaysia and the U.S. Atlantic Coast.

Agreement No.: 012372–001.

Title: CMA CGM/COSCON Slot Exchange Agreement Asia—U.S. West Coast.

Parties: CMA CGM S.A. and COSCO Container Lines Company, Limited.

Filing Party: Eric. C. Jeffrey, Esq.; Nixon Peabody LLP; 799 9th Street NW., Suite 500; Washington, DC 20001.

Synopsis: The amendment revises the initial duration of the Agreement, and clarifies the parties' ability to adjust slot exchange amounts on an ad hoc basis.

Agreement No.: 012377.

Title: MOL/NMCC/WLS/HOEGH Space Charter Agreement.

Parties: Mitsui O.S.K. Lines, Ltd; Nissan Motor Car Carrier Co., Ltd.; World Logistics Service (U.S.A.), Inc.; and Hoegh Autoliners AS.

Filing Party: Eric. C. Jeffrey, Esq.; Nixon Peabody LLP; 799 9th Street NW., Suite 500; Washington, DC 20001.

Synopsis: The agreement would authorize the parties to charter space to/from one another for the carriage of vehicles and other Ro/Ro cargo in the trade between the U.S. and all foreign countries.

Agreement No.: 012378.

Title: Hoegh/Bahri General Cargo Middle East Space Charter Agreement.

Parties: The National Shipping Company of Saudi Arabia d/b/a Bahri AS and Hoegh Autoliners AS.

Filing Party: Wayne R. Rohde, Esq.; Cozen O'Connor; 1200 19th Street NW., Washington, DC 20036.

Synopsis: The agreement would authorize the parties to charter space to/from one another in the trades between all U.S. coasts and ports in countries bordering on the Mediterranean Sea, Red Sea, Arabian Gulf, Persian Gulf, Gulf of Aden, Black Sea, Gulf of Oman, and the Indian Ocean.

By Order of the Federal Maritime Commission.

Dated: December 4, 2015.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2015–31037 Filed 12–8–15; 8:45 am]

BILLING CODE 6731–AA–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: Notice is hereby given of the final approval of a proposed information collection by the Board of Governors of the Federal Reserve System (Board) under OMB delegated authority. Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the Paperwork Reduction Act Submission, supporting statements and approved collection of information instrument(s) are placed into OMB's public docket files. The Federal Reserve may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi— Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551 (202) 452–3829. Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

OMB Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW., Washington, DC 20503.

Final approval under OMB delegated authority of the extension for three years, without revision, of the following report:

Report title: Requirements for Disclosure and Reporting of Community Reinvestment Act (CRA)-Related Agreements (Regulation G).

Agency form number: Reg G.

OMB control number: 7100–0299.

Frequency: On occasion and annual.

Reporters: State member banks and their subsidiaries; bank holding companies; savings and loan holding companies; and affiliates of bank holding companies and savings and loan holding institutions, other than banks, savings associations and subsidiaries of banks and savings associations; and nongovernmental entities or persons (NGEPs) that enter into covered agreements with any of the aforementioned companies.

Estimated annual reporting hours: Disclosure burden for insured depository institutions (IDI) and affiliates: Covered agreements to public, 6 hours; and Agreements relating to activities of CRA affiliates, 6 hours; Reporting burden for IDI and affiliates: Copy of agreements to agency, 8 hours; List of agreements to agency, 8 hours; Annual report, 8 hours; and Filing NGEP annual report, 6 hours; Disclosure burden for NGEP: Covered agreements to public, 6 hours; Reporting burden for NGEP: Copy of agreements to agency, 6 hours; and Annual report, 24 hours.

Estimated average hours per response: Disclosure burden for IDI and affiliates: Covered agreements to public, 1 hour; and Agreements relating to activities of CRA affiliates, 1 hour; Reporting burden for IDI and affiliates: Copy of agreements to agency, 1 hour; List of agreements to agency, 1 hour; Annual report, 4 hours; and Filing NGEP annual report, 1 hour; Disclosure burden for NGEP: Covered agreements to public, 1 hour; Reporting burden for NGEP: Copy of agreements to agency, 1 hour; and Annual report, 4 hours.

Number of respondents: Disclosure burden for IDI and affiliates: Covered agreements to public, 2 respondents; and Agreements relating to activities of CRA affiliates, 2 respondents; Reporting burden for IDI and affiliates: Copy of agreements to agency, 2 respondents; List of agreements to agency, 2 respondents; Annual report, 2 respondents; and Filing NGEP annual report, 2 respondents; Disclosure burden for NGEP: Covered agreements to public, 6 respondents; Reporting burden for NGEP: Copy of agreements to agency, 6 respondents; and Annual report, 6 respondents.

General description of report: This information collection is mandatory pursuant to Section 48 of the Federal Deposit Insurance Act (12 U.S.C. 1831y). The Board does not generally consider the information obtained under Regulation G to be confidential. However, a respondent may request confidential treatment under section (b)(4) of the Freedom of Information Act (FOIA). Section (b)(4) provides an exemption for ''trade secrets and commercial or financial information obtained from a person and privileged or confidential'' (5 U.S.C. 552(b)(4)). In order for a respondent to avail itself of this exemption, the respondent would have to show that the release of information would likely cause substantial harm to their competitive position. In addition, the information obtained under Regulation G may in appropriate circumstances also be withheld pursuant to section (b)(8) of the FOIA, which exempts information contained in ''examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions'' (5 U.S.C. 552(b)(8)).

Abstract: Regulation G implements provisions of the Gramm-Leach-Bliley Act (GLBA) that require reporting and public disclosure of written agreements between (1) IDIs or their affiliates and (2) NGEPs, that are made in connection with the fulfillment of CRA

requirements.[1] The GLBA requires both IDIs and NGEPs to make a copy of any CRA-Related agreement available upon request and file an annual report with each relevant supervisory agency regarding the use of funds under such agreement for that fiscal year. In addition, an IDI and affiliate must provide to the relevant supervisory agency each calendar quarter a list of all CRA-related agreements entered into during the quarter with a copy of the agreement.

Current Actions: On September 23, 2015 the Federal Reserve published a notice in the **Federal Register** (80 FR 57374) requesting public comment for 60 days on the extension, without revision, of the Requirements for Disclosure and Reporting of CRA-Related Agreements (Regulation G). The comment period for this notice expired on November 23, 2015. The Federal Reserve did not receive any comments. The information collection will be extended for three years, without revision, as proposed.

Board of Governors of the Federal Reserve System, December 4, 2015.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2015–31039 Filed 12–8–15; 8:45 am]

BILLING CODE 6210–01–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 January 4, 2016.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *Nicolet Bankshares, Inc.,* Green Bay, Wisconsin; to merge with Baylake Corp., and thereby indirectly acquire Baylake Bank, both in Sturgeon Bay, Wisconsin.

B. Federal Reserve Bank of Minneapolis (Jacquelyn K. Brunmeier, Assistant Vice President) 90 Hennepin Avenue, Minneapolis, Minnesota 55480–0291:

1. *West End Financial Corp,* Ironwood, Michigan; to acquire 100 percent of the voting shares of Gresham Bancshares, Inc., and thereby indirectly acquire State Bank, both in Gresham, Wisconsin.

C. Federal Reserve Bank of San Francisco (Gerald C. Tsai, Director, Applications and Enforcement) 101 Market Street, San Francisco, California 94105–1579:

1. *RBB Bancorp,* Los Angeles, California; to merge with TFC Holding Company, and thereby indirectly acquire TomatoBank, both in Alhambra, California.

Board of Governors of the Federal Reserve System, December 4, 2015.

Michael J. Lewandowski,

Associate Secretary of the Board.

[FR Doc. 2015–31001 Filed 12–8–15; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL TRADE COMMISSION

Agency Information Collection Activities; Submission for Review; Comment Request; Extension

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

ACTION: Notice.

SUMMARY: The FTC intends to ask the Office of Management and Budget (''OMB'') to extend for an additional three years the current Paperwork Reduction Act (''PRA'') clearance for information collection requirements contained in the Children's Online Privacy Protection Act Rule (''COPPA Rule'' or ''Rule''), which will expire on February 29, 2016.

DATES: Comments must be filed by January 8, 2016.

ADDRESSES: Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write ''COPPA Rule: Paperwork Comment, FTC File No. P155408'' on your comment, and file your comment online at *https://ftcpublic.commentworks.com/ftc/coppapra2,* by following the instructions on the web-based form. If you prefer to file your comment on paper, mail your comment to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex J), Washington, DC 20024.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be addressed to Miry Kim, Attorney, (202) 326–3622, Division of Privacy and Identity Protection, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW., Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

Title: COPPA Rule, 16 CFR part 312.

OMB Control Number: 3084–0117.

Type of Review: Extension of currently approved collection.

Abstract: On September 25, 2015, the FTC sought public comment on the information collection requirements associated with subpart N. 80 FR 57818 (''September 25, 2015 **Federal Register** Notice''). No relevant comments were received. Pursuant to the OMB regulations, 5 CFR part 1320, that implement the PRA, 44 U.S.C. 3501 *et seq.,* the FTC is providing a second opportunity for public comment while seeking OMB approval to renew the pre-existing clearance for the Rule.

The COPPA Rule, 16 CFR part 312, requires commercial Web sites to provide notice and obtain parents' consent before collecting, using, and/or disclosing personal information from children under age 13, with limited exceptions. The COPPA Rule contains certain statutorily-required notice requirements that apply to operators of any Web site or online service directed to children, and operators of any Web site or online service with actual knowledge of collecting personal information from children. Covered operators must: Provide online notice and direct notice to parents of how they collect, use, and disclose children's

[1] 12 U.S.C. 2901 *et seq.*

personal information; obtain the prior consent of the child's parent in order to engage in such collection, use, and disclosure, with limited exceptions; provide reasonable means for the parent to obtain access to the information and to direct its deletion; and, establish procedures that protect the confidentiality, security, and integrity of personal information collected from children.

Burden Statement [1]

1. Estimated annual hours burden: 17,500 hours
   (a) New entrant web operators' disclosure burden: 16,800 hours
   (b) Safe harbor applicant reporting requirements: 100 hours, rounded (for an estimated one additional safe harbor applicant)
   (c) Annual audit and report for safe harbor programs: 800 hours
   (d) Safe harbor program recordkeeping requirements: 0 or minimal
2. Estimated annual labor costs: $5,342,500
   (a) New entrant web operators' disclosure burden: $5,297,600
   (b) Safe harbor applicant reporting requirements: $18,500
   (c) Annual audit and report for safe harbor programs: $26,400
   (d) Safe harbor program recordkeeping requirements: $0 or marginal
3. Estimated annual non-labor costs: $0

Request for Comments

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before January 8, 2016. Write ''COPPA Rule: Paperwork Comment, FTC File No. 155408'' on your comment. Your comment—including your name and your state—will be placed on the public record of this proceeding, including to the extent practicable, on the public Commission Web site, at *http://www.ftc.gov/os/publiccomments.shtm.* As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Web site.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment doesn't include any sensitive health information, like medical records or other individually identifiable health information. In addition, don't include any ''[t]rade secret or any commercial or financial information . . . which is privileged or confidential'' as provided in Section 6(f) of the FTC Act 15 U.S.C. 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, don't include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c)).[2] Your comment will be kept confidential only if the FTC General Counsel grants your request in accordance with the law and the public interest.

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at *https://ftcpublic.commentworks.com/ftc/coppapra2,* by following the instructions on the web-based form. When this Notice appears at *http://www.regulations.gov/#!home,* you also may file a comment through that Web site.

If you file your comment on paper, write ''COPPA Rule: Paperwork Comment, FTC File No. 155408'' on your comment and on the envelope, and mail it to the following address: Federal Trade Commission, Office of the Secretary, 600 Pennsylvania Avenue NW., Suite CC–5610 (Annex J), Washington, DC 20580, or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Constitution Center, 400 7th Street SW., 5th Floor, Suite 5610 (Annex J), Washington, DC 20024. If possible, submit your paper comment to the Commission by courier or overnight service.

Comments on the information collection requirements subject to review under the PRA should additionally be submitted to OMB. If sent by U.S. mail, they should be addressed to Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Desk Officer for the Federal Trade Commission, New Executive Office Building, Docket Library, Room 10102, 725 17th Street NW., Washington, DC 20503. Comments sent to OMB by U.S. postal mail, however, are subject to delays due to heightened security precautions. Thus, comments instead should be sent by facsimile to (202) 395–5806.

The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before January 8, 2016. For information on the Commission's privacy policy, including routine uses permitted by the Privacy Act, see *http://www.ftc.gov/ftc/privacy.htm.*

David C. Shonka,

Principal Deputy General Counsel.

[FR Doc. 2015–30935 Filed 12–8–15; 8:45 am]

BILLING CODE 6750–01–P

[1] This discussion and the associated burden estimates concern strictly recurring compliance obligations under the COPPA Rule. Details underlying the estimates within this Burden Statement can be found in the September 25, 2015 **Federal Register** Notice.

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

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

[OMB Control No. 9000–0070; Docket 2015–0055; Sequence 26]

Information Collection; Payments

AGENCY: Department of Defense (DOD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Notice of request for comments regarding the extension of a previously existing OMB clearance.

SUMMARY: Under the provisions of the Paperwork Reduction Act, the Regulatory Secretariat Division will be submitting to the Office of Management and Budget (OMB) a request to review and approve an extension of a previously approved information collection requirement concerning payments.

DATES: Submit comments on or before February 8, 2016.

ADDRESSES: Submit comments identified by Information Collection 9000–0070, Payments, by any of the following methods:

• *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by searching the OMB control number. Select the link ''Submit a Comment'' that corresponds with ''Information Collection 9000–0070, Payments''. Follow the instructions provided at the ''Submit a Comment'' screen. Please include your name, company name (if any), and ''Information Collection 9000–0070, Payments'' on your attached document.

• *Mail:* General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405. ATTN: Ms. Flowers/IC 9000-0070, Payments.

Instructions: Please submit comments only and cite Information Collection 9000-0070, Payments, in all correspondence related to this collection. Comments received generally will be posted without change to *http://www.regulations.gov*, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check *www.regulations.gov*, approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Kathy Hopkins, Procurement Analyst, Office of Acquisition Policy, GSA at 202-969-7226 or email at *kathlyn.hopkins@gsa.gov*.

SUPPLEMENTARY INFORMATION:

A. Purpose

Firms performing under Federal contracts must provide adequate documentation to support requests for payment under these contracts. The documentation may range from a simple invoice to detailed cost data. The information is usually submitted once, at the end of the contract period or upon delivery of the supplies, but could be submitted more often depending on the payment schedule established under the contract (see FAR 52.232–1 through 52.232–4, and FAR 52.232–6 through 52.232–11). The information is used to determine the proper amount of payments to Federal contractors.

B. Annual Reporting Burden

Respondents: 80,000.
Responses per Respondent: 120.
Total Responses: 9,600,000.
Hours per Response: .25.
Total Burden Hours: 2,400,000.

C. Public Comments

Public comments are particularly invited on: Whether this collection of information is necessary for the proper performance of functions of the Federal Acquisition Regulations (FAR), and whether it will have practical utility; whether our estimate of the public burden of this collection of information is accurate, and based on valid assumptions and methodology; ways to enhance the quality, utility, and clarity of the information to be collected; and ways in which we can minimize the burden of the collection of information on those who are to respond, through the use of appropriate technological collection techniques or other forms of information technology.

Obtaining Copies of Proposals: Requesters may obtain a copy of the information collection documents from the General Services Administration, Regulatory Secretariat Division (MVCB), 1800 F Street NW., Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No.9000–0070, Payments, in all correspondence.

Edward Loeb,

Acting Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2015–30969 Filed 12–8–15; 8:45 am]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Statement of Organization, Functions, and Delegations of Authority

Part C (Centers for Disease Control and Prevention) of the Statement of Organization, Functions, and Delegations of Authority of the Department of Health and Human Services (45 FR 67772–76, dated October 14, 1980, and corrected at 45 FR 69296, October 20, 1980, as amended most recently at 80 FR 73766–73769, dated November 25, 2015) is amended to reflect the reorganization of the Division of Global HIV/AIDS, Center for Global Health, Centers for Disease Control and Prevention.

Section C–B, Organization and Functions, is hereby amended as follows:

Delete in its entirety the title and the mission and function statements for the *Division of Global HIV/AIDS (CWG)* and insert the following:

Division of Global HIV and TB (CWG). The Division of Global HIV and TB (DGHT) provides technical assistance to host governments, working through its strong partnerships with Ministries of Health and local and international partners to implement integrated HIV/AIDS clinical and preventive services and systems; develop and strengthen laboratory services; and provide epidemiologic science, informatics, and research support to develop sustainable public health systems in resource-constrained countries. DGHT: (1) Provides leadership, management, and services to DGHT country offices; (2) implements integrated evidence-based prevention, care, and treatment programs and services; (3) evaluates program costs, cost effectiveness and impact to assist with prioritization, inform program planning, and appropriate rates of program expansion, and strengthens capacity for sustainable, high quality research and service implementation to indigenous partners and Ministries of Health; (4) builds sustainable public health capacity in laboratory services and systems; (5) ensures epidemiologic and scientific excellence in HIV/AIDS programs; (6) contributes to the broader scientific body of knowledge in global public health by systematically evaluating the scope and quality of global HIV/AIDS and TB programs; (7) implements operations and effectiveness research to inform the design of current and future programs as well as optimize allocation of human and financial resources; (8) strengthens in-country capacity to design and implement HIV/AIDS surveillance systems and surveys; (9) builds host government public health management capacity and trains in-country public heath workforce with the goal of long-term program sustainability; (10) supports host government capacity to monitor and evaluate the process, outcome, and impact of HIV prevention, care, and treatment programs; and (11) helps countries respond to public health emergencies, assisting in response planning and implementation with Ministries of Health and other international partners.

Office of the Director (CWG1). (1) Provides strategic leadership, guidance, management and oversight to all DGHT programs and ensures coordination and communication across its branches and with other CDC programs including CDC/Washington; U.S. Government (USG) agencies, including the Department of Health and Human Services (HHS), the United States Agency for International Development (USAID), and Department of State (DoS);

and other international organizations; (2) plans, implements, and oversees all field programs along with other USG agencies; (3) provides oversight, leadership, and strategic guidance for the management of DGHT country/program directors and country offices for all matters of daily operation, including management of global workforce staff; (4) provides leadership and guidance on policy development and interpretation, budget formulation, program planning, issues management, management and operations, and evaluation; (5) provides leadership and oversight for the development of communication materials and dissemination strategies to share best practices through media, partners, and other audiences to strengthen the public health response; (6) oversees identification of opportunities for leveraging and enhancing partnerships for public health protection and synergies with other Agency programs and partners; (7) oversees DGHT management and operations services in coordination with appropriate CDC staff offices, including processing travel and assisting with accountability and management of HHS/CDC property, facilities, and equipment; (8) oversees timely and sufficient DGHT staff placement through recruitment, hiring, and orienting of qualified staff; (9) provides leadership to ensure retention of qualified staff by providing workforce management and career development services for DGHT staff; (10) oversees supports to ensure scientific excellence for all DGHT scientific, programmatic, and informational documents/materials which includes providing scientific review and clearance of manuscripts for publication, abstracts for presentation, and protocols for institutional review boards and human subjects review; (11) provides leadership and support for global public health evaluation and operational research to maximize the effectiveness and quality of global HIV/AIDS interventions to guide DGHT programs and policies; (12) establishes and implements standards for organizational excellence; (13) provides direct technical assistance and maintains relationships with host country partners, and responds to other health needs as required; (14) assures accountability of program funds and reports on progress; and (15) collaborates with other CDC and HHS programs and offices; other USG agencies; and other national and international organizations.

International Laboratory Branch (CWGB). (1) Serves as a reference laboratory that provides guidance on quality assurance, continuous quality improvement, certification and accreditation for international laboratory and point of care testing (POCT) sites; (2) provides technical assistance to country programs in the areas of laboratory information systems, laboratory systems, and linkages throughout the diagnostic cascade; (3) provides training packages, training, guidance, and support to host nations, other USG agencies and international and national partners on HIV, tuberculosis (TB), Sexually Transmitted Infection (STI), and opportunistic infection (OI) diagnostics and monitoring techniques; HIV incidence testing; hematology; clinical chemistry; CD4; TB diagnostic and treatment monitoring testing; anti-tuberculosis drug susceptibility testing (DST) ; antiretroviral treatment (ART) resistance testing; dried blood spot polymerase chain reaction for early infant diagnosis; viral load monitoring; and ensuring the quality of laboratories and testing activities; (4) serves as a training center of excellence for HIV/TB/STI diagnostics for international sites; (5) provides laboratory assistance to international surveillance activities to monitor trends of HIV prevalence and incidence; (6) provides technical assistance and quality assurance in support of and TB prevalence and drug resistance surveys (6) assists in the surveillance of HIV subtypes in the overall context of supporting sero-surveillance programs; (7) assists in the surveillance and evaluation of HIV drug resistance as part of antiretroviral care and treatment programs; (8) serves as a reference laboratory for the World Health Organization (WHO)-CDC HIV drug resistance network and as a WHO Supranational TB Reference Laboratory (8) develops strategies and methodologies to meet the clinical and diagnostic needs of HIV/AIDS and TB programs; (9) assists in the evaluation and validation of serologic and nucleic acid assays for measurement of HIV incidence to enable evaluation of effectiveness of prevention programs; evaluates performance of new assays and platforms for HIV and TB diagnosis and treatment monitoring; (11) develops comprehensive testing algorithms for HIV diagnosis; (12) provides technical guidance on introduction of new TB diagnostic tests and algorithms; (13) contributes to operational research to maximize the effectiveness and quality of global HIV/AIDS and TB interventions to guide Division, Agency, and PEPFAR programs and policies; (14) conducts laboratory capacity assessments and assists in development of infrastructure for effective implementation of programs in countries where DGHT operates; (15) provides laboratory guidance and support on national strategic planning and quality management of tiered laboratory systems in host nations and consults on all technical aspects of laboratory procurement, standardization, quality control and quality assurance; (16) works with international accrediting organizations to establish guidance, training, and tools for accreditation of laboratory systems in resource-poor settings; (17) supports ongoing collaboration with international laboratory experts and national and regional laboratory personnel to resolve technical issues and develops international tools, guidelines, curriculum and other resources to improve laboratory capacity in host nations; (18) develops and implements strategies to expand the laboratory health workforce and increase human capacity of host government public health programs to strengthen and ensure sustainable, integrated public health responses to HIV/AIDS and TB; (19) promotes a transition toward greater sustainability of laboratory systems through the support of country-driven efforts; (20) establishes strategic Public Private Partnerships for strengthening laboratory systems, training, development of referral systems for transporting samples, and quality management schemes; (19) ensures scientific excellence for all branch manuscripts, protocols, and programs in collaboration with the DGHT Office of the Director (OD) science office; (21) contributes to the greater body of scientific knowledge through the presentation of laboratory operational research findings at conferences and through publications in peer reviewed journals; and (22) collaborates with other DGHT branches; other CDC (*e.g.,* DTBE, DGHP) and HHS programs and offices; other USG agencies; and other national and international organizations.

HIV Prevention Branch (CWGC). (1) Provides technical assistance and builds capacity to implement, improve, and maximize effectiveness of HIV prevention programs; (2) provides technical assistance for scale-up of prevention interventions and linkage to HIV clinical services; (3) helps to develop, expand, and evaluate HIV testing and counseling programs in both clinical and community settings to assure that all persons know their HIV status; (4) assists in implementing, and monitoring the quality and impact of programs for linking HIV infected

persons to health services for HIV care and treatment; (5) helps strengthen, expand, and make accessible programs to access key populations and to link HIV infected persons to prevention, care, and treatment programs; (6) assists in tailoring HIV prevention programs to meet the special needs of youth, drug-using populations, and other key populations; (7) assists in safe and effective implementation of biomedical interventions, including the scale-up of medical male circumcision; (8) provides technical assistance to PEPFAR partner countries to assure availability of safe blood by attaining blood center accreditation, quality assurance for blood bank laboratories, and appropriate health information systems for blood services; (9) supports global surveillance systems for transfusion- and injection-associated HIV transmission and the transmission of other blood-borne pathogens of public health importance; (10) conducts investigations and supports the development of surveillance systems to track medical injection use and misuse and provides technical assistance to countries to reduce demand for medical injections; (11) contributes to operational research to maximize the effectiveness and quality of global HIV/AIDS prevention interventions to guide programs and policies; (12) establishes strategic Public Private Partnerships to build capacity for and maximize effectiveness of HIV prevention programs in host countries; (13) ensures scientific excellence for all branch manuscripts, protocols, and programs in collaboration with the DGHT OD science office; and (14) collaborates with other DGHT branches, CDC and HHS programs and offices, USG agencies, and national and international organizations.

HIV Care and Treatment Branch (CWGD). (1) Provides technical assistance and builds capacity in developing and implementing sustainable care and treatment programs for persons with HIV/AIDS. This includes diagnosis, linkage to care, and care and treatment services for HIV/AIDS, HIV-related tuberculosis, other opportunistic infections, and opportunistic cancers; (2) assists countries to achieve the 90–90–90 goals articulated by UNAIDS and by PEPFAR 3.0; (3) provides technical expertise and support to country programs, partners, and Ministries of Health in planning, implementing, and evaluating effective strategies for care and treatment of persons with HIV; (4) provides HIV care and treatment expertise to country programs, partners, and Ministries of Health on management, standard operating procedures, human resources, physical infrastructure, training, drug and health commodities management, laboratory services, monitoring and evaluation, community services, linkage between HIV and other programs, promotion of prevention, and sustainability; (5) provides support for continuous quality improvement of HIV care and treatment programs; (6) promotes appropriate integration of services, including HIV prevention interventions into clinical care and treatment settings and HIV services into general medical services; (7) conducts operational research in collaboration with country programs to identify best practices, address barriers, and respond to emerging scientific issues related to HIV care and treatment service delivery; (8) collaborates with international partners to synthesize the scientific body of knowledge on HIV care and treatment, including TB/HIV co-infection; (9) collaborates with international partners to develop and disseminate tools (*e.g.,* protocols and training curricula), guidelines and policies; (10) supports analysis of program costs and cost-effectiveness to assist with prioritization, inform program planning, and determine appropriate rates of program expansion; (11) supports capacity building of host countries to transition responsibility for implementation of HIV care and treatment services to indigenous partners and Ministries of Health, with result of increasing ownership, sustainability and service delivery cost efficiencies; (12) establishes strategic Public Private Partnerships aimed at augmenting capacity for developing and implementing sustainable care and treatment programs, including diagnosis, linkage to care, and care and treatment services for HIV/AIDS, HIV-related tuberculosis, other opportunistic infections, and opportunistic cancers; (13) ensures scientific excellence for all branch Manuscripts, protocols, and programs in collaboration with the DGHT OD science office; and (14) collaborates with other DGHT branches; other CDC and HHS programs and offices; other USG agencies; and other national and international organizations.

Maternal and Child Health Branch (CWGE). (1) Supports the international scale-up of comprehensive, quality prevention of mother-to-child HIV transmission (PMTCT) and pediatric (Peds) programs by developing adaptable training tools, utilizing operational research to identify and implement models of service delivery adapted to district, regional, sub-national and national contexts; (2) provides technical expertise and support to countries in planning, implementing, and evaluating effective strategies for scaling up of sustainable programs for the prevention, diagnosis, and treatment of HIV/AIDS, tuberculosis, and other opportunistic infections in women, infants, and children, including linking PMTCT/Peds HIV programs with HIV clinical and preventive services and other maternal and child health settings/contexts; (3) builds national capacity for and provides guidance on development of policy for formulations for and access to appropriate long-term combination ART for HIV-infected children; (4) conducts operational research in collaboration with country programs to promote best practices, address barriers, and respond to emerging scientific issues for PMTCT/Peds HIV service delivery; (5) collaborates with international partners to contribute to the scientific body of knowledge on global PMTCT/Peds and broader maternal and child health issues and to develop and disseminate tools, guidelines, and policies to translate research for improved program implementation in resource-constrained countries; (6) provides support for continuous quality improvement of PMTCT and Peds HIV care and treatment programs, including those within broader maternal and child health programs; (7) supports analysis of program costs and cost-effectiveness to assist with prioritization, inform program planning, and determine appropriate rates of program expansion; (8) acts as a key part of a broader CDC strategic response to address health needs and gender-related issues of maternal and child health worldwide, supporting a comprehensive, multidisciplinary approach to building maternal and child health services and systems capacity in host countries; (9) establishes strategic public private partnerships for HIV maternal and child health services and systems capacity in host countries; (10) ensures scientific excellence for all branch manuscripts, protocols, and programs in collaboration with the DGHT OD science office; and (11) collaborates with other DGHT branches; other CDC and HHS programs and offices; other USG agencies; and other national and international organizations.

Epidemiology and Surveillance Branch (CWGG). (1) Builds the capacity of countries to develop and/or enhance HIV-related surveillance systems and use the results of surveillance systems and surveys for impact monitoring,

program planning, and HIV policy-making; (2) implements and evaluates novel approaches for conducting surveillance and surveys including small area estimation of HIV prevalence and key population size estimation; (3) provides capacity-building technical assistance for in-country HIV-related epidemiologic investigations; (4) supports surveys and surveillance systems that measure HIV-related behaviors, HIV prevalence and incidence, uptake of HIV related services, clinical outcomes, and health status among the general population and at-risk populations; (5) develops normative guidance to improve the collection and analysis of HIV surveillance data including morbidity and mortality; (6) assists and provides technical expertise and training on collection, analysis, interpretation, dissemination, and use of HIV surveillance data; (7) assists and strengthens capacity of host country governments and organizations to assess and ensure the quality of the data collected in HIV-related surveillance systems and clinic-based HIV data systems; (8) coordinates, oversees, or assists in the formulation of HIV surveillance related funding/budgets and in the execution of a variety of acquisition and assistance awards; (9) ensures scientific excellence for relevant manuscripts, protocols, and programs in collaboration with the DGHT OD science office; and (10) collaborates with other DGHT branches, other CDC and HHS programs and offices, other USG agencies, and other national and international organizations as appropriate.

Economics and Health Services Research Branch (CWGH). (1) Identifies priority information needs for program planning, resource allocation, efficiency and program integration, and develops economic analysis and operational research activities; (2) implements economic studies, including cost and cost-effectiveness studies, and applies advanced modeling techniques to inform and optimize global health planning, policy and programs, and provide a broader understanding of the effects of health programs on improving economic and other non-health outcomes; (3) supports USG efforts in projecting financing needs to efficiently meet program targets in areas of prevention, care and treatment, and human resources for health (HRH); (4) guides development and implementation of monitoring systems to routinely capture program expenditure data to support planning, accountability and efficient programming; (5) trains and mentors partner country personnel in the methods and application of economic analysis of global health programs and policy; (6) provides technical input, guidance, review and implementation support to operational research on and evaluation of global HIV/AIDS activities; (7) provides technical input on the development of partner country health finance systems and capacity to develop sustainable and accountable programs, and assists in the implementation of national AIDS spending assessment activities; (8) implements and provides technical guidance on HIV/AIDS resource tracking exercises and monitoring of HIV/AIDS spending; (9) assesses financial flows and bottlenecks to financing service delivery of HIV/AIDS interventions in order to improve efficient use and allocation of funds; (10) works with health and budget officials to further understanding of issues with a view to improving and sustaining the HIV program as well as improving communication between Ministries of Health and Finance; (11) strengthens the capacity of in-country counterparts of HIV financing, sustainability, and public financial management concepts and practices; (12) develop, models, and analyzes the HIV/AIDS investment and assess the direct impact and broader macroeconomic impacts of the HIV/AIDS investment; (13) participates in USG interagency technical working groups and provides technical leadership to address HIV/AIDS economics and finance, Health Systems Strengthening (HSS), and HRH issues and initiatives; (13) provides technical support for the routine monitoring of health-related governance including financial accountability, programmatic transparency, policy development and enforcement, and engagement and regulation of the private health sector, including the Global Fund to Fight AIDS, Tuberculosis, and Malaria; (14) develops the HSS operational research agenda for DGHT and implements public health evaluations related to health systems; (15) provides broad HSS technical assistance and support to USG in-country teams and host countries to improve the delivery of HIV and other health services and work toward transition to country ownership of program; (16) supports branches in strengthening health systems, developing metrics to assess DGHT's contribution to HSS and implementing monitoring systems to routinely collect DGHT's health system impact, especially in the areas of laboratory systems, maternal child health services, HIV care and treatment service delivery, blood safety programs, and prevention services; (17) helps define CDC's role and identify priority needs for strengthening HRH to support sustainability of HIV programs; (18) provides HRH technical assistance and other support to plan and meet priority HRH needs, including pre-service and in- service training, task-shifting, capacity-building of accreditation and credentialing bodies, HRH planning and management, workplace performance and safety, quality of nursing and midwifery staffing in HIV service delivery, and the development of human resource information systems and their use in health decision-making; (19) conducts monitoring and evaluation of US-supported HRH activities, to help inform U.S. resource and program decision-making; (20) conducts policy analysis and generate evidence to enact evidence-based laws and policies for the sustainable scale-up of the HIV/AIDS response in U.S. supported HIV/AIDS programs; (21) supports operational research activities and public health evaluations that address current HRH questions and monitoring needs; (22) ensures scientific excellence for all branch manuscripts, protocols, and programs in collaboration with the DGHT OD science office; and (23) collaborates with other DGHT branches other CDC and HHS programs and offices, other USG agencies, and other national and international organizations.

Overseas Strategy and Management Branch (CWGJ). (1) Provides and coordinates support to facilitate effective design and delivery of global HIV and TB activities in DGHT country programs in the areas of program strategy and implementation, program monitoring and evaluation, health diplomacy, fiscal management, procurement, personnel, extramural programs, and other domains; (2) serves as the official and overarching linkage between DGHT overseas offices and CDC, including DGHT OD and other DGHT Branches, components of CGH other than DGHT, and other relevant offices of CDC, HHS, and USG; (3) recruits, hires, and supervises DGHT program directors, and plays a major role in those same functions for DGHT Program Deputy Directors; (4) coordinates the hiring of all US Direct Hire (USDH) employees to DGHT overseas positions, and manages their pre-deployment training, preparation, and orientation to those critical positions; (5) facilitates and provides as needed short- and long-term

consultation, technical assistance, and backstopping for program issues to DGHT country offices; (6) manages the Country Office Management and Accountability System (CMAS), a principal DGHT process for accountability across a multiple core functions for performance; (7) provides long-term management and operations support for smaller DGHT overseas offices; and (8) serves as the CDC representative on interagency country support teams for the President's Emergency Plan for AIDS Relief.

Program Budget and Extramural Management Branch (CWGK) (1) Coordinates all DGHT procurement and extramural activities in creating spend plans in compliance with federal appropriations law, congressional intent, and global HIV/AIDS policies; (2) facilitates and manages the development, clearance, and award of all new and ongoing DGHT headquarters and field grants, cooperative agreements, and contracts; (3) provides technical assistance and guidance to the countries and branches on budget and extramural issues including assisting programs in determining the appropriate funding mechanism to support global HIV/AIDS activities; (4) provides training and tools to DGHT country programs to improve budget and cooperative agreement management; (5) manages DGHT headquarters budget and tracks overall DGHT budget, which includes conducting budget planning exercises and managing the annual close-out process; (6) provides funding and budgetary data for regular reports including the Headquarters Operational Plan, GAO and IG audits, country Annual Program Results to OGC, and other requests for data; (8) reviews and provides input on budgetary and procurement policy-related documents; (9) liaises and collaborates, as appropriate, with the DGHT Associate Director for Science, other financial and procurement-related units and offices including Office of Financial Management, as well as other CDC and HHS offices, OGC, and other USG agencies; and (10) collaborates with other DGHT branches; other CDC and HHS programs and offices; other USG agencies; and other national and international organizations.

Global Tuberculosis Prevention and Control Branch (CWGL). (1) Provides technical assistance and builds capacity in developing and implementing sustainable comprehensive global TB prevention and control programs. This includes prevention, diagnosis, and treatment services for TB, HIV/AIDS and other opportunistic infections; (2) coordinates Division and center international TB activities; (3) coordinates the assessment of immigration and its impact on TB patterns in the U.S. and assists with the evaluation of overseas TB screening procedures for immigrants and refugees; (4) conducts and coordinates operational research and demonstrations to improve both the overseas screening for tuberculosis of immigrants and refugees and the domestic follow-up of those entering with suspected TB (done in collaboration with other CIOs); (5) collaborates with WHO, the World Bank, IUATLD, USAID, and others to improve the quality of TB programs globally by supporting implementation of the WHO-recommended directly observed therapy, short-course strategy; (6) collaborates with the nation of Botswana, WHO, the World Bank, IUATLD, USAID, and others, to conduct investigations into the diagnosis, management, and prevention of tuberculosis in persons with and without HIV infection; (7) provides technical expertise and support in addressing the AIDS pandemic in countries where both HIV and TB are reported in epidemic proportions; (8) collaborates with WHO, USAID, and several nations to reduce the impact of multi-drug resistant TB on global TB control; (9) prepares manuscripts for publication in scientific journals; (10) presents findings at national and international scientific meetings; (11) supervises Epidemic Intelligence Service Officers (EIS) in the conduct of their two year assignments; and (12) presents international and operational research findings to Advisory Council for the Elimination of Tuberculosis (ACET) and national and international scientific meetings.

Science Integrity Branch (CWGM). (1) Serves as the principal advisor on standards related to scientific activities and human subjects protection within DGHA, supporting headquarters and country programs; (2) ensures scientific excellence in DGHA scientific documents disseminated to the public by coordinating scientific review of manuscripts for publication, abstracts for presentation, and study protocols; (3) provides coordination and support for implementation science (operational research) to maximize the effectiveness and quality of global HIV/AIDS interventions; (4) conducts regulatory and ethical reviews for activities involving human participants; (5) reviews funded activities for application of human research regulations; (6) provides oversight for DGHA implementation science-related workgroups; (7) encourages internal and external scientific collaborations and partnerships; (8) ensures compliance with good clinical and laboratory practices (GCP and GCLP); and (9) provides training to support science quality and integrity at headquarters and in country programs.

Management and Operations Branch (CWGN). (1) In coordination with appropriate CDC and CGH staff offices provides oversight, guidance and accountability for all administrative functions, domestic and international travel, human resources, and management of equipment, property and facilities; (2) develops and implements administrative policies, procedures and operations as appropriate for the Division; and prepares special reports and studies as required in the administrative management area; (3) provides leadership and guidance in all matters of daily operation, including recruitment, retention and management of a diverse, multi-disciplinary global workforce staff; (4) ensures timely and sufficient DGHT domestic staff placement through recruitment, hiring, and orienting of qualified staff; (5) ensures retention of qualified staff by providing workforce management and career development services for DGHT domestic staff; (6) ensures the full implementation and utilization of agency wide administrative systems and processes in support of Division management and operations.

Strategy, Policy, and Communications Branch (CWGP). (1) Provides leadership and strategic direction for the Division in determining CDC's global HIV and tuberculosis (TB) objectives and priorities; (2) provides policy direction for the Division on sensitive or controversial issues impacting CDC's global HIV and TB policies and programs; (3) provides guidance to top agency officials on strategies necessary to communicate and maximize acceptance of the agency's positions on issues; (4) provides leadership and guidance on policy development and interpretation, budget formulation, and issues management; (5) communicates, through all relevant forms of media, the Division's program priorities, accomplishments, and value to both internal and external stakeholders; (6) leads and facilitates the Division's external relations with key non-governmental partners, faith-based partners, community-based partners, international partners and other constituencies; and (7) facilitates the Division's efforts to work closely with multilateral partners to continually

improve joint planning, data use, and strategic alignment to maximize impact in the fight against HIV/AIDS globally.

Special Initiatives Branch (CWGQ). (1) Supports key leadership in assessing issues, identifying mitigation options, managing resolutions, coordinating DGHT responses to complex issues; (2) convenes relevant CDC SMEs to facilitate quick resolution of critical and complex concerns; (3) assures coordination across DGHT branches, horizontal and vertical, and with other relevant CDC organizations units in response to priority issues as needed; (4) convenes relevant CDC SMEs to conceive, define and develop concept notes which describe new Global HIV/AIDS special initiatives addressing program and/or operations issues; (5) communicates findings and status of current and ongoing priority issues resolution with DGHT Director and senior leadership on a timely basis; (6) initiates foundation documents (task trackers, scopes of work, list of working group participants, reporting platforms) for priority initiatives requiring cross branch collaboration; (7) investigates options for preventing or early detection of emerging issues that impact on effective/efficient use of resources; and (8) directs DGHT external assignees (both domestic and international) to assure DGHT HIV/AIDS expertise and technical assistance is provided to external partners effectively and efficiently while also assuring CDC directly learns and benefits from these partnerships with other organizations.

Health Informatics, Data Management, and Statistics Branch (CWGR). (1) Provides leadership and technical expertise to DGHT, agency, other US government agency, multilateral organizations, and implementing partners in the development, dissemination, and implementation of information system, data management, analytic, and statistical standards, guidance, methods and solutions; (2) provides specialized expertise in health information systems, data management, data analytics and statistics across the life cycle of HIV implementation science, evaluation, and research projects, including expertise study design, sample design and sample size estimation, questionnaire development, information system design and development, data capture, management, monitoring and use, statistical analysis, report and manuscript writing, and data documentation, archival and dissemination; (3) provides specialized expertise in information systems, data management and statistics to DGHT-supported and other HIV surveillance and survey systems and activities to promote better understanding of HIV epidemics and HIV program outcomes and impact; (4) assures statistical, data management, and analytic integrity of DGHT and other global HIV activities and projects through technical review of concepts, protocols, reports, manuscripts and other products; (5) provides leadership and statistical expertise to agency and other US government agencies, multilateral organizations to promote statistical innovation and advance novel approaches in the analysis and modeling of HIV epidemics and evaluation of HIV programs; (6) collaborates with DGHT branches and country offices, host country governments and implementing partners to develop efficient and sustainable approaches to improve the use of national routine health information systems for program monitoring and improvement; (7) provides technical support to DGHT, agency, and interagency global HIV initiatives to strengthen capacity to collect, exchange, access, manage, analyze, use, and release HIV-related data to inform decisions to allocate resources and strengthen programs, including the advancement of innovative techniques and the appropriate use of technology; (8) collaborates with CGH in assuring that DGHT-sponsored information systems comply with all legislatively mandated requirements, including information systems security, capital planning, and reporting requirements; (9) builds global capacity for efficient and sustainable data management and health information system design, implementation, and use, by promoting, supporting and training a DGHT-led community of practice who identify and promote best practices and identify key competencies and curricula needed to advance data management and health information systems; (10) builds and maintains an enterprise performance monitoring data warehouse and engages in technical partnerships with DGHT regional and country offices to apply appropriate data management and analytic methodology to data systems for performance monitoring, accountability, and impact; (11) assures robust, cost effective and sustainable data management and information system infrastructure and methodologies for global HIV projects, by providing reviews of program and research data management plans, disseminating guidelines and policy for data management standards, and, where appropriate, monitoring for adherence to standards and guidelines; (12) advises about the resources needed to execute health information system, data management, analytic, and statistical functions, including human resources, staffing plans, and extramural activities; (13) supports the integration of HIV data into more comprehensive health information systems, the development of comprehensive health information systems, the development of metrics for monitoring and evaluating the implementation and functioning of health information systems; (14) provides technical assistance to DGHT regional and country offices and host national governments to strengthen health information systems, including strategic planning, systems needs assessments, identifying and resolving gaps, describing data standards and data exchange needed across systems, and developing standards for system interoperability; and (15) collaborates with agency, interagency and multilateral organizations to develop standards, tools, and guidance to improve the secure collection and use of HIV associated data, including guidance and tools to improve standardized definitions for HIV-related data, open source tools for the implementation of patient and program monitoring systems; security and confidentiality guidance for HIV data; and guidance on unique identification and matching of patient data across information systems.

Monitoring, Evaluation, and Data Analysis Branch (CWGS). (1) Develops, implements and evaluates standard and novel approaches to program monitoring and evaluation of inputs, outputs, outcomes and impacts for facility- and community-based HIV/AIDS programs, appropriate to the level and type of US government support; (2) provides support and technical expertise at all stages of evaluation, including process and outcome, using quantitative, qualitative and mixed methods in global HIV/AIDS and TB programs; (3) promotes and supports agency and extramural program performance and accountability outcome measurement; (4) assists in and provides training to improve HIV/AIDS program monitoring and evaluation, including site-based service and data quality assessments, M&E systems assessment, and data visualization, analysis and use for program improvement; (5) provides support and technical expertise to US agency collaborations, in-country teams and multinational partners to monitor and evaluate the outputs, outcomes, and impact of US supported global HIV/AIDS activities; (6) develops, implements and supports innovative

analytical approaches integrating multiple sources of data and in using the results for impact monitoring, planning, and HIV/AIDS policy-making; (7) supports and strengthens global and country capacity to monitor and evaluate HIV/AIDS prevention, care, treatment programs, health system strengthening, other related global health programs, and health systems through the development of standards, guidelines, curricula, and other tools; (8) coordinates, oversees, or assists in the formulation of M&E funding/budgets and in the execution of extramural awards; and (9) collaborates with other DGHT branches, other CDC and HHS programs and offices, other USG agencies, and other national and international organizations.

James Seligman,

Acting Chief Operating Officer, Centers for Disease Control and Prevention.

[FR Doc. 2015–30968 Filed 12–8–15; 8:45 am]

BILLING CODE 4160–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Strengthening Relationship Education and Marriage Services (STREAMS) Evaluation

OMB No.: New Collection

Description: The Office of Family Assistance (OFA) within the Administration for Children and Familes (ACF) at the U.S. Department of Health and Human Services has issued grants to 46 organizations to provide healthy marriage and relationship education (HMRE) services. The Office of Planning, Research, and Evaluation (OPRE) within ACF proposes data collection activity in six HMRE grantees as part of the Strengthening Relationship Education and Marriage Services (STREAMS) evaluation. The purpose of STREAMS is to measure the effectiveness and quality of HMRE programs designed to strengthen intimate relationships. In particular, the evaluation will examine HMRE programs for youth in high school, at-risk youth, and adults. The study will fill knowledge gaps about the effectiveness of HMRE programming for youth and adults and strategies for improving program delivery and participant engagement in services. The STREAMS evaluation will include two components, an impact study and a process study.

1. Impact Study. The goal of the impact study is to provide rigorous estimates of the effectiveness of program services and interventions to improve program implementation. The impact study will use an experimental design. Eligible program applicants will be randomly assigned to either a program group that is offered program services or a control group that is not. Grantee staff will use an add-on to an existing program MIS (the nFORM system, OMB no. 0970–0460) to conduct random assignment in sites enrolling at-risk youth and adults. STREAMS will use classroom-level or school-level random assignment for programs serving youth in high school. STREAMS will collect baseline information from eligible program applicants prior to random assignment and administer a follow-up survey to all study participants 12 months after random assignment.

2. Process study. The goal of the process study is to support the interpretation of impact findings and document program operations to support future replication. STREAMS will conduct semi-structured interviews with program staff and selected community stakeholders, conduct focus groups with program participants, administer a paper-and-pencil survey to program staff, and collect data on adherence to program curricula through an add on to an existing program MIS (nForm, OMB no. 0970–0460).

This 60-Day Notice includes the following data collection activities: (1) Introductory script that program staff will use to introduce the study to participants, (2) the MIS functions for conducting random assignment, (3) a baseline survey for youth, (4) a baseline survey for adults, (5) a follow-up survey for youth, (6) a follow-up survey for adults, (7) a topic guide for semi-structured interviews with program staff and community stakeholders, (8) focus group guides for program participants, (9) a staff survey, and (10) the MIS functions for collecting data on adherence to program curricula.

Respondents: Program applicants, study participants, grantee staff, and local stakeholders (such as staff at referral agencies).

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
Impact Study, Introductory Script and Random Assignment					
1. Grantee staff	24	12	313	.08	301
2. Program applicants	7,500	3,750	1	.08	300
3. Study MIS for grantee to conduct random assignment	16	8	313	.08	200
Impact Study, Baseline Surveys					
4. Baseline Survey for Youth	3,100	1,550	1	.5	775
5. Baseline Survey for Adults	4,000	2,000	1	.5	1,000
6. Follow-up Survey for Youth	2,790	1,395	1	.5	698
7. Follow-up Survey for Adults	3,200	1,600	1	.75	1,200
Process Study					
8. Topic guide for process study staff and stakeholder interviews	150	75	1	1	75
9. Focus group guide for adults	90	45	1	1.5	68
10. Focus group guide for youth in schools	60	30	1	1.5	45
11. Focus group guide for youth out of schools	30	15	1	1.5	23
12. Staff survey	120	60	1	.5	30

ANNUAL BURDEN ESTIMATES—Continued

Instrument	Total number of respondents	Annual number of respondents	Number of responses per respondent	Average burden hours per response	Annual burden hours
13. Study MIS nFORM for grantees to report session adherence to curriculum	48	24	312	.08	599

Estimated Total Annual Burden Hours: 5,314

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments 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; (c) 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. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

ACF Certifying Officer.

[FR Doc. 2015–30994 Filed 12–8–15; 8:45 am]

BILLING CODE 4184–73–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–2881]

Standards-Based Approach to Analytical Performance Evaluation of Next Generation Sequencing in Vitro Diagnostic Tests; Public Workshop; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice of a public workshop that appeared in the **Federal Register** of September 9, 2015. In the notice of the public workshop, FDA requested comments on the workshop topics about the proposed standards-based regulatory strategy for next-generation sequencing (NGS) tests that produce results on variation in the human genome. The Agency is taking this action in response to requests to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period for the notice of the public workshop published September 9, 2015. Submit either electronic or written comments by December 24, 2015.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–N–2881 for ''Standards-Based Approach to Analytical Performance Evaluation of Next-Generation Sequencing In Vitro Diagnostic Tests.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information

redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Zivana Tezak, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm. 4544, Silver Spring, MD 20993, 301–796–6206, *zivana.tezak@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 9, 2015 (80 FR 54292), FDA published a notice of a public workshop with a deadline of November 25, 2015, to request comments on the workshop topics about the proposed standards-based regulatory strategy for NGS tests that produce results on variation in the human genome. Comments on the public meeting topics will inform FDA's development of such strategies.

FDA is reopening the comment period for the notice of the public workshop until December 24, 2015. The Agency believes that the extension allows adequate time for interested persons to submit comments without significantly delaying decisionmaking on these important issues.

Dated: December 3, 2015.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2015–30937 Filed 12–8–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–2261]

Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled ''Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings.'' FDA is issuing this guidance to describe the Agency's premarket regulatory requirements and the performance testing needed to support liquid barrier claims for gowns intended for use in health care settings. This guidance is being issued in light of the public health importance of personal protective equipment in health care settings and the recognition that terminology used to describe gowns has evolved, including by FDA, industry, the standards community, and health care professionals.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–2261 for ''Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION''. The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more

information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings '' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Elizabeth Claverie, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2508, Silver Spring, MD 20993–0002, 301–796–6298.

SUPPLEMENTARY INFORMATION:

I. Background

FDA issued a final rule on June 24, 1988 (53 FR 23856 at 23874), defining ''surgical apparel'' under 21 CFR 878.4040. Under this 1988 final rule, surgical gowns and surgical masks were classified as class II subject to premarket review under section 510(k) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act), and surgical apparel other than surgical gowns and surgical masks were classified as class I also subject to 510(k) premarket review requirements. On January 14, 2000, FDA issued a final rule (65 FR 2296 at 2318) to designate as exempt from premarket notification requirements surgical apparel other than surgical gowns and surgical masks, subject to the limitations of exemptions under 21 CFR 878.9, which includes requiring a premarket notification for devices intended for a use different from the intended use of a legally marketed device in that generic type of device.

Since the original 1988 final rule, a number of terms have been used to refer to gowns intended for use in health care settings including, but not limited to, surgical gowns, isolation gowns, surgical isolation gowns, nonsurgical gowns, cover gowns, comfort gowns, procedural gowns, and operating room gowns. The Agency has defined the term ''surgical gowns'' through existing guidance and substantial equivalence decisions to mean ''surgical apparel worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.'' In 2004, FDA recognized the consensus standard American National Standards Institute/Association of the Advancement of Medical Instrumentation (ANSI/AAMI) PB70:2003, ''Liquid barrier performance and classification of protective apparel and drapes intended for use in health care facilities.'' ANSI/AAMI PB 70 utilized new terminology for barrier performance of gowns. This terminology described and assessed the barrier protection levels of gowns and other protective apparel intended for use in health care facilities by specifying test methods and performance results necessary to verify and validate the newly defined levels of barrier protection. The definitions and terminology used in this standard are inconsistent with FDA's historical definitions of these terms and thus have added confusion in the market place. The purpose of this guidance is to clarify and describe the premarket regulatory requirements pertaining to gowns regulated under § 878.4040 and the performance testing needed to support liquid barrier claims for gowns intended for use in health care settings.

In the **Federal Register** of June 30, 2015 (80 FR 37275), FDA announced the availability of the draft of this guidance. Interested persons were invited to comment by August 31, 2015. FDA considered the public comments received and revised the guidance, where applicable. Multiple comments requested revisions to the terminology used in the guidance; however, the intent of the guidance was not to change existing terminology as used by the Agency, but rather to clarify and describe the premarket regulatory requirements concerning gowns intended for use in health care settings. While the focus of any future actions on this topic may include discussion on changing terminology, such changes would require additional regulatory action and are outside the scope of this guidance. Additionally, several comments were received regarding the Agency's expectation that submitters submit a 510(k) within 60 days if they are not currently in compliance with the expectations outlined in the guidance. We continue to believe this timeframe for submission is appropriate since submitters should already have conducted the testing to support their particular liquid barrier claims. For the comments received related to specific products, FDA is encouraging submitters to contact the review Division directly or submit a pre-submission to address these concerns as it is not appropriate to address such product-specific concerns in the guidance.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Premarket Notification Requirements Concerning Gowns Intended for Use in Health Care Settings'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500025 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 807, subparts A through D

have been approved under OMB control number 0910–0625; the collections of information in 21 CFR part 807, subpart E have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910–0485.

Dated: December 3, 2015.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2015–30972 Filed 12–8–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–3015]

Use of Databases for Establishing the Clinical Relevance of Human Genetic Variants; Public Workshop; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice of a public workshop that appeared in the **Federal Register** of September 9, 2015. In the notice of the public workshop, FDA requested comments on the workshop topics about the use of databases that contain information linking human genetic variations to disease, where such information has been curated by qualified professionals, to inform regulatory oversight of the clinical performance of genetic tests. The Agency is taking this action in response to requests to allow interested persons additional time to submit comments.

DATES: FDA is reopening the comment period for the notice of public workshop published September 9, 2015. Submit either electronic or written comments by December 24, 2015.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–N–3015 for ''Use of Databases for Establishing the Clinical Relevance of Human Genetic Variants.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: David Litwack, Center for Devices and Radiological Health, Food and Drug Administration, Bldg. 66, Rm. 4548, Silver Spring, MD 20993, 301–796–6697, *ernest.litwack@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 9, 2015 (80 FR 54290), FDA published a notice of a public workshop with a deadline of November 25, 2015, to request comments on the workshop topics about the use of databases that contain information linking human genetic variations to disease, where such information has been curated by qualified professionals, to inform regulatory oversight of the clinical performance of genetic tests. Comments on the public workshop topics will inform FDA's optimization of regulatory approaches for next-generation-based in vitro diagnostics.

FDA is reopening the comment period for the notice of the public workshop until December 24, 2015. The Agency believes that the extension allows adequate time for interested persons to submit comments without significantly delaying decision making on these important issues.

Dated: December 3, 2015.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2015–30936 Filed 12–8–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–4380]

Best Practices for Communication Between Investigational New Drug Sponsors and Food and Drug Administration During Drug Development; Draft Guidance for Industry and Review Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry and review staff entitled ''Best Practices for Communication Between IND Sponsors and FDA During Drug Development.'' The purpose of this guidance is to describe best practices and procedures for timely, transparent, and effective communications between investigational new drug application (IND) sponsors and FDA at critical junctures in drug development, which may facilitate earlier availability of safe and effective drugs to the American public.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by February 8, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

• Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

• If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

• *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

• For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2015–D–4380 for ''Best Practices for Communication Between IND Sponsors and FDA During Drug Development; Draft Guidance for Industry and Review Staff; Availability.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

• *Confidential Submissions*—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002, or Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Rachel E. Hartford, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 6312, Silver Spring, MD 20993–0002, 301–796–0319; or Stephen Ripley, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry and review staff entitled ''Best Practices for Communication Between IND Sponsors and FDA During Drug Development.'' As part of the Prescription Drug User Fee Amendments of 2012, described in ''Reauthorization Performance Goals

and Procedures; Fiscal Years 2013 through 2017,'' the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) agreed to publish a joint guidance for industry and review staff on best practices for communication between IND sponsors and FDA during drug development.

To establish the best practices described in this guidance, CDER and CBER gathered the experiences of review staff and incorporated input from interested parties who responded to a notice published in the **Federal Register** (79 FR 64397; October 29, 2014) or who provided input directly to CDER's Enhanced Communication Team.

This guidance describes FDA's philosophy regarding timely interactive communication with IND sponsors as a core activity; the scope of appropriate interactions between the review team and the sponsor; the types of advice appropriate for sponsors to seek from FDA in pursuing their drug development program; the general expectations for the timing of FDA response to IND sponsor inquiries; best practices and communication methods to facilitate interactions between the FDA review team and the IND sponsor during drug development; and expectations on appropriate methods and frequency of such communications. This guidance does not apply to communications or inquiries from industry trade organizations, consumer or patient advocacy organizations, other government agencies, or other stakeholders not pursuing a development program under an IND.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on best practices for communication between IND sponsors and FDA during drug development. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR parts 312 and 314 have been approved under OMB control numbers 0910–0014 and 0910–0001, respectively.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm,* or *http://www.regulations.gov.*

Dated: December 3, 2015.

Peter Lurie,

Associate Commissioner for Public Health Strategy and Analysis.

[FR Doc. 2015–30931 Filed 12–8–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–N–0001]

Psychopharmacologic Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Psychopharmacologic Drugs Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on January 12, 2016, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.*

Contact Person: Jennifer Shepherd, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, Rm. 2417, Silver Spring, MD 20993–0002, 301–796–9001, FAX: 301–847–8533, *PDAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss new drug application (NDA) 204442, PROBUPHINE (buprenorphine hydrochloride and ethylene vinyl acetate) subdermal implant, submitted by Braeburn Pharmaceuticals, Inc., on behalf of Titan Pharmaceuticals for the proposed indication of maintenance treatment of opioid dependence.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm.* Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before December 28, 2015. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before December 17, 2015. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by December 18, 2015.

Persons attending FDA's advisory committee meetings are advised that the

Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Jennifer Shepherd at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: *December 3, 2015.*

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2015–30970 Filed 12–8–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Pandemic Influenza Medical Countermeasures—Amendment

ACTION: Notice of Amendment to the October 17, 2008, Declaration under the Public Readiness and Emergency Preparedness Act, as amended June 11, 2009; the December 22, 2008, Declaration under the Public Readiness and Emergency Preparedness Act, and the February 29, 2012, Declaration under the Public Readiness and Emergency Preparedness Act.

SUMMARY: The Secretary is amending the declarations issued on October 10, 2008 (73 FR 61861), as amended June 11, 2009 (74 FR 29213); December 17, 2008 (73 FR 78362); and February 29, 2012 (77 FR 13329), pursuant to section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d) to: Cover vaccines, antivirals, diagnostics and devices used against pandemic influenza A viruses in a single declaration; extend coverage to additional antivirals and devices and to biologics and other drugs; simplify descriptions of covered diagnostics and devices; clarify the disease threat and description of pandemic influenza A viruses and influenza A viruses with pandemic potential; include coverage for countermeasures authorized for use under sections 564A and 564B of the Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. 360bbb–3a and 360bbb–3b); extend the effective time period of the prior declarations; reformat the declarations for antivirals and for diagnostics and devices; modify or clarify terms of the declarations; and republish the prior declarations as a single declaration in its entirety, as amended.

DATES: The amendment of the October 10, 2008, declaration as amended June 11, 2009, the December 17, 2008, declaration and February 29, 2012, declaration is effective as of January 1, 2016.

FOR FURTHER INFORMATION CONTACT: Nicole Lurie, MD, MSPH, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW., Washington, DC 20201; Telephone 202–205–2882.

SUPPLEMENTARY INFORMATION:

Background

The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the administration or use of medical countermeasures (Covered Countermeasures), except for claims that meet the PREP Act's definition of willful misconduct. The Secretary may, though publication in the **Federal Register**, amend any portion of a declaration. Using this authority, the Secretary issued several declarations for countermeasures against pandemic influenza: (1) An October 10, 2008, declaration covering the neuraminidase class of antivirals Oseltamivir Phosphate (*e.g.,* Tamiflu) and Zanamivir (*e.g.* Relenza) (hereinafter, ''antivirals declaration''); (2) a December 17, 2008, declaration covering pandemic influenza diagnostics, personal respiratory protection devices, and respiratory support devices (hereinafter ''diagnostics and other devices declaration''); and a February 29, 2012, amended declaration covering pandemic influenza vaccines (hereinafter, ''vaccines declaration'') and is amending these declarations.[1]

The major actions taken by this amendment to the pandemic influenza countermeasures declarations include the following: (1) Issuing a single declaration to cover vaccines, antivirals, diagnostics and other devices used against pandemic influenza A viruses; (2) extending coverage to additional antivirals and devices and to biologics and other drugs; (3) updating the description of Covered Countermeasures to include those authorized for use under sections 564A and 564B of the Federal Food, Drug, and Cosmetic (FD&C) Act;[2] (4) clarifying the disease threat and the description of pandemic influenza A viruses and influenza A viruses with pandemic potential; (5) changing the description of qualified persons to include persons authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act; (6) clarifying that liability immunity for antivirals, diagnostics and other devices extends to other transactions and to activities related to any federal agreements including clinical trials agreements by adding the terms ''other transactions'' and ''other federal agreements'' to the clause describing the types of federal agreements for which immunity is in effect; (7) deleting references to specific federal contracts in the antivirals declaration to clarify that immunity is not limited to activities conducted under listed contracts; (8) clarifying that liability immunity extends to activities directly conducted by the federal government by adding the phrase ''or directly conducted by the federal Government'' to the section describing methods of distribution for which liability immunity is in effect; (9) narrowing the definition of ''administration'' in the antivirals declaration and in the diagnostics and other devices declaration to cover ''slip-and-fall'' claims only to the extent they are directly tied to the operation of a countermeasure program; (10) extending the time period for which liability immunity is in effect for all of the Covered Countermeasures to December 31, 2022, and; (11) changing the antivirals declaration and the diagnostics and other devices declaration to the format used for the February 29, 2012, amendment to the declaration for pandemic influenza. Other minor modifications and clarifications are also made, as more fully explained below.

The vaccines, antivirals, and diagnostics and other devices declarations are republished as a single pandemic influenza countermeasures declaration (hereinafter, ''declaration'') in full. We explain the substantive and format changes in this supplementary section.

[1] 73 FR 61861, 73 FR 78362, 74 FR 29213, 77 FR 13329.

[2] 21 U.S.C. 360bbb–3a and 360bbb–3b.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, Section 2. It amended the Public Health Service (PHS) Act, adding section 319F–3, which addresses liability immunity, and section 319F–4, which creates a compensation program. These sections are codified in the U.S. Code as 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively.

The Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, was enacted on March 13, 2013. Among other things, PAHPRA added sections 564A and 564B to the FD&C Act to provide new authorities for emergency use of approved products in emergencies and products held for emergency use. PAHPRA accordingly amended the definitions of ''Covered Countermeasures'' and ''qualified pandemic and epidemic products'' in section 319F–3 of the Public Health Service Act (the PREP Act provisions), so that products made available under these new FD&C Act authorities could be covered under PREP Act declarations. PAHPRA extended the definition of qualified pandemic and epidemic products to include products or technologies intended to enhance the use or effect of a drug, biological product, or device used against the pandemic or epidemic or against adverse events from these products.

Unless otherwise noted, all statutory citations below are to the U.S. Code.

Section I, Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

Before issuing a declaration under the PREP Act, the Secretary is required to determine that a disease or other health condition, or threat to health constitutes a public health emergency, or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency.[3] This determination is separate and apart from a declaration issued by the Secretary under section 319 of the PHS Act [4] that a disease or disorder presents a public health emergency or that a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists, or other declarations or determinations made under other authorities of the Secretary. In the previous PREP Act declarations for antivirals and for diagnostics and other devices, this determination appeared in the declarations' introduction as the conclusion to the ''whereas'' clauses. In the vaccines declaration, this determination appeared in section I. This change to the antivirals and the diagnostics and other devices declarations was made to improve readability and is not intended to have any substantive legal effect.

In addition, a substantive change was made to the determination. The determination made in the ''whereas'' clauses in the antivirals declaration and the determination made in the diagnostics and other devices declaration stated that the Secretary ''determined there is a credible risk that the spread of avian and other influenza viruses that pose a pandemic threat and resulting disease could in the future constitute a public health emergency.'' The antivirals declaration also determined that ''the spread of H1N1 swine influenza viruses and resulting disease constitutes a public health emergency.'' The Secretary is amending these determinations to refer to ''influenza A viruses'' rather than ''avian influenza viruses'' to make the determinations in the antivirals declaration and the diagnostics and other devices declaration consistent with the determination made in the more recent vaccines declaration and to ensure that the health threat is described comprehensively. The declaration now reads: ''I have determined that there is a credible risk that pandemic influenza A viruses, and influenza A viruses with pandemic potential could cause an influenza pandemic with resulting disease that may in the future constitute a public health emergency.'' This change is made for clarification and consistency.

Section II, Factors Considered

In deciding whether and under what circumstances to issue a declaration with respect to a Covered Countermeasure, the Secretary must consider the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the countermeasure.[5] We stated these considerations in the introductory ''whereas'' clauses to the antivirals declaration, the diagnostics and other devices declaration, and in section II of the vaccines declaration. This change was made to the antivirals declaration and the diagnostics and other devices declaration to improve readability; it is not intended to have any substantive legal effect.

Section III, Recommended Activities

The Secretary must recommend the activities for which the PREP Act's liability immunity is in effect. These activities may include, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more Covered Countermeasures (''Recommended Activities'').[6] In the previous antivirals declaration and devices and other diagnostics declaration, we included the Recommended Activities in section I of the Covered Countermeasures declaration. In the vaccines declaration, Recommended Activities appeared in section III. This change was made to the antivirals and diagnostics and other devices declarations to improve readability and we do not intend that it have any substantive legal effect. In addition, we deleted the phrases ''as defined in section IX below'' and ''with respect to the category of disease and population described in sections II and IV below'' from these declarations for consistency with formatting changes, and changed ''and usage'' to ''or use'' for consistency with the statute. These changes are not intended to have any substantive legal effect. We also deleted specific references to the influenza antiviral drugs Oseltamivir Phosphate (Tamiflu) and Zanamivir (Relenza) from the antivirals declaration. This change could expand coverage if new antivirals, other drugs, or biologics against pandemic influenza are developed; to the extent coverage is consistent with the statute and the terms of this declaration.

Section IV, Liability Immunity

The Secretary must also state that liability protections available under the PREP Act are in effect with respect to the Recommended Activities.[7] These liability protections provide that, ''[s]ubject to other provisions of [the PREP Act], a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered countermeasure if a declaration . . . has been issued with respect to such countermeasure.'' [8] In the previous antivirals declaration and diagnostics and other devices declaration, we included a statement

[3] 42 U.S.C. 247d–6d(b)(1).

[4] 42 U.S.C. 247d.

[5] 42 U.S.C. 247d–6d(b)(6).

[6] 42 U.S.C. 247d–6d(b)(1).

[7] 42 U.S.C. 247d–6d(b)(1).

[8] 42 U.S.C. 247d–6d(a)(1).

referring to liability immunity specified under the PREP Act in section I of the declaration, ''Covered Countermeasures.'' The vaccines declaration included a statement regarding liability in section IV. The declaration includes the statement that liability immunity is in effect for Recommended Activities in a separate section IV. This change was made to the antivirals and diagnostics and other devices declarations to improve readability and we do not intend that it have any substantive legal effect.

Section V, Covered Persons

The PREP Act's liability immunity applies to Covered Persons with respect to administration or use of a Covered Countermeasure. ''Covered Persons'' has a specific meaning, and is defined in the PREP Act to include manufacturers, distributors, program planners, and qualified persons, and their officials, agents, and employees, and the United States.[9] The PREP Act further defines the terms ''manufacturer,'' ''distributor,'' ''program planner,'' and ''qualified person'' as described below.[10]

A *manufacturer* includes a contractor or subcontractor of a manufacturer; a supplier or licenser of any product, intellectual property, service, research tool or component or other article used in the design, development, clinical testing, investigation or manufacturing of a Covered Countermeasure; and any or all of the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer.[11]

A *distributor* means a person or entity engaged in the distribution of drug, biologics, or devices, including but not limited to: Manufacturers; repackers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; warehouses and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies.[12]

A *program planner* means a state or local government, including an Indian tribe; a person employed by the state or local government; or other person who supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a Covered Countermeasure, including a person who establishes requirements, provides policy guidance, or supplies technical or scientific advice or assistance or provides a facility to administer or use a Covered Countermeasure in accordance with the Secretary's declaration.[13] Under this definition, a private sector employer or community group or other person can be a program planner when it carries out the described activities.

A *qualified person* means a licensed health professional or other individual authorized to prescribe, administer, or dispense Covered Countermeasures under the law of the state in which the countermeasure was prescribed, administered, or dispensed; or a person within a category of persons identified as qualified in the Secretary's declaration.[14] Under this definition, the Secretary can describe in the declaration other qualified persons, such as volunteers, who are Covered Persons. Section V describes other qualified persons covered by this declaration.

The PREP Act defines the word ''person'' as used in the Act: A *person* includes an individual, partnership, corporation, association, entity, or public or private corporation, including a federal, state, or local government agency or department.[15]

The provisions regarding Covered Persons appeared in the antivirals declaration and diagnostics and other devices declaration as a definition in section IX, ''Definitions'' and in section VI, ''Qualified Persons.'' We combined these two provisions into a section V, ''Covered Persons'' and added ''to perform an activity'' to the description of ''Other Qualified Persons'' authorized under an Emergency Use Authorization for clarity. We made these changes to improve readability and clarity and do not intend them to have any substantive legal effect. The vaccine declaration included a description of Covered Persons in section V.

We also modified the description of Covered Persons in the antivirals declaration, the diagnostics and other devices declaration, and the vaccines declaration to include a new category of qualified persons in this declaration: ''Any person authorized to prescribe, administer, or dispense covered countermeasures in accordance with Section 564A of the FD&C Act.'' This change ensures that persons who prescribe, administer, or dispense Covered Countermeasures in accordance with section 564A of the FD&C Act are Covered Persons under the declaration.

Section VI, Covered Countermeasures

As noted above, section III describes the Secretary's Recommended Activities for which liability immunity is in effect. This section identifies the countermeasures for which the Secretary has recommended such activities. The PREP Act states that a Covered Countermeasure must be: A ''qualified pandemic or epidemic product,'' or a ''security countermeasure,'' as described immediately below; or a drug, biological product or device authorized for emergency use in accordance with section 564, 564A, or 564B of the FD&C Act.[16]

A *qualified pandemic or epidemic product* means a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act[17] that is: (i) Manufactured, used, designed, developed, modified, licensed or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm such a pandemic or epidemic might otherwise cause; (ii) manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by such a drug, biological product or device; (iii) or a product or technology intended to enhance the use or effect of such a drug, biological product, or device.[18]

A *security countermeasure* is a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act[19] that: (i) (a) The Secretary determines to be a priority to diagnose, mitigate, prevent or treat harm from any biological, chemical, radiological, or nuclear agent identified as a material threat by the Secretary of Homeland Security, or (b) to diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent; and (ii) is determined by the Secretary of Health and Human Services to be a necessary countermeasure to protect public health.[20]

To be a Covered Countermeasure, qualified pandemic or epidemic products and security countermeasures must be approved or cleared under the FD&C Act;[21] licensed under the PHS Act;[22] or authorized for emergency use

[9] 42 U.S.C. 247d–6d(i)(2).

[10] 42 U.S.C. 247d–6d(i).

[11] 42 U.S.C. 247d–6d(i)(4).

[12] 42 U.S.C. 247d–6d(i)(3).

[13] 42 U.S.C. 247d–6d(i)(6).

[14] 42 U.S.C. 247d–6d(i)(8).

[15] 42 U.S.C. 247d–6d(i)(5).

[16] 42 U.S.C. 247d–6d(i)(1). Sections 564, 564A, and 564B of the FD&C Act may be found at 21 U.S.C. 360bbb–3, 360bbb–3a, and 360bbb–3b.

[17] 21 U.S.C. 321(g)(1), (h); 42 U.S.C. 262(i).

[18] 42 U.S.C. 247d–6d(i)(1)(A), (i)(7).

[19] 21 U.S.C. 321(g)(1), (h); 42 U.S.C. 262(i).

[20] 42 U.S.C. 247d–6d(i)(1)(B),(c)(1)(B).

[21] 21 U.S.C. 301 *et seq.*

[22] 42 U.S.C. 262.

under sections 564, 564A, or 564B of the FD&C Act.[23]

A qualified pandemic or epidemic product may be a Covered Countermeasure when it is subject to an exemption (that is, it is permitted to be used under an Investigational Drug Application or an Investigational Device Exemption) under the FD&C Act [24] and is the object of research for possible use for diagnosis, mitigation, prevention, treatment, cure or limit harm of a pandemic or epidemic or serious or life-threatening condition caused by such a drug or device. A security countermeasure also may be a Covered Countermeasure if it may reasonably be determined to qualify for approval or licensing within 10 years after the Department's determination that procurement of the countermeasure is appropriate.

Provisions regarding Covered Countermeasures appeared in section I of the antivirals declaration and the diagnostics and other devices declaration, ''Covered Countermeasures'' and section IX of these declarations, ''Definitions.'' Section I of these declarations included a description of the Covered Countermeasure and the Secretary's recommendation, statement regarding liability immunity, and additional conditions characterizing countermeasures. We have combined sections I and IX and simplified the language so that it now only identifies the Covered Countermeasures. We have relocated the other conditions previously included in the ''Covered Countermeasure'' section to new sections, ''Recommended Activities,'' ''Liability Immunity,'' and ''Limitations on Distribution,'' to improve readability and for consistency with the vaccines declaration. We do not intend for this change to have any substantive legal effect.

Section I of the antivirals declaration and the diagnostics and other devices declaration also stated that the declarations applied to Covered Countermeasures administered or used during the effective time period of the declaration. We have deleted this language as it is redundant of the provisions stated in sections XII, ''Effective Time Period,'' and XIII, ''Additional Time Period of Coverage.''

We have also revised the descriptions and definitions of the Covered Countermeasure that previously appeared in section IX, ''Definitions'' of the antivirals and the diagnostics and other devices declarations.

Section IX of the antivirals declaration defined the term ''Pandemic Countermeasures'' as: ''the neuraminidase class of Antivirals Oseltamivir Phosphate (*e.g.,* Tamiflu) and Zanamivir (*e.g.,* Relenza).'' The declaration now refers to ''any antiviral, any other drug'' and ''any biologic.'' This substantive change is made for consistency with other PREP Act declarations and to extend coverage to antiviral drugs, other drugs, and biologics that may be developed for use against pandemic influenza, to the extent coverage is consistent with the statute and terms of this declaration.

Section IX of the diagnostics and other devices declaration included the following definitions:

> ''Pandemic Influenza Diagnostics: Means diagnostics to identify avian or other animal influenza A viruses that pose a pandemic threat, or to otherwise aid in the diagnosis of pandemic influenza, when (1) Licensed under section 351 of the Public Health Service Act; (2) approved under section 505 or section 515 of the Federal Food, Drug, and Cosmetic Act (FDCA); (3) cleared under section 510(k) of the FDCA; (4) authorized for emergency use under section 564 of the FDCA; (5) used under section 505(i) of the FDCA or section 351(a)(3) of the PHS Act, and 21 CFR part 312; or (6) used under section 520(g) of the FDCA and 21 CFR part 812.''
>
> ''Pandemic Influenza Personal Respiratory Protection Devices: Means personal respiratory protection devices for use by the general public to reduce wearer exposure to pathogenic biological airborne particulates during public health medical emergencies, such as an influenza pandemic, when (1) Licensed under section 351 of the Public Health Service Act; (2) approved under section 505 or section 515 of the Federal Food, Drug, and Cosmetic Act (FDCA); (3) cleared under section 510(k) of the FDCA; (4) authorized for emergency use under section 564 of the FDCA; (5) used under section 505(i) of the FDCA or section 351(a)(3) of the PHS Act, and 21 CFR part 312; or (6) used under section 520(g) of the FDCA and 21 CFR part 812.''
>
> ''Pandemic Influenza Respiratory Support Devices: Means devices to support respiratory function for patients infected with highly pathogenic influenza A H5N1 viruses or other influenza viruses that pose a pandemic threat when (1) Licensed under section 351 of the Public Health Service Act; (2) approved under section 505 or section 515 of the Federal Food, Drug, and Cosmetic Act (FDCA); (3) cleared under section 510(k) of the FDCA; (4) authorized for emergency use under section 564 of the FDCA; (5) used under section 505(i) of the FDCA or section 351(a)(3) of the PHS Act, and 21 CFR part 312; or (6) used under section 520(g) of the FDCA and 21 CFR part 812.

The declaration now refers to ''any diagnostic and any other device.'' This change is intended to extend coverage to any diagnostic or other device used as Covered Countermeasures against pandemic influenza to the extent consistent with the statute and the terms of the declaration.

The vaccines declaration included the following description of Covered Countermeasures in section VI:

> Covered Countermeasures are vaccines against pandemic influenza A viruses and influenza A viruses with pandemic potential, all components and constituent materials of these vaccines, and all devices and their constituent components used in the administration of these vaccines, except that influenza A vaccines and their associated components, constituent materials and devices covered under the National Vaccine Injury Compensation Program are not Covered Countermeasures.

This description of vaccines is unchanged but has been combined with the description of antivirals and other drugs, biologics, and diagnostics and other devices into a single description.

The description of covered countermeasures in this declaration now reads:

> Covered countermeasures are any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine used against pandemic influenza A viruses and influenza A viruses with pandemic potential, all components and constituent materials of vaccines, and all devices and their constitution components used in the administration of vaccines, except that vaccines against influenza A and their associated components, constitute materials and devices covered under the National Vaccine Injury Compensation Program are not Covered Countermeasures.

Section I of the antivirals and diagnostics and other devices declarations also referred to the Act for the definition of ''Covered Countermeasures.'' We include a statement in the declaration referencing the statutory definitions of Covered Countermeasures to make clear that these statutory definitions limit the scope of Covered Countermeasures. Specifically, we note that they ''must be ''qualified pandemic or epidemic products,'' or ''security countermeasures,'' or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.'' By referencing the statutory provisions, the revised definition also incorporates changes to the PREP Act definitions of Covered Countermeasure and qualified pandemic or epidemic product made by PAHPRA.

Section VII, Limitations on Distribution

The Secretary may specify that liability immunity is in effect only to

[23] 21 U.S.C. 360bbb–3, 360bbb–3a, 360bbb–3b.

[24] 21 U.S.C. 355(i), 360j(g).

Covered Countermeasures obtained through a particular means of distribution.[25] These limitations on distribution previously appeared in section I, ''Covered Countermeasures,'' and section IX, ''Definitions'' of the antivirals and diagnostics and other devices declaration, and in section VII of the vaccines declaration. This declaration states the limitations in a separate section and combines them with relevant definitions for improved readability.

The declaration states that liability immunity is afforded to Covered Persons for Recommended Activities related to:

(a) Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, or memoranda of understanding or other federal agreements or activities directly conducted by the federal government; or

(b) Activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a declaration of an emergency.

For governmental program planners only, liability immunity is afforded only to the extent they obtain Covered Countermeasures through voluntary means, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from state, local, or private stockpiles.

In regard to (a), we added to the antivirals declaration and the diagnostics and other devices declaration the phrase ''other transactions,'' which may be used for some Covered Countermeasure activities,[26] and added the phrase ''or other Federal agreements'' to clarify that the provision is intended to cover all types of federal agreements. We also added to the antivirals declaration, the diagnostics and other devices declaration, and the vaccines declaration the phrase ''or activities directly conducted by the Federal Government'' to clarify that activities such as manufacture of vaccines for clinical trials by the HHS National Institutes of Health Vaccine Research Center or distribution of countermeasures by federal employees are covered. In the antivirals and diagnostics and other devices declarations, we also changed the conjunction ''and'' to ''or'' between (a) and (b) to clarify that immunity is available under either of these circumstances; the activities do not have to both relate to a federal award or agreement and be used in a public health and medical response in order for immunity to apply. The conjunction ''and'' used in the previous declaration was a drafting error; the Secretary's intent in that previous declarations has been the meaning conferred by the term ''or.'' Provisions (a) and (b) are intended to afford immunity to federal government conducted and supported activities that precede a public health emergency and to activities in accordance with all Authorities Having Jurisdiction during a declared public health emergency. These changes are intended as clarifications and to improve readability, and are not intended as substantive changes.

In regard to (b), the meaning of the terms ''Authority Having Jurisdiction'' and ''Declaration of an Emergency'' are unchanged.

Finally, we slightly modified the last limitation in the antivirals declaration and the diagnostics and other devices declaration by deleting extraneous statutory references and other language and by replacing the final sentence with the word ''only'' after ''planners'' to improve readability. We do not intend for the changes to this provision to alter its substantive legal effect. As stated in the ''whereas'' clauses of the prior declarations, this limitation on distribution is intended to deter program planners that are government entities from seizing privately held stockpiles of Covered Countermeasures. It does not apply to any other Covered Persons, including other program planners who are not government entities.

Section VIII, Category of Disease, Health Condition, or Threat

The Secretary must identify for each Covered Countermeasure the categories of diseases, health conditions, or threats to health for which the Secretary recommends the administration or use of the countermeasure.[27] This information appeared in section II, ''Category of Disease'' of the antivirals and diagnostics and other devices declarations, and in section VIII of the vaccines declaration.

In addition, we have made the following substantive changes. The antivirals declaration described the category of disease as ''the threat of or actual human influenza that results from the infection of humans with highly pathogenic avian H5N1 influenza A viruses or other animal Influenza A viruses (including, but not limited to, H1N1 swine influenza) that are, or may be capable of developing into, a pandemic strain.'' The diagnostics and other devices declaration described the threat as: ''The threat of or actual human influenza that results from the infection of humans with highly pathogenic avian H5N1 influenza A viruses or other animal influenza A viruses that are, or maybe capable of developing into, a pandemic strain.'' These descriptions have been modified to delete references to specific viral strains and to animal influenza viruses, to instead refer to ''pandemic influenza A viruses and influenza A viruses with pandemic potential.'' This change is made to the antivirals and diagnostics and other devices declarations to ensure that the category of disease is described comprehensively and for consistency with the vaccines declaration.

We have also revised the description of pandemic influenza A viruses and influenza A viruses with pandemic potential that appeared in the vaccines declaration to clarify that viruses circulating in humans are included in the definition, and added the revised definition to the antivirals and diagnostics and other devices declarations: Pandemic influenza A viruses and influenza A viruses with pandemic potential mean: Animal viruses and/or human influenza A viruses that are circulating in wild birds, domestic animals and/or humans that cause or have significant potential to cause sporadic or ongoing human infections, or historically have caused pandemics in humans, or have mutated to cause pandemics in humans, and for which the majority of the population is immunologically naive.

Section IX, Administration of Covered Countermeasures

The PREP Act does not explicitly define the term ''administration'' but does assign the Secretary the responsibility to provide relevant conditions in the declaration. This definition previously appeared in section IX, ''Definitions'' of the antivirals declaration and diagnostics and other devices declaration. We have moved it to a separate section to improve readability. The Secretary has also narrowed the definition of ''administration'' that was provided in these declarations. These declarations previously defined ''administration'' to include physical provision of a Covered Countermeasure, as well as management and operation of systems and locations

[25] 42 U.S.C. 247d–6d(a)(5), (b)(2)(E).

[26] See, *e.g.,* 42 U.S.C. 247d–7d(c)(5).

[27] 42 U.S.C. 247d–6d(b)(2)(A).

at which Covered Countermeasures may be provided to recipients:

Administration of a Covered Countermeasure: As used in section 319F–3(a)(2)(B) of the Act includes, but is not limited to, public and private delivery, distribution, and dispensing activities relating to physical administration of the countermeasures to patients/recipients, management and operation of delivery systems, and management and operation of distribution and dispensing locations.

The definition has been revised for the antivirals declaration and the diagnostics and other devices declaration as follows:

Administration of a Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients; management and operation of countermeasure programs; or management and operation of locations for purpose of distributing and dispensing countermeasures.

As clarified in the antivirals declaration and the diagnostics and other devices declaration, the definition of ''administration'' extends only to physical provision of a countermeasure to a recipient, such as vaccination or handing drugs to patients, and to activities related to management and operation of programs and locations for providing countermeasures to recipients, such as decisions and actions involving security and queuing, but only insofar as those activities directly relate to the countermeasure activities. Claims for which Covered Persons are provided immunity under the Act are losses caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a Covered Countermeasure consistent with the terms of a declaration issued under the Act.[28] Under the Secretary's definition, these liability claims are precluded if the claims allege an injury caused by physical provision of a countermeasure to a recipient, or if the claims are directly due to conditions of delivery, distribution, dispensing, or management and operation of countermeasure programs at distribution and dispensing sites.

Thus, it is the Secretary's interpretation that, when a declaration is in effect, the Act precludes, for example, liability claims alleging negligence by a manufacturer in creating a vaccine, or negligence by a health care provider in prescribing the wrong dose, absent willful misconduct. Likewise, the Act precludes a liability claim relating to the management and operation of a countermeasure distribution program or site, such as a slip-and–fall injury or vehicle collision by a recipient receiving a countermeasure at a retail store serving as an administration or dispensing location that alleges, for example, lax security or chaotic crowd control. However, a liability claim alleging an injury occurring at the site that was not directly related to the countermeasure activities is not covered, such as a slip-and–fall with no direct connection to the countermeasure's administration or use. In each case, whether immunity is applicable will depend on the facts and circumstances.

Section X, Population

The Secretary must identify, for each Covered Countermeasure specified in a declaration, the population or populations of individuals for which liability immunity is in effect with respect to administration or use of the countermeasure.[29] This section explains which individuals should use the countermeasure or to whom the countermeasure should be administered—in short, those who should be vaccinated or take a drug or other countermeasure. These provisions previously appeared in section IV, ''Population,'' of the antivirals declaration and the diagnostics and other devices declaration and section X of the vaccines declaration. The antivirals declaration and diagnostics and other devices declaration stated that the population specified in the declaration included:

The populations specified in this declaration are all persons who use a Covered Countermeasure or to whom a Covered Countermeasure is administered in accordance with this declaration, including, but not limited to: (1) Any person conducting research and development of Covered Countermeasures directly for the federal government or pursuant to a contract, grant, or cooperative agreement with the federal government; (2) Any person who receives a Covered Countermeasure from persons authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasure, and their officials, agents, employees, contractors, and volunteers following a declaration of an emergency; (3) Any person who receives a Covered Countermeasure from a person authorized to prescribe, administer or dispense the countermeasure or who is otherwise authorized under an Emergency Use Authorization; (4) Any person who receives a Covered Countermeasure as an investigational new drug in human clinical trials being conducted directly by the federal government or pursuant to a contract, grant, or cooperative agreement with the federal government.

We have amended the antivirals declaration and the diagnostics and other devices declaration to provide that the population includes ''any individual who uses or who is administered a Covered Countermeasure in accordance with the declaration.'' We believe this broad statement encompasses all of the previously listed populations given as examples of that phrase and ensures that no populations that use or are administered the Covered Countermeasures in accordance with the terms of the declaration are omitted.

In addition, the PREP Act specifies that liability immunity is afforded: (1) To manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; and (2) to program planners and qualified persons when the countermeasure is either used by or administered to this population or the program planner or qualified person reasonably could have believed the recipient was in this population.[30] We included these statutory conditions in the declaration for clarity.

Section XI, Geographic Area

The Secretary must identify, for each Covered Countermeasure specified in the declaration, the geographic area or areas for which liability immunity is in effect with respect to administration or use of the countermeasure, including, as appropriate, whether the declaration applies only to individuals physically present in the area or, in addition, applies to individuals who have a described connection to the area.[31] This section previously appeared in section V, ''Geographic Area'' of the antivirals declaration and diagnostics and other devices declaration, and section XI of the vaccines declaration.

In addition, the PREP Act specifies that liability immunity is afforded: (1) To manufacturers and distributors without regard to whether the countermeasure is used by or administered to individuals in the geographic areas; and (2) to program

[28] 42 U.S.C. 247d–6d(a).

[29] 42 U.S.C. 247d–6d(b)(2)(C).

[30] 42 U.S.C. 247d–6d(a)(4).

[31] 42 U.S.C. 247d–6d(b)(2)(D).

planners and qualified persons when the countermeasure is either used or administered in the geographic areas or the program planner or qualified person reasonably could have believed the countermeasure was used or administered in the areas.[32] We included these statutory conditions in the declaration for clarity.

Section XII, Effective Time Period

The Secretary must identify, for each Covered Countermeasure, the period or periods during which liability immunity is in effect, designated by dates, milestones, or other description of events, including factors specified in the PREP Act.[33] This section appeared in the antivirals declaration and the diagnostics and other devices declaration as section III, ''Effective Time Period'' and in the vaccines declaration in section XII.

The declaration is amended to clarify when liability takes effect for different means of distribution. These changes are intended to have no legal effect. The declaration is also amended to extend the period for which liability immunity is in effect. The previous declaration was in effect through December 31, 2015. We have extended the effective time period to December 31, 2022.

Section XIII, Additional Time Period of Coverage

The Secretary must specify a date after the ending date of the effective period of the declaration that is reasonable for manufacturers to arrange for disposition of the Covered Countermeasure, including return of the product to the manufacturer, and for other Covered Persons to take appropriate actions to limit administration or use of the Covered Countermeasure.[34] In addition, the PREP Act specifies that for Covered Countermeasures that are subject to a declaration at the time they are obtained for the Strategic National Stockpile under 42 U.S.C. 247d–6b(a), the effective period of the declaration extends through the time the countermeasure is used or administered pursuant to a distribution or release from the Stockpile. Liability immunity under the provisions of the PREP Act and the conditions of the declaration continues during these additional time periods. Thus, liability immunity is afforded during the ''Effective Time Period,'' described under XII of the declaration, plus the ''Additional Time Period'' described under section XIII of the declaration.

The provision for additional time periods appeared as section VII, ''Additional Time Periods of Coverage After Expiration of the Declaration'' in the antivirals declaration and the diagnostics and other devices declaration, and in section XIII of the vaccines declaration. The provision is amended in the antivirals declaration and the diagnostics and other devices declaration to clarify the statutory provisions as they apply to manufacturers and to other covered persons, and to clarify that extended coverage applies to any products obtained for the Strategic National Stockpile during the effective period of the declaration. We included the statutory provision for clarity.

Section XIV, Countermeasures Injury Compensation Program

Section 319F–4 of the PREP Act authorizes a Countermeasures Injury Compensation Program (CICP) to provide benefits to eligible individuals who sustain a serious physical injury or die as a direct result of the administration or use of a Covered Countermeasure.[35] Compensation under the CICP for an injury directly caused by a Covered Countermeasure is based on the requirements set forth in this declaration, the administrative rules for the Program,[36] and the statute.[37] To show direct causation between a Covered Countermeasure and a serious physical injury, the statute requires ''compelling, reliable, valid, medical and scientific evidence.'' [38] The administrative rules for the Program further explain the necessary requirements for eligibility under the CICP. Please note that, by statute, requirements for compensation under the CICP may not always align with the requirements for liability immunity provided under the PREP Act. We have added section XIV, ''Countermeasures Injury Compensation Program'' to the antivirals and diagnostics and other devices declarations to explain the types of injury and standard of evidence needed to be considered for compensation under the CICP. We included this information to inform readers of this Program.

Section XV, Amendments

The Secretary may amend any portion of a declaration through publication in the **Federal Register**.[39] This section appeared in section VIII, ''Amendments'' of the antivirals declaration and the diagnostics and other devices declaration, and section XV of the vaccines declaration. The section has been updated to reflect that the Republished Declaration amends the prior October 10, 2008 (as amended June 11, 2009), December 17, 2008, and February 29, 2012 declarations.

Deleted Sections

The prior antivirals declaration and diagnostics and other devices declaration included a number of ''whereas'' clauses as introductory to the declaration. As described above, we have incorporated whereas clauses that made necessary findings under the PREP Act into the text of the declaration itself. We have deleted the remaining whereas clauses. We do not intend this change to have legal effect.

The prior antivirals declaration and diagnostics and other devices declaration contained a definitions section. These definitions have been incorporated into the relevant sections of the declaration as noted above, and modified or deleted where indicated above.

An appendix previously appeared in the antivirals declaration that listed federal government contracts for research, development, and procurement of Covered Countermeasures. We deleted this appendix to clarify that liability immunity under the provisions of the PREP Act and terms of the declaration is not limited to the contracts listed in the appendix. Coverage is available for any award or agreement that meets the description provided in section VII of the declaration. In addition, deleting the appendix relieves the Department of the need to periodically update the appendix.

We made these deletions for clarity and do not intend them to have legal effect.

Republished Declaration

Declaration, as Amended, for Public Readiness and Emergency Preparedness Act Coverage for Pandemic Influenza Countermeasures

This declaration amends the October 17, 2008, Declaration under the Public Readiness and Emergency Preparedness Act, as amended on June 11, 2009; the December 22, 2008, Declaration under the Public Readiness and Emergency Preparedness Act; and the February 29, 2012, Declaration under the Public Readiness and Emergency Preparedness

[32] 42 U.S.C. 247d–6d(a)(4).

[33] 42 U.S.C. 246d–6d(b)(2)(B), (b)(6).

[34] 42 U.S.C. 247d–6d(b)(3).

[35] 42 U.S.C. 247d-6e.

[36] 42 CFR part 110.

[37] 42 U.S.C.247d–6e.

[38] 42 U.S.C.247d–6e(b)(4).

[39] 42 U.S.C. 247d–6d(b)(4).

Act. It republishes these prior declarations as a single declaration. To the extent any term of the prior declarations are inconsistent with any provision of this Republished Declaration, the terms of this Republished Declaration are controlling.

I. Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

42 U.S.C. 247d–6d(b)(1)

I have determined there is a credible risk that pandemic influenza A viruses and influenza A viruses with pandemic potential could cause an influenza pandemic with resulting disease that may constitute a public health emergency.

II. Factors Considered

42 U.S.C. 247d–6d(b)(6)

I have considered the desirability of encouraging the design, development, clinical testing, or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the Covered Countermeasures.

III. Recommended Activities

42 U.S.C. 247d–6d(b)(1)

I recommend, under the conditions stated in this declaration, the manufacture, testing, development, distribution, administration, or use of the Covered Countermeasures.

IV. Liability Immunity

42 U.S.C. 247d–6d(a), 247d–6d(b)(1)

Liability immunity as prescribed in the PREP Act and conditions stated in this declaration is in effect for the Recommended Activities described in section III.

V. Covered Persons

42 U.S.C. 247d–6d(i)(2),(3),(4),(6),(8)(A) and (B)

Covered Persons who are afforded liability immunity under this declaration are manufacturers, distributors, program planners, ''qualified persons,'' and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States.

In addition, I have determined that the following additional persons are qualified persons: (a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a declaration of an emergency; (b) any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with section 564 of the FD&C Act, and; (c) Any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act.

VI. Covered Countermeasures

42 U.S.C. 247d–6b(c)(1)(B), 42 U.S.C. 247d–6d(i)(1) and (7)

Covered Countermeasures are any antiviral, any other drug, any biologic, any diagnostic, any other device, or any vaccine used against pandemic influenza A viruses and influenza A viruses with pandemic potential, all components and constituent materials of vaccines, and all devices and their constitution components used in the administration of vaccines, except that vaccines against influenza A and their associated components, constitute materials and devices covered under the National Vaccine Injury Compensation Program are not Covered Countermeasures.

Covered Countermeasures must be ''qualified pandemic or epidemic products,'' or ''security countermeasures,'' or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.

VII. Limitations on Distribution

42 U.S.C. 247d–6d(a)(5) and (b)(2)(E)

I have determined that liability immunity is afforded to Covered Persons only for Recommended Activities involving Covered Countermeasures that are related to:

(a) Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements, or activities directly conducted by the federal government;

or

(b) Activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a declaration of an emergency.

i. The Authority Having Jurisdiction means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (*e.g.,* city, county, tribal, state, or federal boundary lines) or functional (*e.g.,* law enforcement, public health) range or sphere of authority.

ii. A declaration of emergency means any declaration by any authorized local, regional, state, or federal official of an emergency specific to events that indicate an immediate need to administer and use the Covered Countermeasures, with the exception of a federal declaration in support of an Emergency Use Authorization under section 564 of the FD&C Act unless such declaration specifies otherwise;

I have also determined that for governmental program planners only, liability immunity is afforded only to the extent such program planners obtain Covered Countermeasures through voluntary means, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from state, local, or private stockpiles.

VIII. Category of Disease, Health Condition, or Threat

42 U.S.C. 247d–6d(b)(2)(A)

The category of disease, health condition, or threat for which I recommend the administration or use of the Covered Countermeasures is the threat of or actual human influenza that results from the infection of humans following exposure to pandemic influenza A viruses or influenza A viruses with pandemic potential.

Pandemic influenza A viruses and influenza A viruses with pandemic potential mean: Animal viruses and/or human influenza A viruses circulating in wild birds, domestic animals and/or humans that cause or have significant potential to cause sporadic or ongoing human infections, or historically have caused pandemics in humans, or have mutated to cause pandemics in humans, and for which the majority of the population is immunologically naive.

IX. Administration of Covered Countermeasures

42 U.S.C. 247d–6d(a)(2)(B)

Administration of the Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of

countermeasure programs, or management and operation of locations for purpose of distributing and dispensing countermeasures.

X. Population

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(C)

The populations of individuals include any individual who uses or is administered the Covered Countermeasures in accordance with this declaration.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered to this population or the program planner or qualified person reasonably could have believed the recipient was in this population.

XI. Geographic Area

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(D)

Liability immunity is afforded for the administration or use of a Covered Countermeasure without geographic limitation.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered in these geographic areas; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered in these geographic areas, or the program planner or qualified person reasonably could have believed the recipient was in these geographic areas.

XII. Effective Time Period

42 U.S.C. 247d–6d(b)(2)(B)

For any Covered Countermeasure subsequently covered under the National Vaccine Injury Compensation Program, liability immunity under this declaration expires immediately upon such coverage.

Liability immunity for Covered Countermeasures obtained through means of distribution other than in accordance with the public health and medical response of the Authority Having Jurisdiction extends through December 31, 2022 or until a Covered Countermeasure is covered under the National Vaccine Injury Compensation Program, as applicable, whichever occurs first.

Liability immunity for Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction begins with a declaration and lasts through (1) the final day the emergency declaration is in effect; (2) December 31, 2022; or (3) until a Covered Countermeasure is covered under the National Vaccine Injury Compensation Program, as applicable, whichever occurs first.

XIII. Additional Time Period of Coverage

42 U.S.C. 247d–6d(b)(3)(A),(B) and (C)

I have determined that an additional twelve (12) months of liability protection is reasonable to allow for the manufacturer(s) to arrange for disposition of the Covered Countermeasure, including return of the Covered Countermeasures to the manufacturer, and for Covered Persons to take other appropriate actions to limit the administration or use of the Covered Countermeasures.

Covered Countermeasures obtained for the Strategic National Stockpile (SNS) during the effective period of this declaration for Covered Countermeasures obtained through means of distribution other than in accordance with the public health and medical response of the Authority Having Jurisdiction are covered through the date of administration or use pursuant to a distribution or release from the SNS.

XIV. Countermeasures Injury Compensation Program

42 U.S.C. 247d–6e

The PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to certain individuals or estates of individuals who sustain a serious physical covered injury as the direct result of the administration or use of the Covered Countermeasures and/or benefits to certain survivors of individuals who die as a direct result of the administration or use of the Covered Countermeasures. The causal connection between the countermeasure and the serious physical injury must be supported by compelling, reliable, valid, medical, and scientific evidence in order for the individual to be considered for compensation. The CICP is administered by the Health Resources and Services Administration, within the Department of Health and Human Services. Information about the CICP is available toll-free at 1–855–266–2427 or *http://www.hrsa.gov/cicp/.*

XV. Amendments

42 U.S.C. 247d–6d(b)(4)

The October 10, 2008, Declaration Under the Public Readiness and Emergency Preparedness Act for pandemic influenza antivirals was first published on October 17, 2008, and amended on June 11, 2009. This is the second amendment to that declaration.

The December 17, 2008, Declaration Under the Public Readiness and Emergency Preparedness Act for diagnostics and other devices was first published on December 22, 2008. This is the first amendment to that declaration.

The Declaration for the Use of the Public Readiness and Emergency Preparedness Act for H5N1 vaccines was first published on January 26, 2007. The declaration was amended on November 30, 2007, to add H7 and H9 vaccines; amended on October 17, 2008, to add H2 and H6 vaccines; amended on June 15, 2009, to add 2009 H1N1 vaccines and republished in its entirety; amended on September 28, 2009, to provide targeted liability protections for pandemic countermeasures to enhance distribution and to add provisions consistent with other declarations and republished in its entirety; amended on March 1, 2010, to revise the Covered Countermeasures to include countermeasures against pandemic influenza A viruses, extend the effective date and republished in its entirety; and amended on February 29, 2012, to extend the effective time period, reformat the declaration, and republish the declaration.

This declaration incorporates all amendments to these declarations prior to the date of its publication in the **Federal Register**. Further amendments to this declaration will be published in the **Federal Register**.

Authority: 42 U.S.C. 247d–6d.

Dated: December 1, 2015.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2015–31087 Filed 12–8–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Anthrax Medical Countermeasures—Amendment

ACTION: Notice of Amendment to the October 1, 2008, Declaration under the Public Readiness and Emergency Preparedness Act.

SUMMARY: The Secretary is amending the declaration issued on October 1, 2008 (73 FR 58239) pursuant to section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d) to: Include countermeasures authorized for use under sections 564A and 564B of the Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. 360bbb–3a and 360bbb–3b); revise the description of covered countermeasures and the disease threat; extend the effective time period of the declaration; reformat the declaration; modify or clarify terms of the declaration; and republish the declaration in its entirety, as amended.

DATES: The amendment of the October 1, 2008, declaration is effective as of January 1, 2016.

FOR FURTHER INFORMATION CONTACT: Nicole Lurie, MD, MSPH, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW., Washington, DC 20201, Telephone 202–205–2882.

SUPPLEMENTARY INFORMATION:

Background

The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (''the Secretary'') to issue a declaration to provide liability immunity to certain individuals and entities (''Covered Persons'') against any claim of loss caused by, arising out of, relating to, or resulting from the administration or use of medical countermeasures (''Covered Countermeasures''), except for claims that meet the PREP Act's definition of willful misconduct. The Secretary may, though publication in the **Federal Register**, amend any portion of a declaration. Using this authority, the Secretary issued a declaration for anthrax countermeasures against the agent *Bacillus anthracis* (''*B. anthracis''*) on October 1, 2008 and is amending this declaration.[1]

The major actions taken by this amendment to the anthrax countermeasures declaration are the following: (1) Updating the description of covered countermeasures to include countermeasures authorized for use under sections 564A and 564B of the Federal Food, Drug, and Cosmetic (FD&C) Act;[2] (2) revising the description of covered countermeasures to clarify that coverage for vaccines includes all components and constituent materials of the vaccines, and all devices and their constituent components used in the administration of the vaccines and to accurately describe the types of countermeasures used against anthrax by deleting ''antitoxin'' and adding ''biologic'' to the section describing covered countermeasures; (3) revising the description of the disease threat and category of disease to refer to the ''spread of *Bacillus anthracis* and/or spores of *Bacillus anthracis;''* (4) changing the description of qualified persons to include persons authorized to prescribe, administer, or dispense covered countermeasures in accordance with Section 564A of the FD&C Act; (5) clarifying that liability immunity extends to ''other transactions'' and to activities related to any federal agreements including *e.g.,* clinical trials agreements by adding the terms ''other transactions'' and ''other Federal agreements'' to the clause describing the types of federal agreements for which immunity is in effect; (6) deleting references to specific federal contracts to clarify that immunity is not limited to activities conducted under listed contracts; (7) clarifying that liability immunity extends to activities directly conducted by the federal government by adding the phrase ''or directly conducted by the Federal Government'' to the section describing methods of distribution for which liability immunity is in effect; (8) narrowing the definition of ''administration'' to cover ''slip-and-fall'' claims only to the extent they are directly tied to the operation of a countermeasure program; (9) extending the time period for which liability immunity is in effect for the Covered Countermeasures to December 31, 2022, and (10) changing the entire declaration to the new format that was first used with the February 29, 2012, amendment to the declaration for pandemic influenza to make the declaration easier for readers to follow. Other minor modifications and clarifications are also made, as more fully explained below.

The declaration is republished in full. We explain both the substantive and format changes in this supplementary section.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, Section 2. It amended the Public Health Service (PHS) Act, adding section 319F–3, which addresses liability immunity, and section 319F–4, which creates a compensation program. These sections are codified in the U.S. Code as 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively.

The Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, was enacted on March 13, 2013. Among other things, PAHPRA added sections 564A and 564B to the FD&C Act to provide new authorities for the emergency use of approved products in emergencies and products held for emergency use. PAHPRA accordingly amended the definitions of ''Covered Countermeasures'' and ''qualified pandemic and epidemic products'' in section 319F–3 of the Public Health Service Act (the PREP Act provisions), so that products made available under these new FD&C Act authorities could be covered under PREP Act declarations. PAHPRA also extended the definition of qualified pandemic and epidemic products to include products or technologies intended to enhance the use or effect of a drug, biological product, or device used against the pandemic or epidemic or against adverse events from these products.

Unless otherwise noted, all statutory citations below are to the U.S. Code.

Section I, Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

Before issuing a declaration under the PREP Act, the Secretary is required to determine that a disease or other health condition or threat to health constitutes a public health emergency or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency.[3] This determination is separate and apart from a declaration issued by the Secretary under section 319 of the PHS Act[4] that a disease or disorder presents a public health emergency or that a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists, or other declarations or determinations made under other authorities of the Secretary. In the previous PREP Act declaration for anthrax countermeasures (''declaration''), this determination appeared in the declaration's introduction as the conclusion to the ''whereas'' clauses. The determination is now stated in the first section of the declaration. This change was made to improve readability and is not intended to have any substantive legal effect.

In addition, we made a substantive change to the determination. The determination made in the ''whereas'' clauses in the October 1, 2008, declaration stated that the Secretary ''determined there is a credible risk that the threat of exposure of *B. anthracis* and the resulting disease constitutes a

[1] 73 FR 58239.

[2] 21 U.S.C. 360bbb–3a and 360bbb–3b.

[3] 42 U.S.C. 247d–6d(b)(1).

[4] 42 U.S.C. 247d.

public health emergency.'' The Secretary is amending this determination: (1) To clarify that the threat posed is the spread of *Bacillus anthracis* and/or the spores of *Bacillus anthracis* and the resulting disease or condition; (2) to state that the threat may be in the future in order to be consistent with the language used in the PREP Act.[5] Thus, in this amended declaration, the Secretary determines ''that there is a credible risk that the spread of *Bacillus anthracis* and/or the spores of *Bacillus anthracis* and the resulting disease or conditions may in the future constitute a public health emergency.'' This change is provided for clarification.

Section II, Factors Considered

In deciding whether and under what circumstances to issue a declaration with respect to a Covered Countermeasure, the Secretary must consider the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the countermeasure.[6] We previously stated these considerations in the introductory ''whereas'' clauses to the declaration. The declaration now states these considerations in section II. We made this change to improve readability and do not intend that it have any substantive legal effect.

Section III, Recommended Activities

The Secretary must recommend the activities for which the PREP Act's liability immunity is in effect. These activities may include, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more Covered Countermeasures (''Recommended Activities'').[7] In the previous declaration, we included the Recommended Activities in section I of the declaration, ''Covered Countermeasures.'' The declaration now states them in section III. We made this change to improve readability and do not intend that it have any substantive legal effect. In addition, we deleted the term ''dispensing,'' as it does not appear in the PREP Act, changed ''and usage'' to ''or use'' for consistency with the statute, and deleted the phrase ''with respect to the category of disease and population described in sections II and IV below'' for consistency with formatting changes. These changes are not intended to have any substantive legal effect.

Section IV, Liability Immunity

The Secretary must also state that liability protections available under the PREP Act are in effect with respect to the Recommended Activities.[8] These liability protections provide that, ''[s]ubject to other provisions of [the PREP Act], a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered countermeasure if a declaration . . . has been issued with respect to such countermeasure.'' [9] In the previous declaration, we included a statement referring to liability immunity under the PREP Act in section I of the declaration, ''Covered Countermeasures.'' The declaration now includes the statement that liability immunity is in effect for Recommended Activities in a separate section IV. We made this change to improve readability and do not intend that it have any substantive legal effect.

Section V, Covered Persons

The PREP Act's liability immunity applies to ''Covered Persons'' with respect to administration or use of a Covered Countermeasure. The term ''Covered Persons'' has a specific meaning, and is defined in the PREP Act to include manufacturers, distributors, program planners, and qualified persons, and their officials, agents, and employees, and the United States.[10] The PREP Act further defines the terms ''manufacturer,'' ''distributor,'' ''program planner,'' and ''qualified person'' as described below.[11]

A *manufacturer* includes a contractor or subcontractor of a manufacturer; a supplier or licenser of any product, intellectual property, service, research tool or component or other article used in the design, development, clinical testing, investigation or manufacturing of a Covered Countermeasure; and any or all of the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer; [12]

A *distributor* means a person or entity engaged in the distribution of drug, biologics, or devices, including but not limited to: Manufacturers; repackers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; warehouses and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies; [13]

A *program planner* means a state or local government, including an Indian tribe; a person employed by the state or local government; or other person who supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a Covered Countermeasure, including a person who establishes requirements, provides policy guidance, or supplies technical or scientific advice or assistance or provides a facility to administer or use a Covered Countermeasure in accordance with the Secretary's declaration.[14] Under this definition, a private-sector employer or community group or other person can be a program planner when it carries out the described activities.

A *qualified person* means a licensed health professional or other individual who is authorized to prescribe, administer, or dispense Covered Countermeasures under the law of the state in which the countermeasure was prescribed, administered, or dispensed; or a person within a category of persons identified as qualified in the Secretary's declaration.[15] Under this definition, the Secretary can describe in the declaration other qualified persons, such as volunteers, who are Covered Persons. Section V describes other qualified persons covered by this declaration. The PREP Act also defines the word ''person'' as used in the Act: A *person* includes an individual, partnership, corporation, association, entity, or public or private corporation, including a federal, state, or local government agency or department.[16]

The provisions regarding Covered Persons previously appeared in the declaration as a definition in section IX, ''Definitions'' and in section VI, ''Qualified Persons.'' We combined these two provisions into a new section V, ''Covered Persons'' and added ''to perform an activity'' to the description of ''Other Qualified Persons'' authorized under an Emergency Use Authorization for clarity. We made these changes to improve readability and clarity and do not intend them to have any substantive legal effect.

We also modified the description of Covered Persons to include a new category of qualified persons: ''Any person authorized to prescribe,

[5] See 42 U.S.C. 247d–6d(b)(1).

[6] 42 U.S.C. 247d–6d(b)(6).

[7] 42 U.S.C. 247d–6d(b)(1).

[8] 42 U.S.C. 247d–6d(b)(1).

[9] 42 U.S.C. 247d–6d(a)(1).

[10] 42 U.S.C. 247d–6d (i)(2).

[11] 42 U.S.C. 247d–6d(i).

[12] 42 U.S.C. 247d 6–d(i)(4).

[13] 42 U.S.C. 247d–6d(i)(3).

[14] 42 U.S.C. 247d–6d(i)(6).

[15] 42 U.S.C. 247d–6d(i)(8).

[16] 42 U.S.C. 247d–6d(i)(5).

administer, or dispense covered countermeasures in accordance with Section 564A of the FD&C Act.'' This change ensures that persons who prescribe, administer, or dispense covered countermeasures in accordance with section 564A of the FD&C Act are Covered Persons under the declaration.

Section VI, Covered Countermeasures

As noted above, section III describes the Secretary's Recommended Activities for which liability immunity is in effect. This section identifies the countermeasures for which the Secretary has recommended such activities. The PREP Act states that a ''Covered Countermeasure'' must be: A ''qualified pandemic or epidemic product,'' or a ''security countermeasure,'' as described immediately below; or a drug, biological product or device authorized for emergency use in accordance with section 564, 564A, or 564B of the FD&C Act.[17]

A *qualified pandemic or epidemic product* means a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act [18] that is: (i) Manufactured, used, designed, developed, modified, licensed or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm such a pandemic or epidemic might otherwise cause; (ii) manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by such a drug, biological product or device; (iii) or a product or technology intended to enhance the use or effect of such a drug, biological product, or device.[19]

A *security countermeasure* is a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act [20] that: (i) (a) The Secretary determines to be a priority to diagnose, mitigate, prevent or treat harm from any biological, chemical, radiological, or nuclear agent identified as a material threat by the Secretary of Homeland Security, or (b) to diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent; and (ii) is determined by the Secretary of Health and Human Services to be a necessary countermeasure to protect public health.[21]

To be a Covered Countermeasure, qualified pandemic or epidemic products and security countermeasures also must be approved or cleared under the FD&C Act; [22] licensed under the PHS Act; [23] authorized for emergency use under sections 564, 564A, or 564B of the FD&C Act.[24]

A qualified pandemic or epidemic product also may be a Covered Countermeasure when it is subject to an exemption (that is, it is permitted to be used under an Investigational Drug Application or an Investigational Device Exemption) under the FD&C Act [25] and is the object of research for possible use for diagnosis, mitigation, prevention, treatment, cure or limit harm of a pandemic or epidemic or serious or life-threatening condition caused by such a drug or device. A security countermeasure also may be a Covered Countermeasure if it may reasonably be determined to qualify for approval or licensing within 10 years after the Department's determination that procurement of the countermeasure is appropriate.

Provisions regarding Covered Countermeasures previously appeared in section I of the declaration, ''Covered Countermeasures'' and section IX of the declaration, ''Definitions.'' Section I included not only a description of the Covered Countermeasure but also the Secretary's recommendation, statement regarding liability immunity, and additional conditions characterizing countermeasures. We have combined sections I and IX and simplified the language so that it now only identifies the Covered Countermeasures. We have relocated the other conditions previously included in the ''Covered Countermeasure'' section to new sections, ''Recommended Activities,'' ''Liability Immunity,'' and ''Limitations on Distribution,'' to improve readability. We do not intend for this change to have any substantive legal effect.

Section I of the declaration also stated that the declaration applied to Covered Countermeasures administered or used during the effective time period of the declaration. We have deleted this language as it is redundant of the provisions stated in sections XII, ''Effective Time Period,'' and XIII, ''Additional Time Period of Coverage.'' Section I also stated that it applied to ''Covered Countermeasures (Appendix I), administered or used by or on behalf of the Department of Defense.'' As explained under ''Deletions,'' below, we deleted Appendix I. Correspondingly, we have deleted the reference that appeared in section I to DOD countermeasures listed in the appendix. We do not intend this change to have legal effect. Any Covered Countermeasures that are administered and used under the terms of this declaration, including those used by or on behalf of the Department of Defense, are covered by the declaration.

We have also revised the definition and description of the Covered Countermeasure that previously appeared in sections I, ''Covered Countermeasures,'' and IX, ''Definitions.'' Section I referred to the statute for the definition of ''Covered Countermeasures,'' and section IX defined the term ''Anthrax Countermeasure'' as ''any vaccine; antimicrobial/antibiotic, other drug or antitoxin; or diagnostic or device to identify, prevent or treat anthrax or adverse events from such countermeasures (1) Licensed under section 351 of the Public Health Service Act; (2) approved under section 505 or section 515 of the Federal Food, Drug, and Cosmetic Act (FDCA); (3) cleared under section 510(k) of the FDCA; (4) authorized for emergency use under section 564 of the FDCA; (5) used under section 505(i) of the FDCA or section 351(a)(3) of the PHS Act, and 21 CFR part 312; or (6) used under section 520(g) of the FDCA and 21 CFR part 812.''

We revised the description of anthrax countermeasures to clarify that coverage for vaccines includes components and constituent materials of the vaccines and device and constituent components used in administration of the vaccines. We also deleted the term ''antitoxin'' and added ''biologic'' to more accurately describe the types of countermeasures used against anthrax. The definition now reads: ''any vaccine, including all components and constituent materials of these vaccines, and all devices and their constituent components used in the administration of these vaccines; any antimicrobial/antibiotic; any other drug or biologic; or any diagnostic or other device to identify, prevent or treat anthrax or adverse events from such countermeasures''. These changes are intended as clarification.

We also added a statement referencing the statutory definitions of Covered Countermeasures to make clear that these statutory definitions limit the scope of Covered Countermeasures. Specifically, we noted that they must be

[17] 42 U.S.C. 247d–6d(i)(1). Sections 564, 564A, and 564B of the FD&C Act may be found at 21 U.S.C. 360bbb–3, 360bbb–3a, and 360bbb–3b.

[18] 21 U.S.C. 321(g)(1), (h); 42 U.S.C. 262(i).

[19] 42 U.S.C. 247d–6d(i)(1)(A), (i)(7).

[20] 21 U.S.C. 321(g)(1), (h); 42 U.S.C. 262(i).

[21] 42 U.S.C. 247d–6d(i)(1)(B), (c)(1)(B).

[22] 21 U.S.C. 301 *et seq.*

[23] 42 U.S.C. 262.

[24] 21 U.S.C. 360bbb–3, 360bbb–3a, 360bbb–3b.

[25] 21 U.S.C. 355(i), 360j(g).

''qualified pandemic or epidemic products,'' or ''security countermeasures,'' or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.'' By referencing the statutory provisions, the revised definition also incorporates changes to the PREP Act definitions of covered countermeasure and qualified pandemic or epidemic product made by PAHPRA.

Section VII, Limitations on Distribution

The Secretary may specify that liability immunity is in effect only to Covered Countermeasures obtained through a particular means of distribution.[26] These limitations on distribution previously appeared in section I, ''Covered Countermeasures,'' and section IX, ''Definitions.'' We now state the limitations in a separate section and combine them with relevant definitions for improved readability.

The declaration now states that liability immunity is afforded to Covered Persons for Recommended Activities related to:

(a) Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, or memoranda of understanding or other federal agreements or activities directly conducted by the federal government; or

(b) Activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a declaration of an emergency.

For governmental program planners only, liability immunity is afforded only to the extent they obtain Covered Countermeasures through voluntary means, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from state, local, or private stockpiles.

In regard to (a), we deleted a reference to Appendix I, added the phrase ''other transactions,'' which may be used for some Covered Countermeasure activities,[27] added the phrase ''or other Federal agreements'' to clarify that the provision is intended to cover all types of federal agreements, and added the phrase ''or activities directly conducted by the Federal Government'' to clarify that activities such as manufacture of vaccines for clinical trials by the HHS National Institutes of Health Vaccine Research Center or distribution of countermeasures by federal employees are covered. We changed the conjunction ''and'' to ''or'' between (a) and (b) to clarify that immunity is available under either of these circumstances; the activities do not have to both relate to a federal award or agreement and be used in a public health and medical response in order for immunity to apply. The conjunction ''and'' used in the previous declaration was a drafting error; the Secretary's intent in that previous declarations has been the meaning conferred by the term ''or.'' Provisions (a) and (b) are intended to afford immunity to federal government conducted and supported activities that precede a public health emergency and to activities in accordance with all Authorities Having Jurisdiction during a declared public health emergency. These changes are intended as clarifications and to improve readability, and are not intended as substantive changes.

In regard to (b), the meaning of the terms ''Authority Having Jurisdiction'' and ''Declaration of an Emergency'' remain unchanged.

Finally, we slightly modified the last limitation by deleting extraneous statutory references and other language and by replacing the final sentence with the word ''only'' after ''planners'' to improve readability. We do not intend for the changes to this provision to alter its substantive legal effect. As stated in the ''whereas'' clauses of the prior declaration, this limitation on distribution is intended to deter program planners that are government entities from seizing privately held stockpiles of Covered Countermeasures. It does not apply to any other Covered Persons, including other program planners who are not government entities.

Section VIII, Category of Disease, Health Condition, or Threat

The Secretary must identify, for each Covered Countermeasure, the categories of diseases, health conditions, or threats to health for which the Secretary recommends the administration or use of the countermeasure.[28] This information previously appeared in section II, ''Category of Disease.'' We have modified the category of disease, health condition, or threat to also refer to exposure to *Bacillus anthracis spores* as a potential threat, so that the description reads: ''The category of disease, health condition, or threat to health for which I recommend the administration or use of the Covered Countermeasures is anthrax, which may result from exposure to *Bacillus anthracis* and/or to *Bacillus anthracis* spores.'' This change is intended as clarification, and is not intended to be substantive.

Section IX, Administration of Covered Countermeasures

The PREP Act does not explicitly define the term ''administration'' but does assign the Secretary the responsibility to provide relevant conditions in the declaration. This definition previously appeared in section IX, ''Definitions.'' We have moved it to a separate section to improve readability. The Secretary has also narrowed the definition of ''administration'' that was previously provided in the declaration. The declaration previously defined the term ''administration'' to include physical provision of a Covered Countermeasure, as well as management and operation of systems and locations at which Covered Countermeasures may be provided to recipients:

Administration of a Covered Countermeasure: As used in section 319F–3(a)(2)(B) of the Act includes, but is not limited to, public and private delivery, distribution, and dispensing activities relating to physical administration of the countermeasures to patients/recipients, management and operation of delivery systems, and management and operation of distribution and dispensing locations.

The definition has been revised as follows:

Administration of a Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients; management and operation of countermeasure programs; or management and operation of locations for purpose of distributing and dispensing countermeasures.

As clarified, the definition of ''administration'' extends only to physical provision of a countermeasure to a recipient, such as vaccination or handing drugs to patients, and to activities related to management and operation of programs and locations for providing countermeasures to recipients, such as decisions and actions involving security and queuing, but only insofar as those activities directly relate to the countermeasure activities. Claims for which Covered Persons are provided immunity under the Act are

[26] 42 U.S.C. 247d–6d(a)(5), (b)(2)(E).

[27] See, *e.g.,* 42 U.S.C. 247d–7d(c)(5).

[28] 42 U.S.C. 247d–6d(b)(2)(A).

losses caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a Covered Countermeasure consistent with the terms of a declaration issued under the Act.[29] Under the Secretary's definition, these liability claims are precluded if the claims allege an injury caused by physical provision of a countermeasure to a recipient, or if the claims are directly due to conditions of delivery, distribution, dispensing, or management and operation of countermeasure programs at distribution and dispensing sites.

Thus, it is the Secretary's interpretation that, when a declaration is in effect, the Act precludes, for example, liability claims alleging negligence by a manufacturer in creating a vaccine, or negligence by a health care provider in prescribing the wrong dose, absent willful misconduct. Likewise, the Act precludes a liability claim relating to the management and operation of a countermeasure distribution program or site, such as a slip-and-fall injury or vehicle collision by a recipient receiving a countermeasure at a retail store serving as an administration or dispensing location that alleges, for example, lax security or chaotic crowd control. However, a liability claim alleging an injury occurring at the site that was not directly related to the countermeasure activities is not covered, such as a slip and fall with no direct connection to the countermeasure's administration or use. In each case, whether immunity is applicable will depend on the particular facts and circumstances.

Section X, Population

The Secretary must identify, for each Covered Countermeasure specified in a declaration, the population or populations of individuals for which liability immunity is in effect with respect to administration or use of the countermeasure.[30] This section explains which individuals should use the countermeasure or to whom the countermeasure should be administered—in short, those who should be vaccinated or take a drug or other countermeasure. These provisions previously appeared in section IV, ''Population.'' The previous declaration stated that the population specified included:

The populations specified in this declaration are all persons who use a Covered Countermeasure or to whom a Covered Countermeasure is administered in accordance with this declaration, including, but not limited to: Department of Defense military personnel and supporting civilian-employee and contractor personnel; any person conducting research and development of Covered Countermeasures directly by the Federal government or pursuant to a contract, grant, or cooperative agreement with the Federal government; any person who receives a Covered Countermeasure from persons authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasure, and their officials, agents, employees, contractors, and volunteers following a declaration of an emergency; any person who receives a Covered Countermeasure from a person authorized to prescribe, administer or dispense the countermeasure or who is otherwise authorized to prescribe, administer, or dispense the countermeasure under an Emergency Use Authorization (EUA); any person who receives a Covered Countermeasure as an investigational new drug in human clinical trials being conducted directly by the federal government or pursuant to a contract, grant, or cooperative agreement with the federal government.

We have amended the declaration to provide that the population includes ''any individual who uses or who is administered a Covered Countermeasure in accordance with the declaration.'' We believe this broad statement accurately encompasses all of the previously listed populations given as examples of that phrase and ensures that no populations that use or are administered the Covered Countermeasures in accordance with the terms of the declaration are omitted.

In addition, the PREP Act specifies that liability immunity is afforded: (1) To manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; and (2) to program planners and qualified persons when the countermeasure is either used by or administered to this population or the program planner or qualified person reasonably could have believed the recipient was in this population.[31] We included these statutory conditions in the declaration for clarity.

Section XI, Geographic Area

The Secretary must identify, for each Covered Countermeasure specified in the declaration, the geographic area or areas for which liability immunity is in effect with respect to administration or use of the countermeasure, including, as appropriate, whether the declaration applies only to individuals physically present in the area or, in addition, applies to individuals who have a described connection to the area.[32] This section previously appeared in section V, ''Geographic Area.''

In addition, the PREP Act specifies that liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to individuals in the geographic areas and to program planners and qualified persons when the countermeasure is either used or administered in the geographic areas or the program planner or qualified person reasonably could have believed the countermeasure was used or administered in the areas.[33] We included these statutory conditions in the declaration for clarity.

Section XII, Effective Time Period

The Secretary must identify, for each Covered Countermeasure, the period or periods during which liability immunity is in effect, designated by dates, milestones, or other description of events, including factors specified in the PREP Act.[34] This section previously appeared as section III, ''Effective Time Period.''

The declaration is amended to clarify when liability takes effect for different means of distribution. These changes are intended to have no legal effect. The declaration is also amended to extend the period for which liability immunity is in effect. The previous declaration was in effect through December 31, 2015. We have extended the effective time period to December 31, 2022.

Section XIII, Additional Time Period of Coverage

The Secretary must specify a date after the ending date of the effective period of the declaration that is reasonable for manufacturers to arrange for disposition of the Covered Countermeasure, including return of the product to the manufacturer, and for other Covered Persons to take appropriate actions to limit administration or use of the Covered Countermeasure.[35] In addition, the PREP Act specifies that for Covered Countermeasures that are subject to a declaration at the time they are obtained for the Strategic National Stockpile (SNS) under 42 U.S.C. 247d–6b(a), the

[29] 42 U.S.C. 247d–6d(a).

[30] 42 U.S.C. 247d–6d(b)(2)(C).

[31] 42 U.S.C. 247d–6d(a)(4).

[32] 42 U.S.C. 247d–6d(b)(2)(D).

[33] 42 U.S.C. 247d–6d(a)(4).

[34] 42 U.S.C. 246d-6d(b)(2)(B), (b)(6).

[35] 42 U.S.C. 247d–6d(b)(3).

effective period of the declaration extends through the time the countermeasure is used or administered pursuant to a distribution or release from the Stockpile. Liability immunity under the provisions of the PREP Act and the conditions of the declaration continues during these additional time periods. Thus, liability immunity is afforded during the ''Effective Time Period,'' described under XII of the declaration, plus the ''Additional Time Period'' described under section XIII of the declaration.

The provision for additional time periods previously appeared as section VII, ''Additional Time Periods of Coverage After Expiration of the Declaration.'' The provision is amended to clarify the statutory provisions as they apply to manufacturers and to other covered persons, and to clarify that extended coverage applies to any products obtained for the SNS during the effective period of the declaration. We included the statutory provision for clarity.

Section XIV, Countermeasures Injury Compensation Program

Section 319F–4 of the PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to eligible individuals who sustain a serious physical injury or die as a direct result of the administration or use of a Covered Countermeasure.[36] Compensation under the CICP for an injury directly caused by a Covered Countermeasure is based on the requirements set forth in this declaration, the administrative rules for the Program,[37] and the statute.[38] To show direct causation between a Covered Countermeasure and a serious physical injury, the statute requires ''compelling, reliable, valid, medical and scientific evidence.'' [39] The administrative rules for the Program further explain the necessary requirements for eligibility under the CICP. Please note that, by statute, requirements for compensation under the CICP may not always align with the requirements for liability immunity provided under the PREP Act. We have added section XIV, ''Countermeasures Injury Compensation Program'' to explain the types of injury and standard of evidence needed to be considered for compensation under the CICP. We included this information to inform readers of this Program.

[36] 42 U.S.C. 247d–6e.

[37] 42 CFR part 110.

[38] 42 U.S.C. 247d–6e.

[39] 42 U.S.C. 247d–6e(b)(4).

Section XV, Amendments

The Secretary may amend any portion of a declaration through publication in the **Federal Register.**[40] This section previously appeared in section VIII, ''Amendments.'' The section has been updated to reflect that the Republished Declaration amends the prior October 1, 2008 declaration.

Deleted Sections

The prior declaration included a number of ''whereas'' clauses as introductory to the declaration. As described above, we have incorporated ''whereas'' clauses that made necessary findings under the PREP Act into the text of the declaration itself. We have deleted the remaining ''whereas'' clauses. We do not intend this change to have legal effect.

The prior declaration contained a definitions section. These definitions have been incorporated into the relevant sections of the declaration as noted above, and modified or deleted where indicated above.

An appendix previously appeared in the declaration that listed federal government contracts for research, development, and procurement of Covered Countermeasures. We deleted this appendix to clarify that liability immunity under the provisions of the PREP Act and terms of the declaration are not limited to the contracts listed in the appendix. Coverage is available for any award or agreement that meets the description provided in section VII of the declaration, including those under which Covered Countermeasures are administered or used by the Department of Defense. In addition, deleting the appendix relieves the Department of the need to periodically update the appendix.

We made these deletions for clarity and do not intend them to have legal effect.

Republished Declaration

Declaration, as Amended, for Public Readiness and Emergency Preparedness Act Coverage for Anthrax Countermeasures

This declaration amends and republishes the October 1, 2008, Declaration Under the PREP Act for anthrax countermeasures. To the extent any term of the October 1, 2008, Declaration is inconsistent with any provision of this Republished Declaration, the terms of this Republished Declaration are controlling.

[40] 42 U.S.C. 247d–6d(b)(4).

I. Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

42 U.S.C. 247d–6d(b)(1)

I have determined that there is a credible risk that the spread of *Bacillus anthracis* and/or the spores of *Bacillus anthracis* and the resulting disease or conditions may in the future constitute a public health emergency.

II. Factors Considered

42 U.S.C. 247d–6d(b)(6)

I have considered the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the Covered Countermeasures.

III. Recommended Activities

42 U.S.C. 247d–6d(b)(1)

I recommend, under the conditions stated in this declaration, the manufacture, testing, development, distribution, administration, or use of the Covered Countermeasures.

IV. Liability Immunity

42 U.S.C. 247d–6d(a), 247d–6d(b)(1)

Liability immunity as prescribed in the PREP Act and conditions stated in this declaration is in effect for the Recommended Activities described in section III.

V. Covered Persons

42 U.S.C. 247d–6d(i)(2), (3), (4), (6), (8)(A) and (B)

Covered Persons who are afforded liability immunity under this declaration are manufacturers, distributors, program planners, qualified persons, and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States.

In addition, I have determined that the following additional persons are qualified persons: (a) Any person who is authorized to prescribe, administer, deliver, distribute or dispense Covered Countermeasures to Department of Defense military personnel and supporting civilian-employee and contractor personnel; (b) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and

volunteers, following a declaration of an emergency; (c) Any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with section 564 of the FD&C Act; (d) Any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act.

VI. Covered Countermeasures

42 U.S.C. 247d–6b(c)(1)(B), 42 U.S.C. 247d–6d(i)(1) and (7)

Covered Countermeasures are any vaccine, including all components and constituent materials of these vaccines, and all devices and their constituent components used in the administration of these vaccines; any antimicrobial/antibiotic; any other drug or biologic; or any diagnostic or other device to identify, prevent or treat anthrax or adverse events from such countermeasures.

Covered Countermeasures must be ''qualified pandemic or epidemic products,'' or ''security countermeasures,'' or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.

VII. Limitations on Distribution

42 U.S.C. 247d–6d(a)(5) and (b)(2)(E)

I have determined that liability immunity is afforded to Covered Persons only for Recommended Activities involving Covered Countermeasures that are related to:

(a) Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements, or activities directly conducted by the federal government; or (b) Activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a declaration of an emergency.

i. The Authority Having Jurisdiction means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (*e.g.,* city, county, tribal, state, or federal boundary lines) or functional (*e.g.,* law enforcement, public health) range or sphere of authority.

ii. A declaration of emergency means any declaration by any authorized local, regional, state, or federal official of an emergency specific to events that indicate an immediate need to administer and use the Covered Countermeasures, with the exception of a federal declaration in support of an Emergency Use Authorization under section 564 of the FD&C Act unless such declaration specifies otherwise;

I have also determined that for governmental program planners only, liability immunity is afforded only to the extent such program planners obtain Covered Countermeasures through voluntary means, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from state, local, or private stockpiles.

VIII. Category of Disease, Health Condition, or Threat

42 U.S.C. 247d–6d(b)(2)(A)

The category of disease, health condition, or threat for which I recommend the administration or use of the Covered Countermeasures is anthrax, which may result from exposure to *Bacillus anthracis* and/or to *Bacillus anthracis* spores.

IX. Administration of Covered Countermeasures

42 U.S.C. 247d–6d(a)(2)(B)

Administration of the Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for purpose of distributing and dispensing countermeasures.

X. Population

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(C)

The populations of individuals include any individual who uses or is administered the Covered Countermeasures in accordance with this declaration.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered to this population or the program planner or qualified person reasonably could have believed the recipient was in this population.

XI. Geographic Area

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(D)

Liability immunity is afforded for the administration or use of a Covered Countermeasure without geographic limitation.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered in these geographic areas; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered in these geographic areas, or the program planner or qualified person reasonably could have believed the recipient was in these geographic areas.

XII. Effective Time Period

42 U.S.C. 247d–6d(b)(2)(B)

Liability immunity for Covered Countermeasures obtained through means of distribution other than in accordance with the public health and medical response of the Authority Having Jurisdiction extends through December 31, 2022.

Liability immunity for Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction begins with a declaration and lasts through (1) the final day the emergency declaration is in effect or (2) December 31, 2022, whichever occurs first.

XIII. Additional Time Period of Coverage

42 U.S.C. 247d–6d(b)(3)(A), (B) and (C)

I have determined that an additional twelve (12) months of liability protection is reasonable to allow for the manufacturer(s) to arrange for disposition of the Covered Countermeasure, including return of the Covered Countermeasures to the manufacturer, and for Covered Persons to take such other actions as are appropriate to limit the administration or use of the Covered Countermeasures.

Covered Countermeasures obtained for the SNS during the effective period of this declaration for Covered Countermeasures obtained through means of distribution other than in accordance with the public health and medical response of the Authority Having Jurisdiction are covered through the date of administration or use

pursuant to a distribution or release from the SNS.

Further, as to doses shipped by the Centers for Disease Control and Prevention (CDC) to the Department of Defense (DOD) pursuant to the DoD/CDC Interagency Agreement (IAA) dated March 10, 2008, an additional period of time of liability protection shall extend for as long as the SNS or its successor exists and the IAA remains in effect, plus, if the additional twelve (12) months following the time period in paragraph 1 of this section has expired, an additional twelve (12) months upon expiration of the IAA.

XIV. Countermeasures Injury Compensation Program

42 U.S.C. 247d–6e

The PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to certain individuals or estates of individuals who sustain a serious physical covered injury as the direct result of the administration or use of the Covered Countermeasures and/or benefits to certain survivors of individuals who die as a direct result of the administration or use of the Covered Countermeasures. The causal connection between the countermeasure and the serious physical injury must be supported by compelling, reliable, valid, medical and scientific evidence in order for the individual to be considered for compensation. The CICP is administered by the Health Resources and Services Administration, within the Department of Health and Human Services. Information about the CICP is available at 855–266–2427 (toll-free) or *http://www.hrsa.gov/cicp/.*

XV. Amendments

42 U.S.C. 247d–6d(b)(4)

The October 1, 2008, Declaration Under the Public Readiness and Emergency Preparedness Act for anthrax countermeasures was first published on October 6, 2008. This is the first amendment to that declaration.

Any further amendments to this declaration will be published in the **Federal Register**.

Authority: 42 U.S.C. 247d–6d.

Dated: December 1, 2015.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2015–31090 Filed 12–8–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Acute Radiation Syndrome Medical Countermeasures—Amendment

ACTION: Notice of Amendment to the October 10, 2008, Declaration Under the Public Readiness and Emergency Preparedness Act.

SUMMARY: The Secretary is amending the declaration issued on October 10, 2008, (73 FR 61866) pursuant to section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d) to: include countermeasures authorized for use under sections 564A and 564B of the Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. 360bbb–3a and 360bbb–3b); clarify and expand the description of covered countermeasures; extend the effective time period of the declaration; reformat the declaration; modify or clarify terms of the declaration; and republish the declaration in its entirety, as amended.

DATES: The amendment of the October 10, 2008, declaration is effective as of January 1, 2016.

FOR FURTHER INFORMATION CONTACT: Nicole Lurie, MD, MSPH, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW., Washington, DC 20201. Telephone 202–205–2882.

SUPPLEMENTARY INFORMATION:

Background

The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the administration or use of medical countermeasures (Covered Countermeasures), except for claims that meet the PREP Act's definition of willful misconduct. The Secretary may, though publication in the **Federal Register**, amend any portion of a declaration. Using this authority, the Secretary issued a declaration for countermeasures to botulinum toxin(s) and the resulting disease(s) from a manmade or natural source on October 10, 2008, and is amending the October 10, 2008 declaration.[1]

The major actions taken by this amendment to the acute radiation syndrome countermeasures declaration are the following: (1) Updating the description of covered countermeasures to include countermeasures authorized for use under sections 564A and 564B of the Federal Food, Drug, and Cosmetic (FD&C) Act; [2] (2) expanding covered countermeasures to include countermeasures administered acutely during the response for delayed effects to acute radiation exposure; (3) clarifying the description of covered countermeasures to delete vaccines and antitoxins and to add biologics; (4) changing the description of qualified persons to include persons authorized to prescribe, administer, or dispense covered countermeasures in accordance with Section 564A of the FD&C Act; (5) clarifying that liability immunity extends to ''other transactions'' and to activities related to any federal agreements including clinical trials agreements by adding the terms ''other transactions'' and ''other federal agreements'' to the clause describing the types of federal agreements for which immunity is in effect; (6) deleting references to specific federal contracts to clarify that immunity is not limited to activities conducted under listed contracts; (7) clarifying that liability immunity extends to activities directly conducted by the Federal government by adding the phrase ''or directly conducted by the Federal Government'' to the section describing methods of distribution for which liability immunity is in effect; (8) narrowing the definition of ''administration'' to cover ''slip-and–fall'' claims only to the extent they are directly tied to the operation of a countermeasure program; (9) extending the time period for which liability immunity is in effect for the Covered Countermeasures to December 31, 2022; and, (10) changing the entire declaration to the new format that was first used with the February 29, 2012, amendment to the declaration for pandemic influenza to make the declaration easier for readers to follow. Other minor modifications and clarifications are also made, as more fully explained below.

The declaration is republished in full. We explain the substantive and format changes in this supplementary section.

The PREP Act was enacted on December 30, 2005 as Public Law 109–148, Division C, Section 2. It amended the Public Health Service (PHS) Act, adding section 319F–3, which addresses liability immunity, and section 319F–4, which creates a compensation program.

[1] 73 FR 61869.

[2] 21 U.S.C. 360bbb–3a and 360bbb–3b.

These sections are codified in the U.S. Code as 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively.

The Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, was enacted on March 13, 2013. Among other things, PAHPRA added sections 564A and 564B to the FD&C Act to provide new authorities for the emergency use of approved products in emergencies and products held for emergency use. PAHPRA accordingly amended the definitions of ''Covered Countermeasures'' and ''qualified pandemic and epidemic products'' in section 319F–3 of the Public Health Service Act (the PREP Act provisions), so that products made available under these new FD&C Act authorities could be covered under PREP Act declarations. PAHPRA also extended the definition of qualified pandemic and epidemic products to include products or technologies intended to enhance the use or effect of a drug, biological product, or device used against the pandemic or epidemic or against adverse events from these products.

Unless otherwise noted, all statutory citations below are to the U.S. Code.

Section I, Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

Before issuing a declaration under the PREP Act, the Secretary is required to determine that a disease or other health condition or threat to health constitutes a public health emergency or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency.[3] This determination is separate and apart from a declaration issued by the Secretary under section 319 of the PHS Act [4] that a disease or disorder presents a public health emergency or that a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists, or other declarations or determinations made under other authorities of the Secretary. In the previous PREP Act declaration for acute radiation syndrome countermeasures (''declaration''), this determination appeared in the declaration's introduction as the conclusion to the ''whereas'' clauses. The determination is stated in the first section of the declaration. This change was made to improve readability and is not intended to have any substantive legal effect.

In addition, we made a substantive change to the determination. The determination made in the ''whereas'' clauses in the October 10, 2008 declaration stated that the Secretary ''determined there is a credible risk of an unintentional radioactive release, a deliberate detonation of a nuclear device, or other radiological nuclear incident and the resulting incidence of ARS constitutes a public health emergency.'' The Secretary is amending this determination to state that the threat may be ''in the future,'' to be consistent with language used in the PREP Act and changing ''and the resulting incidence of ARS'' to ''that could result in population exposures to radiation and resulting acute radiation syndrome and/or delayed effects to acute radiation exposure'' to more completely describe the public health risk.[5] Thus, in this amended declaration, the Secretary determines ''that there is a credible risk that an unintentional radioactive release, a deliberate detonation of a nuclear device, or other radiological or nuclear incident that could result in population exposures to radiation and resulting acute radiation syndrome and/or delayed effects of acute radiation exposure may in the future constitute a public health emergency.''

Section II, Factors Considered

In deciding whether and under what circumstances to issue a declaration with respect to a Covered Countermeasure, the Secretary must consider the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the countermeasure.[6] We previously stated these considerations in the introductory ''whereas'' clauses to the declaration. The declaration now states these considerations in section II. These changes were made to improve readability and do not intend that it have any substantive legal effect.

Section III, Recommended Activities

The Secretary must recommend the activities for which the PREP Act's liability immunity is in effect. These activities may include, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more Covered Countermeasures (''Recommended Activities'').[7] In the previous declaration, we included the Recommended Activities in section I of the declaration, ''Covered Countermeasures.'' The declaration now states them in section III. We made this change to improve readability and do not intend that it have any substantive legal effect. In addition, we deleted the phrases ''as defined in section IX below'' and ''with respect to the category of disease and population described in sections II and IV below'' for consistency with formatting changes, and changed ''and usage'' to ''or use'' for consistency with the statute. These changes are not intended to have any substantive legal effect.

Section IV, Liability Immunity

The Secretary must also state that liability protections available under the PREP Act are in effect with respect to the Recommended Activities.[8] These liability protections provide that, ''[s]ubject to other provisions of [the PREP Act], a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered countermeasure if a declaration . . . has been issued with respect to such countermeasure.'' [9] In the previous declaration, we included a statement referring to liability immunity specified under the PREP Act in section I of the declaration, ''Covered Countermeasures.'' The declaration now includes the statement that liability immunity is in effect for Recommended Activities in a separate section IV. This change was made to improve readability and is not intended to have any substantive legal effect.

Section V, Covered Persons

The PREP Act's liability immunity applies to ''Covered Persons'' with respect to administration or use of a Covered Countermeasure. The term ''Covered Persons'' has a specific meaning, and is defined in the PREP Act to include manufacturers, distributors, program planners, and qualified persons, and their officials, agents, and employees, and the United States.[10] The PREP Act further defines the terms ''manufacturer,'' ''distributor,'' ''program planner,'' and ''qualified person'' as described below.[11]

A *manufacturer* includes a contractor or subcontractor of a manufacturer; a supplier or licenser of any product, intellectual property, service, research

[3] 42 U.S.C. 247d–6d(b)(1).

[4] 42 U.S.C. 247d.

[5] See 42 U.S.C. 247d–6d(b)(1).

[6] 42 U.S.C. 247d–6d(b)(6).

[7] 42 U.S.C. 247d–6d(b)(1).

[8] 42 U.S.C. 247d–6d(b)(1).

[9] 42 U.S.C. 247d–6d(a)(1).

[10] 42 U.S.C. 247d–6d(i)(2).

[11] 42 U.S.C. 247d–6d(i).

tool or component or other article used in the design, development, clinical testing, investigation or manufacturing of a Covered Countermeasure; and any or all of the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer; [12]

A *distributor* means a person or entity engaged in the distribution of drug, biologics, or devices, including but not limited to: manufacturers; repackers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; warehouses and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies; [13]

A *program planner* means a state or local government, including an Indian Tribe; a person employed by the state or local government; or other person who supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a Covered Countermeasure, including a person who establishes requirements, provides policy guidance, or supplies technical or scientific advice or assistance or provides a facility to administer or use a Covered Countermeasure in accordance with the Secretary's declaration; [14] Under this definition, a private-sector employer or community group or other person can be a program planner when it carries out the described activities.

A *qualified person* means a licensed health professional or other individual who is authorized to prescribe, administer, or dispense Covered Countermeasures under the law of the state in which the countermeasure was prescribed, administered, or dispensed; or a person within a category of persons identified as qualified in the Secretary's declaration.[15] Under this definition, the Secretary can describe in the declaration other qualified persons, such as volunteers, who are Covered Persons. Section V describes other qualified persons covered by this declaration. The PREP Act also defines ''person'' as used in the Act: A *person* includes an individual, partnership, corporation, association, entity, or public or private corporation, including a federal, state, or local government agency or department.[16]

The provisions regarding Covered Persons previously appeared in the declaration as a definition in section IX, ''Definitions'' and in section VI, ''Qualified Persons.'' These two provisions were combined into a new section V, ''Covered Persons'' and added ''to perform an activity'' to the description of ''Other Qualified Persons'' authorized under an Emergency Use Authorization for clarity. These changes were made to improve readability and clarity and do not intend them to have any substantive legal effect.

The description of Covered Persons was also modified to include a new category of qualified persons: ''Any person authorized to prescribe, administer, or dispense covered countermeasures in accordance with Section 564A of the FD&C Act.'' This change ensures that persons who prescribe, administer, or dispense covered countermeasures in accordance with section 564A of the FD&C Act are Covered Persons under the declaration.

Section VI, Covered Countermeasures

As noted above, section III describes the Secretary's Recommended Activities for which liability immunity is in effect. This section identifies the countermeasures for which the Secretary has recommended such activities. The PREP Act states that a ''Covered Countermeasure'' must be: A ''qualified pandemic or epidemic product,'' or a ''security countermeasure,'' as described immediately below; or a drug, biological product or device authorized for emergency use in accordance with section 564, 564A, or 564B of the FD&C Act.[17]

A *qualified pandemic or epidemic product* means a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act [18] that is: (i) Manufactured, used, designed, developed, modified, licensed or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm such a pandemic or epidemic might otherwise cause; (ii) manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by such a drug, biological product or device; (iii) or a product or technology intended to enhance the use or effect of such a drug, biological product, or device.[19]

A *security countermeasure* is a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act [20] that: (i)(a) the Secretary determines to be a priority to diagnose, mitigate, prevent or treat harm from any biological, chemical, radiological, or nuclear agent identified as a material threat by the Secretary of Homeland Security, or (b) to diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent; and (ii) is determined by the Secretary of Health and Human Services to be a necessary countermeasure to protect public health.[21]

To be a Covered Countermeasure, qualified pandemic or epidemic products and security countermeasures also must be approved or cleared under the FD&C Act; [22] licensed under the PHS Act; [23] authorized for emergency use under sections 564, 564A, or 564B of the FD&C Act.[24]

A qualified pandemic or epidemic product also may be a Covered Countermeasure when it is subject to an exemption (that is, it is permitted to be used under an Investigational Drug Application or an Investigational Device Exemption) under the FD&C Act [25] and is the object of research for possible use for diagnosis, mitigation, prevention, treatment, cure or limit harm of a pandemic or epidemic or serious or life-threatening condition caused by such a drug or device. A security countermeasure also may be a Covered Countermeasure if it may reasonably be determined to qualify for approval or licensing within ten years after the Department's determination that procurement of the countermeasure is appropriate.

Provisions regarding Covered Countermeasures previously appeared in section I of the declaration, ''Covered Countermeasures'' and section IX of the declaration, ''Definitions.'' Section I included not only a description of the Covered Countermeasure but also the Secretary's recommendation, statement regarding liability immunity, and additional conditions characterizing countermeasures. Sections I and IX were combined and the language was simplified so that it now only identifies the Covered Countermeasures. The other conditions included in the ''Covered Countermeasure'' section were relocated to new sections,

[12] 42 U.S.C. 247d–6d(i)(4).
[13] 42 U.S.C. 247d–6d(i)(3).
[14] 42 U.S.C. 247d–6d(i)(6).
[15] 42 U.S.C. 247d–6d(i)(8).
[16] 42 U.S.C. 247d–6d(i)(5).
[17] 42 U.S.C. 247d–6d(i)(1). Sections 564, 564A, and 564B of the FD&C Act may be found at 21 U.S.C. 360bbb–3, 360bbb–3a, and 360bbb–3b.
[18] 21 U.S.C. 321(g)(1), (h); 42 U.S.C. 262(i).
[19] 42 U.S.C. 247d–6d(i)(1)(A), (i)(7).
[20] 21 U.S.C. 321(g)(1), (h); 42 U.S.C. 262(i).
[21] 42 U.S.C. 247d–6d(i)(1)(B), (c)(1)(B).
[22] 21 U.S.C. 301 *et seq.*
[23] 42 U.S.C. 262.
[24] 21 U.S.C. 360bbb–3, 360bbb–3a, 360bbb–3b.
[25] 21 U.S.C. 355(i), 360j(g).

''Recommended Activities,'' ''Liability Immunity,'' and ''Limitations on Distribution,'' to improve readability. This change is not intended to have any substantive legal effect.

Section I of the declaration also stated that the declaration applied to Covered Countermeasures administered or used during the effective time period of the declaration. This language was deleted as it is redundant of the provisions stated in sections XII, ''Effective Time Period,'' and XIII, ''Additional Time Period of Coverage.''

Substantive changes were made to the description and definition of the Covered Countermeasure that previously appeared in sections I, ''Covered Countermeasures'' and IX, ''Definitions.'' Section I referred to the Act for the definition of ''Covered Countermeasures,'' and section IX defined the term ''Acute Radiation Syndrome Countermeasure'' as ''Any vaccine; antimicrobial/antibiotic, other drug or antitoxin; or diagnostic or device to identify, prevent or treat acute radiation syndrome or adverse events from such countermeasures (1) licensed under section 351 of the Public Health Service Act; (2) approved under section 505 or section 515 of the Federal Food, Drug, and Cosmetic Act (FDCA); (3) cleared under section 510(k) of the FDCA; (4) authorized for emergency use under section 564 of the FDCA; (5) used under section 505(i) of the FDCA or section 351(a)(3) of the PHS Act, and 21 CFR part 312; or (6) used under section 520(g) of the FDCA and 21 CFR part 812.''

The description of acute radiation syndrome countermeasures was clarified to: Delete vaccines and antitoxins, as such countermeasures are not relevant to acute radiation syndrome; explain the term ''antimicrobial'' with regard to use against acute radiation syndrome; add ''biologics'' that are relevant to acute radiation syndrome; add ''other'' before ''device''; and add references to clinical manifestations of acute radiation syndrome and delayed effects of acute radiation exposure. The description now reads: ''any antimicrobial (antibiotic, antifungal, antiviral); any other drug; any biologic; or any diagnostic or other device administered acutely during the response to identify, prevent or treat acute radiation syndrome and its associated clinical manifestations, or delayed effects of acute radiation exposure or adverse events from such countermeasures.'' These changes are intended to clarify the description of covered countermeasures and to expand countermeasures covered by the declaration to include biologics and countermeasures against delayed effects of acute radiation exposure, consistent with the statute and terms and conditions of the declaration.

A statement referencing the statutory definitions of Covered Countermeasures was added to make clear that these statutory definitions limit the scope of Covered Countermeasures. Specifically, it was noted they must be ''qualified pandemic or epidemic products,'' or ''security countermeasures,'' or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.'' By referencing the statutory provisions, the revised definition also incorporates changes to the PREP Act definitions of covered countermeasure and qualified pandemic or epidemic product made by PAHPRA.

Section VII, Limitations on Distribution

The Secretary may specify that liability immunity is in effect only to Covered Countermeasures obtained through a particular means of distribution.[26] These limitations on distribution previously appeared in section I, ''Covered Countermeasures,'' and section IX, ''Definitions.'' We now state the limitations in a separate section and combine them with relevant definitions for improved readability.

The declaration now states that liability immunity is afforded to Covered Persons for Recommended Activities related to:

(a) Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, or memoranda of understanding or other federal agreements or activities directly conducted by the federal government; or,

(b) Activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a declaration of an emergency.

For governmental program planners only, liability immunity is afforded only to the extent they obtain Covered Countermeasures through voluntary means, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from state, local, or private stockpiles.

In regard to (a), we, added the phrase ''other transactions,'' which may be used for some Covered Countermeasure activities,[27] added the phrase ''or other Federal agreements'' to clarify that the provision is intended to cover all types of federal agreements, and added the phrase ''or activities directly conducted by the Federal Government'' to clarify that activities such as manufacture of vaccines for clinical trials by the HHS National Institutes of Health Vaccine Research Center or distribution of countermeasures by federal employees are covered. We changed the conjunction ''and'' to ''or'' between (a) and (b) to clarify that immunity is available under either of these circumstances; the activities do not have to both relate to a federal award or agreement and be used in a public health and medical response in order for immunity to apply. The conjunction ''and'' used in the previous declaration was a drafting error; the Secretary's intent in that previous declaration has been the meaning conferred by the term ''or.'' Provisions (a) and (b) are intended to afford immunity to federal government conducted and supported activities that precede a public health emergency and to activities in accordance with all Authorities Having Jurisdiction during a declared public health emergency. These changes are intended as clarifications and to improve readability, and are not intended as substantive changes.

In regard to (b), the meaning of the terms ''Authority Having Jurisdiction'' and ''Declaration of an Emergency'' are unchanged.

Finally, the last limitation was slightly modified by deleting extraneous statutory references and other language and by replacing the final sentence with the word ''only'' after ''planners'' to improve readability. The changes to this provision are not intended to alter its substantive legal effect. As stated in the ''whereas'' clauses of the prior declaration, this limitation on distribution is intended to deter program planners that are government entities from seizing privately held stockpiles of Covered Countermeasures. It does not apply to any other Covered Persons, including other program planners who are not government entities.

Section VIII, Category of Disease, Health Condition, or Threat

The Secretary must identify, for each Covered Countermeasure, the categories of diseases, health conditions, or threats to health for which the Secretary

[26] 42 U.S.C. 247d–6d(a)(5), (b)(2)(E).

[27] See, *e.g.,* 42 U.S.C. 247d–7d(c)(5).

recommends the administration or use of the countermeasure.[28] This information previously appeared in section II, ''Category of Disease.'' The category of disease threat was modified to include delayed effects of acute radiation exposure. This change is intended to clarify and expand the category of disease, health condition or health threat caused by exposure to acute radiation.

Section IX, Administration of Covered Countermeasures

The PREP Act does not explicitly define the term ''administration'' but does assign the Secretary the responsibility to provide relevant conditions in the declaration. This definition previously appeared in section IX, ''Definitions.'' It was moved to a separate section to improve readability. The Secretary also narrowed the definition of ''administration'' that was previously provided in the declaration. The declaration previously defined the term ''administration'' to include physical provision of a Covered Countermeasure, as well as management and operation of systems and locations at which Covered Countermeasures may be provided to recipients.

Administration of a Covered Countermeasure: As used in section 319F–3(a)(2)(B) of the Act includes, but is not limited to, public and private delivery, distribution, and dispensing activities relating to physical administration of the countermeasures to patients/recipients, management and operation of delivery systems, and management and operation of distribution and dispensing locations.

The definition has been revised as follows:

Administration of a Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients; management and operation of countermeasure programs; or management and operation of locations for purpose of distributing and dispensing countermeasures.

As clarified, *administration* extends only to physical provision of a countermeasure to a recipient, such as vaccination or handing drugs to patients, and to activities related to management and operation of programs and locations for providing countermeasures to recipients, such as decisions and actions involving security and queuing, but only insofar as those activities directly relate to the countermeasure activities. Claims for which Covered Persons are provided immunity under the Act are losses caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a Covered Countermeasure consistent with the terms of a declaration issued under the Act.[29] Under the Secretary's definition, these liability claims are precluded if the claims allege an injury caused by physical provision of a countermeasure to a recipient, or if the claims are directly due to conditions of delivery, distribution, dispensing, or management and operation of countermeasure programs at distribution and dispensing sites.

Thus, it is the Secretary's interpretation that, when a declaration is in effect, the Act precludes, for example, liability claims alleging negligence by a manufacturer in creating a vaccine, or negligence by a health care provider in prescribing the wrong dose, absent willful misconduct. Likewise, the Act precludes a liability claim relating to the management and operation of a countermeasure distribution program or site, such as a ''slip-and-fall'' injury or vehicle collision by a recipient receiving a countermeasure at a retail store serving as an administration or dispensing location that alleges, for example, lax security or chaotic crowd control. However, a liability claim alleging an injury occurring at the site that was not directly related to the countermeasure activities is not covered, such as a slip and fall with no direct connection to the countermeasure's administration or use. In each case, whether immunity is applicable will depend on the particular facts and circumstances.

Section X, Population

The Secretary must identify, for each Covered Countermeasure specified in a declaration, the population or populations of individuals for which liability immunity is in effect with respect to administration or use of the countermeasure.[30] This section explains which individuals should use the countermeasure or to whom the countermeasure should be administered—in short, those who should be vaccinated or take a drug or other countermeasure. These provisions previously appeared in section IV, ''Population.'' The previous declaration stated that the population specified in the declaration included:

The populations specified in this declaration are all persons who use a Covered Countermeasure or to whom a Covered Countermeasure is administered in accordance with this declaration, including, but not limited to: (1) Any person conducting research and development of Covered Countermeasures directly for the federal government or pursuant to a contract, grant, or cooperative agreement with the federal government; (2) any person who receives a Covered Countermeasure from persons authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasure, and their officials, agents, employees, contractors, and volunteers following a declaration of an emergency; (3) any person who receives a Covered Countermeasure from a person authorized to prescribe, administer or dispense the countermeasure or who is otherwise authorized to prescribe, administer or dispense the countermeasure under an Emergency Use Authorization; (4) any person who receives a Covered Countermeasure as an investigational new drug in human clinical trials being conducted directly by the federal government or pursuant to a contract, grant, or cooperative agreement with the federal government.

The declaration was amended to provide that the population includes ''any individual who uses or who is administered a Covered Countermeasure in accordance with the declaration.'' We believe this broad statement accurately encompasses all of the previously listed populations given as examples of that phrase and ensures that no populations that use or are administered the Covered Countermeasures in accordance with the terms of the declaration are omitted.

In addition, the PREP Act specifies that liability immunity is afforded: (1) To manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; and (2) to program planners and qualified persons when the countermeasure is either used by or administered to this population or the program planner or qualified person reasonably could have believed the recipient was in this population.[31] These statutory conditions were included in the declaration for clarity.

Section XI, Geographic Area

The Secretary must identify, for each Covered Countermeasure specified in

[28] 42 U.S.C. 247d–6d(b)(2)(A).

[29] 42 U.S.C. 247d–6d(a).

[30] 42 U.S.C. 247d–6d(b)(2)(C).

[31] 42 U.S.C. 247d–6d(a)(4).

the declaration, the geographic area or areas for which liability immunity is in effect with respect to administration or use of the countermeasure, including, as appropriate, whether the declaration applies only to individuals physically present in the area or, in addition, applies to individuals who have a described connection to the area.[32] This section previously appeared in section V, ''Geographic Area.''

In addition, the PREP Act specifies that liability immunity is afforded: (1) To manufacturers and distributors without regard to whether the countermeasure is used by or administered to individuals in the geographic areas; and (2) to program planners and qualified persons when the countermeasure is either used or administered in the geographic areas or the program planner or qualified person reasonably could have believed the countermeasure was used or administered in the areas.[33] These statutory conditions were included in the declaration for clarity.

Section XII, Effective Time Period

The Secretary must identify, for each Covered Countermeasure, the period or periods during which liability immunity is in effect, designated by dates, milestones, or other description of events, including factors specified in the PREP Act.[34] This section previously appeared as section III, ''Effective Time Period.''

The declaration is amended to clarify when liability takes effect for different means of distribution. These changes are intended to have no legal effect. The declaration is also amended to extend the period for which liability immunity is in effect. The previous declaration was in effect through December 31, 2015. The effective time period is extended to December 31, 2022.

Section XIII, Additional Time Period of Coverage

The Secretary must specify a date after the ending date of the effective period of the declaration that is reasonable for manufacturers to arrange for disposition of the Covered Countermeasure, including return of the product to the manufacturer, and for other Covered Persons to take appropriate actions to limit administration or use of the Covered Countermeasure.[35] In addition, the PREP Act specifies that for Covered Countermeasures that are subject to a declaration at the time they are obtained for the Strategic National Stockpile (SNS) under 42 U.S.C. 247d–6b(a), the effective period of the declaration extends through the time the countermeasure is used or administered pursuant to a distribution or release from the Stockpile. Liability immunity under the provisions of the PREP Act and the conditions of the declaration continues during these additional time periods. Thus, liability immunity is afforded during the ''Effective Time Period,'' described under XII of the declaration, plus the ''Additional Time Period'' described under section XIII of the declaration.

The provision for additional time periods previously appeared as section VII, ''Additional Time Periods of Coverage After Expiration of the Declaration.'' The provision is amended to clarify the statutory provisions as they apply to manufacturers and to other covered persons, and to clarify that extended coverage applies to any products obtained for the SNS during the effective period of the declaration. The statutory provision was included for clarity.

Section XIV, Countermeasures Injury Compensation Program

Section 319F–4 of the PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to eligible individuals who sustain a serious physical injury or die as a direct result of the administration or use of a Covered Countermeasure.[36] Compensation under the CICP for an injury directly caused by a Covered Countermeasure is based on the requirements set forth in this declaration, the administrative rules for the Program,[37] and the statute.[38] To show direct causation between a Covered Countermeasure and a serious physical injury, the statute requires ''compelling, reliable, valid, medical and scientific evidence.'' [39] The administrative rules for the Program further explain the necessary requirements for eligibility under the CICP. Please note that, by statute, requirements for compensation under the CICP may not always align with the requirements for liability immunity provided under the PREP Act. Section XIV, ''Countermeasures Injury Compensation Program'' was added to explain the types of injury and standard of evidence needed to be considered for compensation under the CICP. This information was included to inform readers of this Program.

Section XV, Amendments

The Secretary may amend any portion of a declaration through publication in the **Federal Register**.[40] This section previously appeared in section VIII, ''Amendments.'' The section has been updated to reflect that the Republished Declaration amends the prior October 10, 2008, declaration.

Deleted Sections

The prior declaration included a number of ''whereas'' clauses as introductory to the declaration. As described above, we have incorporated ''whereas'' clauses that made necessary findings under the PREP Act into the text of the declaration itself. We have deleted the remaining ''whereas'' clauses. This change is not intended to have legal effect.

The prior declaration contained a definitions section. These definitions have been incorporated into the relevant sections of the declaration as noted above, and modified or deleted where indicated above.

An appendix previously appeared in the declaration that listed federal government contracts for research, development, and procurement of Covered Countermeasures. This appendix was deleted to clarify that liability immunity under the provisions of the PREP Act and terms of the declaration is not limited to the contracts listed in the appendix. Coverage is available for any award or agreement that meets the description provided in section VII of the declaration. In addition, deleting the appendix relieves the Department of the need to periodically update the appendix.

These deletions were made for clarity and do not intend them to have legal effect.

Republished Declaration

Declaration, as Amended, for Public Readiness and Emergency Preparedness Act Coverage for Acute Radiation Syndrome Countermeasures

This declaration amends and republishes the October 10, 2008, Declaration Under the Public Readiness and Emergency Preparedness Act (PREP Act) for acute radiation syndrome countermeasures. To the extent any term of the October 10, 2008, Declaration is inconsistent with any provision of this Republished Declaration, the terms of this Republished Declaration are controlling.

[32] 42 U.S.C. 247d–6d(b)(2)(D).

[33] 42 U.S.C. 247d–6d(a)(4).

[34] 42 U.S.C. 246d–6d(b)(2)(B), (b)(6).

[35] 42 U.S.C. 247d–6d(b)(3).

[36] 42 U.S.C. 247d–6e.

[37] 42 CFR part 110.

[38] 42 U.S.C. 247d–6e.

[39] 42 U.S.C. 247d–6e(b)(4).

[40] 42 U.S.C. 247d–6d(b)(4).

I. Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

42 U.S.C. 247d–6d(b)(1)

I have determined that there is a credible risk that an unintentional radioactive release, a deliberate detonation of a nuclear device, or other radiological or nuclear incident that could result in population exposures to radiation and resulting acute radiation syndrome and/or delayed effects of acute radiation exposure may in the future constitute a public health emergency.

II. Factors Considered

42 U.S.C. 247d–6d(b)(6)

I have considered the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the Covered Countermeasures.

III. Recommended Activities

42 U.S.C. 247d–6d(b)(1)

I recommend, under the conditions stated in this declaration, the manufacture, testing, development, distribution, administration, or use of the Covered Countermeasures.

IV. Liability Immunity

42 U.S.C. 247d–6d(a), 247d–6d(b)(1)

Liability immunity as prescribed in the PREP Act and conditions stated in this declaration is in effect for the Recommended Activities described in section III.

V. Covered Persons

42 U.S.C. 247d–6d(i)(2), (3), (4), (6), (8)(A) and (B)

Covered Persons who are afforded liability immunity under this declaration are manufacturers, distributors, program planners, qualified persons, and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States.

In addition, I have determined that the following additional persons are qualified persons: (a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a declaration of an emergency; (b) any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with section 564 of the FD&C Act; (c) any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act.

VI. Covered Countermeasures

42 U.S.C. 247d–6b(c)(1)(B), 42 U.S.C. 247d–6d(i)(1) and (7)

Covered Countermeasures are any antimicrobial (antibiotic, antifungal, antiviral); any other drug; any biologic; or any diagnostic or other device administered acutely during the response to identify, prevent or treat acute radiation syndrome and its associated clinical manifestations, or delayed effects of acute radiation exposure or adverse events from such countermeasures.

Covered Countermeasures must be ''qualified pandemic or epidemic products,'' or ''security countermeasures,'' or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.

VII. Limitations on Distribution

42 U.S.C. 247d–6d(a)(5) and (b)(2)(E)

I have determined that liability immunity is afforded to Covered Persons only for Recommended Activities involving Covered Countermeasures that are related to:

(a) Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements, or activities directly conducted by the federal government; or

(b) Activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a declaration of an emergency.

i. The Authority Having Jurisdiction means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (*e.g.,* city, county, tribal, state, or federal boundary lines) or functional (*e.g.,* law enforcement, public health) range or sphere of authority.

ii. A declaration of emergency means any declaration by any authorized local, regional, state, or federal official of an emergency specific to events that indicate an immediate need to administer and use the Covered Countermeasures, with the exception of a federal declaration in support of an Emergency Use Authorization under section 564 of the FD&C Act unless such declaration specifies otherwise;

I have also determined that for governmental program planners only, liability immunity is afforded only to the extent such program planners obtain Covered Countermeasures through voluntary means, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from state, local, or private stockpiles.

VIII. Category of Disease, Health Condition, or Threat

42 U.S.C. 247d–6d(b)(2)(A)

The category of disease, health condition, or threat for which I recommend the administration or use of the Covered Countermeasures is acute radiation syndrome or delayed effects of acute radiation exposure resulting from an unintentional radioactive release, a deliberate detonation of a nuclear device, or other radiological or nuclear incident.

IX. Administration of Covered Countermeasures

42 U.S.C. 247d–6d(a)(2)(B)

Administration of the Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for purpose of distributing and dispensing countermeasures.

X. Population

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(C)

The populations of individuals include any individual who uses or is administered the Covered Countermeasures in accordance with this declaration.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; liability immunity is afforded to program planners and

qualified persons when the countermeasure is used by or administered to this population or the program planner or qualified person reasonably could have believed the recipient was in this population.

XI. Geographic Area

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(D)

Liability immunity is afforded for the administration or use of a Covered Countermeasure without geographic limitation.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered in these geographic areas; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered in these geographic areas, or the program planner or qualified person reasonably could have believed the recipient was in these geographic areas.

XII. Effective Time Period

42 U.S.C. 247d–6d(b)(2)(B)

Liability immunity for Covered Countermeasures obtained through means of distribution other than in accordance with the public health and medical response of the Authority Having Jurisdiction extends through December 31, 2022.

Liability immunity for Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction begins with a declaration and lasts through (1) the final day the emergency declaration is in effect, or (2) December 31, 2022, whichever occurs first.

XIII. Additional Time Period of Coverage

42 U.S.C. 247d–6d(b)(3)(A), (B) and (C)

I have determined that an additional twelve (12) months of liability protection is reasonable to allow for the manufacturer(s) to arrange for disposition of the Covered Countermeasure, including return of the Covered Countermeasures to the manufacturer, and for Covered Persons to take such other actions as are appropriate to limit the administration or use of the Covered Countermeasures.

Covered Countermeasures obtained for the SNS during the effective period of this declaration for Covered Countermeasures obtained through means of distribution other than in accordance with the public health and medical response of the Authority Having Jurisdiction are covered through the date of administration or use pursuant to a distribution or release from the SNS.

XIV. Countermeasures Injury Compensation Program

42 U.S.C 247d–6e

The PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to certain individuals or estates of individuals who sustain a serious physical covered injury as the direct result of the administration or use of the Covered Countermeasures and/or benefits to certain survivors of individuals who die as a direct result of the administration or use of the Covered Countermeasures. The causal connection between the countermeasure and the serious physical injury must be supported by compelling, reliable, valid, medical and scientific evidence in order for the individual to be considered for compensation. The CICP is administered by the Health Resources and Services Administration, within the Department of Health and Human Services. Information about the CICP is available at 855–266–2427 (toll-free) or *http://www.hrsa.gov/cicp/.*

XV. Amendments

42 U.S.C. 247d–6d(b)(4)

The October 10, 2008, Declaration Under the Public Readiness and Emergency Preparedness Act for botulinum toxin countermeasures was first published on October 17, 2008. This is the first amendment to that declaration.

Any further amendments to this declaration will be published in the **Federal Register**.

Authority: 42 U.S.C. 247d–6d.

Dated: December 1, 2015.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2015–31094 Filed 12–8–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Botulinum Toxin Medical Countermeasures—Amendment

ACTION: Notice of Amendment to the October 10, 2008, Declaration under the Public Readiness and Emergency Preparedness Act.

SUMMARY: The Secretary is amending the declaration issued on October 10, 2008 (73 FR 61864) pursuant to section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d) to: Include countermeasures authorized for use under sections 564A and 564B of the Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. 360bbb–3a and 360bbb–3b); clarify the description of covered countermeasures; extend the effective time period of the declaration; reformat the declaration; modify or clarify terms of the declaration; and republish the declaration in its entirety, as amended.

DATES: The amendment of the October 10, 2008, declaration is effective as of January 1, 2016.

FOR FURTHER INFORMATION CONTACT: Nicole Lurie, MD, MSPH, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW., Washington, DC 20201, Telephone 202–205–2882.

SUPPLEMENTARY INFORMATION:

Background

The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the administration or use of medical countermeasures (Covered Countermeasures), except for claims that meet the PREP Act's definition of willful misconduct. The Secretary may, though publication in the **Federal Register**, amend any portion of a declaration. Using this authority, the Secretary issued a declaration for countermeasures to botulinum toxin(s) and the resulting disease(s) from a manmade or natural source on October 10, 2008, and is amending this declaration.[1]

The major actions taken by this amendment to the botulinum toxin countermeasures declaration are the following: (1) Updating the description of covered countermeasures to include countermeasures authorized for use under sections 564A and 564B of the Federal Food, Drug, and Cosmetic (FD&C) Act;[2] (2) revising the description of covered countermeasures to clarify that coverage for vaccines includes all components and

[1] 73 FR 61869.

[2] 21 U.S.C. 360bbb–3a and 360bbb–3b.

constituent materials of the vaccines, and all devices and their constituent components used in the administration of the vaccines; (3) revising the description of covered countermeasures to clarify that antitoxins are covered; (4) changing the description of qualified persons to include persons authorized to prescribe, administer, or dispense covered countermeasures in accordance with Section 564A of the FD&C Act; (5) clarifying that liability immunity extends to other transactions and to activities related to any federal agreements including clinical trials agreements by adding the terms ''other transactions'' and ''other Federal agreements'' to the clause describing the types of federal agreements for which immunity is in effect; (6) deleting references to specific federal contracts to clarify that immunity is not limited to activities conducted under listed contracts; (7) clarifying that liability immunity extends to activities directly conducted by the federal government by adding the phrase ''or directly conducted by the federal Government'' to the section describing methods of distribution for which liability immunity is in effect; (8) narrowing the definition of ''administration'' to cover ''slip-and-fall'' claims only to the extent they are directly tied to the operation of a countermeasure program; (9) extending the time period for which liability immunity is in effect for the Covered Countermeasures to December 31, 2022, and (10) changing the entire declaration to the new format that was first used with the February 29, 2012, amendment to the declaration for pandemic influenza to make the declaration easier for readers to follow. Other minor modifications and clarifications are also made, as more fully explained below.

The declaration is republished in full. We explain both the substantive and format changes in this supplementary section.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, Section 2. It amended the Public Health Service (PHS) Act, adding section 319F–3, which addresses liability immunity, and section 319F–4, which creates a compensation program. These sections are codified in the U.S. Code as 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively.

The Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, was enacted on March 13, 2013. Among other things, PAHPRA added sections 564A and 564B to the FD&C Act to provide new authorities for the emergency use of approved products in emergencies and products held for emergency use. PAHPRA accordingly amended the definitions of ''Covered Countermeasures'' and ''qualified pandemic and epidemic products'' in section 319F–3 of the Public Health Service Act (the PREP Act provisions), so that products made available under these new FD&C Act authorities could be covered under PREP Act declarations. PAHPRA also extended the definition of qualified pandemic and epidemic products to include products or technologies intended to enhance the use or effect of a drug, biological product, or device used against the pandemic or epidemic or against adverse events from these products.

Unless otherwise noted, all statutory citations below are to the U.S. Code.

Section I, Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

Before issuing a declaration under the PREP Act, the Secretary is required to determine that a disease or other health condition or threat to health constitutes a public health emergency or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency.[3] This determination is separate and apart from a declaration issued by the Secretary under section 319 of the PHS Act [4] that a disease or disorder presents a public health emergency or that a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists, or other declarations or determinations made under other authorities of the Secretary. In the previous PREP Act declaration for botulinum toxin countermeasures (''declaration''), this determination appeared in the declaration's introduction as the conclusion to the ''whereas'' clauses. The determination is now stated in the first section of the declaration. This change was made to improve readability and is not intended to have any substantive legal effect.

In addition, we made a substantive change to the determination. The determination made in the ''whereas'' clauses in the October 10, 2008, declaration stated that the Secretary ''determined there is a credible risk that botulinum toxin(s) and the resulting disease(s) from a manmade or natural sources constitutes a public health emergency.'' The Secretary is amending this determination to state that the threat may be in the future, to refer to ''exposure'' to botulinum toxins, and to refer to both ''diseases'' and ''conditions'' to more accurately describe the risk and to be consistent with the language used in the PREP Act.[5] Thus, in this amended declaration, the Secretary determines ''that there is a credible risk that exposure to botulinum toxin(s) and the resulting diseases or conditions from manmade or natural sources may in the future constitute a public health emergency.'' This change is provided for clarification.

Section II, Factors Considered

In deciding whether and under what circumstances to issue a declaration with respect to a Covered Countermeasure, the Secretary must consider the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the countermeasure.[6] We previously stated these considerations in the introductory ''whereas'' clauses to the declaration. The declaration now states these considerations in section II. We made this change to improve readability and do not intend that it have any substantive legal effect.

Section III, Recommended Activities

The Secretary must recommend the activities for which the PREP Act's liability immunity is in effect. These activities may include, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more Covered Countermeasures (''Recommended Activities'').[7] In the previous declaration, we included the Recommended Activities in section I of the declaration, ''Covered Countermeasures.'' The declaration now states them in section III. We made this change to improve readability and do not intend that it have any substantive legal effect. In addition, we deleted the phrases ''as defined in section IX below'' and ''with respect to the category of disease and population described in sections II and IV below'' for consistency with formatting changes, and changed ''and usage'' to ''or use'' for consistency with the statute. These changes are not intended to have any substantive legal effect.

[3] 42 U.S.C. 247d–6d(b)(1).

[4] 42 U.S.C. 247d.

[5] See 42 U.S.C. 247d–6d(b)(1).

[6] 42 U.S.C. 247d–6d(b)(6).

[7] 42 U.S.C. 247d–6d(b)(1).

Section IV, Liability Immunity

The Secretary must also state that liability protections available under the PREP Act are in effect with respect to the Recommended Activities.[8] These liability protections provide that, ''[s]ubject to other provisions of [the PREP Act], a covered person shall be immune from suit and liability under federal and state law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered countermeasure if a declaration . . . has been issued with respect to such countermeasure.'' [9] In the previous declaration, we included a statement referring to liability immunity specified under the PREP Act in section I of the declaration, ''Covered Countermeasures.'' The declaration now includes the statement that liability immunity is in effect for Recommended Activities in a separate section IV. We made this change to improve readability and do not intend that it have any substantive legal effect.

Section V, Covered Persons

The PREP Act's liability immunity applies to ''Covered Persons'' with respect to administration or use of a Covered Countermeasure. The term ''Covered Persons'' has a specific meaning, and is defined in the PREP Act to include manufacturers, distributors, program planners, and qualified persons, and their officials, agents, and employees, and the United States.[10] The PREP Act further defines the terms ''manufacturer,'' ''distributor,'' ''program planner,'' and ''qualified person'' as described below.[11]

A *manufacturer* includes a contractor or subcontractor of a manufacturer; a supplier or licenser of any product, intellectual property, service, research tool or component or other article used in the design, development, clinical testing, investigation or manufacturing of a Covered Countermeasure; and any or all of the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer; [12]

A *distributor* means a person or entity engaged in the distribution of drug, biologics, or devices, including but not limited to: Manufacturers; repackers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; warehouses and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies.[13]

A *program planner* means a state or local government, including an Indian tribe; a person employed by the state or local government; or other person who supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a Covered Countermeasure, including a person who establishes requirements, provides policy guidance, or supplies technical or scientific advice or assistance or provides a facility to administer or use a Covered Countermeasure in accordance with the Secretary's declaration.[14] Under this definition, a private sector employer or community group or other person can be a program planner when it carries out the described activities.

A *qualified person* means a licensed health professional or other individual who is authorized to prescribe, administer, or dispense Covered Countermeasures under the law of the state in which the countermeasure was prescribed, administered, or dispensed; or a person within a category of persons identified as qualified in the Secretary's declaration.[15] Under this definition, the Secretary can describe in the declaration other qualified persons, such as volunteers, who are Covered Persons. Section V describes other qualified persons covered by this declaration.

The PREP Act also defines the word ''person'' as used in the Act: A *person* includes an individual, partnership, corporation, association, entity, or public or private corporation, including a federal, state, or local government agency or department.[16]

The provisions regarding Covered Persons previously appeared in the declaration as a definition in section IX, ''Definitions'' and in section VI, ''Qualified Persons.'' We combined these two provisions into a new section V, ''Covered Persons'' and added ''to perform an activity'' to the description of ''Other Qualified Persons'' authorized under an Emergency Use Authorization (EUA) for clarity. We made these changes to improve readability and clarity and do not intend them to have any substantive legal effect.

We also modified the description of Covered Persons to include a new category of qualified persons: ''Any person authorized to prescribe, administer, or dispense covered countermeasures in accordance with Section 564A of the FD&C Act.'' This change ensures that persons who prescribe, administer, or dispense covered countermeasures in accordance with section 564A of the FD&C Act are Covered Persons under the declaration.

Section VI, Covered Countermeasures

As noted above, section III describes the Secretary's Recommended Activities for which liability immunity is in effect. This section identifies the countermeasures for which the Secretary has recommended such activities. The PREP Act states that a ''Covered Countermeasure'' must be: A ''qualified pandemic or epidemic product,'' or a ''security countermeasure,'' as described immediately below; or a drug, biological product or device authorized for emergency use in accordance with section 564, 564A, or 564B of the FD&C Act.[17]

A *qualified pandemic or epidemic product* means a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act [18] that is: (i) Manufactured, used, designed, developed, modified, licensed or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm such a pandemic or epidemic might otherwise cause; (ii) manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by such a drug, biological product or device; (iii) or a product or technology intended to enhance the use or effect of such a drug, biological product, or device.[19]

A *security countermeasure* is a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act [20] that: (i) (a) The Secretary determines to be a priority to diagnose, mitigate, prevent or treat harm from any biological, chemical, radiological, or nuclear agent identified as a material threat by the Secretary of Homeland Security, or (b) to diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent; and (ii) is determined by the Secretary of Health and Human Services to be a necessary

[8] 42 U.S.C. 247d–6d(b)(1).

[9] 42 U.S.C. 247d–6d(a)(1).

[10] 42 U.S.C. 247d–6d (i)(2).

[11] 42 U.S.C. 247d–6d(i).

[12] 42 U.S.C. 247d–6d(i)(4).

[13] 42 U.S.C. 247d–6d(i)(3).

[14] 42 U.S.C. 247d–6d(i)(6).

[15] 42 U.S.C. 247d–6d(i)(8).

[16] 42 U.S.C. 247d–6d(i)(5).

[17] 42 U.S.C. 247d–6d(i)(1). Sections 564, 564A, and 564B of the FD&C Act may be found at 21 U.S.C. 360bbb–3, 360bbb–3a, and 360bbb–3b.

[18] 21 U.S.C. 321(g)(1), (h); 42 U.S.C. 262(i).

[19] 42 U.S.C. 247d–6d(i)(1)(A), (i)(7).

[20] 21 U.S.C. 321(g)(1), (h); 42 U.S.C. 262(i).

countermeasure to protect public health.[21]

To be a Covered Countermeasure, qualified pandemic or epidemic products and security countermeasures also must be approved or cleared under the FD&C Act;[22] licensed under the PHS Act;[23] authorized for emergency use under sections 564, 564A, or 564B of the FD&C Act.[24]

A qualified pandemic or epidemic product also may be a Covered Countermeasure when it is subject to an exemption (that is, it is permitted to be used under an Investigational Drug Application or an Investigational Device Exemption) under the FD&C Act[25] and is the object of research for possible use for diagnosis, mitigation, prevention, treatment, cure or limit harm of a pandemic or epidemic or serious or life-threatening condition caused by such a drug or device. A security countermeasure also may be a Covered Countermeasure if it may reasonably be determined to qualify for approval or licensing within 10 years after the Department's determination that procurement of the countermeasure is appropriate.

Provisions regarding Covered Countermeasures appeared in section I of the declaration, ''Covered Countermeasures'' and section IX of the declaration, ''Definitions.'' Section I included not only a description of the Covered Countermeasure but also the Secretary's recommendation, statement regarding liability immunity, and additional conditions characterizing countermeasures. We have combined sections I and IX and simplified the language so that it now only identifies the Covered Countermeasures. We have relocated the other conditions previously included in the ''Covered Countermeasure'' section to new sections, ''Recommended Activities,'' ''Liability Immunity,'' and ''Limitations on Distribution,'' to improve readability. We do not intend for this change to have any substantive legal effect.

Section I of the declaration also stated that the declaration applied to Covered Countermeasures administered or used during the effective time period of the declaration. We have deleted this language as it is redundant of the provisions stated in sections XII, ''Effective Time Period,'' and XIII, ''Additional Time Period of Coverage.''

We have also revised the description and definition of the Covered Countermeasure that previously appeared in sections I, ''Covered Countermeasures'' and IX, ''Definitions.'' Section I referred to the Act for the definition of ''Covered Countermeasures,'' and section IX defined the term ''Botulinum Toxin Countermeasure'' as ''Any vaccine; antimicrobial/antibiotic, other drug or antitoxin; or diagnostic or device to identify, prevent or treat botulinum toxin or adverse events from such countermeasures (1) licensed under section 351 of the Public Health Service Act; (2) approved under section 505 or section 515 of the Federal Food, Drug, and Cosmetic Act (FDCA); (3) cleared under section 510(k) of the FDCA; (4) authorized for emergency use under section 564 of the FDCA; (5) used under section 505(i) of the FDCA or section 351(a)(3) of the PHS Act, and 21 CFR part 312; or (6) used under section 520(g) of the FDCA and 21 CFR part 812.''

We revised the description of botulinum toxin countermeasures to clarify that coverage for vaccines includes components and constituent materials of the vaccines and device and constituent components used in administration of the vaccines and that antitoxins are also covered. The definition now reads: ''Any vaccine, including all components and constituent materials of these vaccines, and all devices and their constituent components used in the administration of these vaccines; any antimicrobial/antibiotic; any other drug or antitoxin; any biologic; or any diagnostic or other device to identify, prevent or treat botulinum toxin or adverse events from such countermeasures.'' These changes are intended as clarification, and are not intended to be substantive.

We also added a statement referencing the statutory definitions of Covered Countermeasures to make clear that these statutory definitions limit the scope of Covered Countermeasures. Specifically, we noted that they must be ''qualified pandemic or epidemic products,'' or ''security countermeasures,'' or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.'' By referencing the statutory provisions, the revised definition also incorporates changes to the PREP Act definitions of covered countermeasure and qualified pandemic or epidemic product made by PAHPRA.

Section VII, Limitations on Distribution

The Secretary may specify that liability immunity is in effect only to Covered Countermeasures obtained through a particular means of distribution.[26] These limitations on distribution previously appeared in section I, ''Covered Countermeasures,'' and section IX, ''Definitions.'' We now state the limitations in a separate section and combine them with relevant definitions for improved readability.

The declaration now states that liability immunity is afforded to Covered Persons for Recommended Activities related to:

(a) Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, or memoranda of understanding or other federal agreements or activities directly conducted by the federal government; or

(b) Activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a declaration of an emergency.

For governmental program planners only, liability immunity is afforded only to the extent they obtain Covered Countermeasures through voluntary means, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from State, local, or private stockpiles.

In regard to (a), we, added the phrase ''other transactions,'' which may be used for some Covered Countermeasure activities,[27] added the phrase ''or other Federal agreements'' to clarify that the provision is intended to cover all types of federal agreements, and added the phrase ''or activities directly conducted by the Federal Government'' to clarify that activities such as manufacture of vaccines for clinical trials by the HHS National Institutes of Health Vaccine Research Center or distribution of countermeasures by federal employees are covered. We changed the conjunction ''and'' to ''or'' between (a) and (b) to clarify that immunity is available under either of these circumstances; the activities do not have to both relate to a federal award or agreement and be used in a public health and medical response in order for immunity to apply. The conjunction ''and'' used in the previous declaration was a drafting error; the Secretary's intent in that previous declarations has been the meaning conferred by the term ''or.'' Provisions (a) and (b) are intended

[21] 42 U.S.C. 247d–6d(i)(1)(B), (c)(1)(B).

[22] 21 U.S.C. 301 *et seq.*

[23] 42 U.S.C. 262.

[24] 21 U.S.C. 360bbb–3, 360bbb–3a, 360bbb–3b.

[25] 21 U.S.C. 355(i), 360j(g).

[26] 42 U.S.C. 247d–6d(a)(5), (b)(2)(E).

[27] See, *e.g.,* 42 U.S.C. 247d–7d(c)(5).

to afford immunity to Federal government conducted and supported activities that precede a public health emergency and to activities in accordance with all Authorities Having Jurisdiction during a declared public health emergency. These changes are intended as clarifications and to improve readability, and are not intended as substantive changes.

In regard to (b), the meaning of the terms ''Authority Having Jurisdiction'' and ''Declaration of an Emergency'' are unchanged.

Finally, we slightly modified the last limitation by deleting extraneous statutory references and other language and by replacing the final sentence with the word ''only'' after ''planners'' to improve readability. We do not intend for the changes to this provision to alter its substantive legal effect. As stated in the ''whereas'' clauses of the prior declaration, this limitation on distribution is intended to deter program planners that are government entities from seizing privately held stockpiles of Covered Countermeasures. It does not apply to any other Covered Persons, including other program planners who are not government entities.

Section VIII, Category of Disease, Health Condition, or Threat

The Secretary must identify, for each Covered Countermeasure, the categories of diseases, health conditions, or threats to health for which the Secretary recommends the administration or use of the countermeasure.[28] This information appeared in section II, ''Category of Disease.''

Section IX, Administration of Covered Countermeasures

The PREP Act does not explicitly define the term ''administration'' but does assign the Secretary the responsibility to provide relevant conditions in the declaration. This definition previously appeared in section IX, ''Definitions.'' We have moved it to a separate section to improve readability. The Secretary has also narrowed the definition of ''administration'' that was previously provided in the declaration. The declaration previously defined the term ''administration'' to include physical provision of a Covered Countermeasure, as well as management and operation of systems and locations at which Covered Countermeasures may be provided to recipients:

Administration of a Covered Countermeasure: As used in section 319F–3(a)(2)(B) of the Act includes, but is not limited to, public and private delivery, distribution, and dispensing activities relating to physical administration of the countermeasures to patients/recipients, management and operation of delivery systems, and management and operation of distribution and dispensing locations.

The definition has been revised as follows:

Administration of a Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients; management and operation of countermeasure programs; or management and operation of locations for purpose of distributing and dispensing countermeasures.

As clarified, ''*administration*'' extends only to physical provision of a countermeasure to a recipient, such as vaccination or handing drugs to patients, and to activities related to management and operation of programs and locations for providing countermeasures to recipients, such as decisions and actions involving security and queuing, but only insofar as those activities directly relate to the countermeasure activities. Claims for which Covered Persons are provided immunity under the Act are losses caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a Covered Countermeasure consistent with the terms of a declaration issued under the Act.[29] Under the Secretary's definition, these liability claims are precluded if the claims allege an injury caused by physical provision of a countermeasure to a recipient, or if the claims are directly due to conditions of delivery, distribution, dispensing, or management and operation of countermeasure programs at distribution and dispensing sites.

Thus, it is the Secretary's interpretation that, when a declaration is in effect, the Act precludes, for example, liability claims alleging negligence by a manufacturer in creating a vaccine, or negligence by a health care provider in prescribing the wrong dose, absent willful misconduct. Likewise, the Act precludes a liability claim relating to the management and operation of a countermeasure distribution program or site, such as a ''slip-and-fall'' injury or vehicle collision by a recipient receiving a countermeasure at a retail store serving as an administration or dispensing location that alleges, for example, lax security or chaotic crowd control. However, a liability claim alleging an injury occurring at the site that was not directly related to the countermeasure activities is not covered, such as a slip and fall with no direct connection to the countermeasure's administration or use. In each case, whether immunity is applicable will depend on the particular facts and circumstances.

Section X, Population

The Secretary must identify, for each Covered Countermeasure specified in a declaration, the population or populations of individuals for which liability immunity is in effect with respect to administration or use of the countermeasure.[30] This section explains which individuals should use the countermeasure or to whom the countermeasure should be administered—in short, those who should be vaccinated or take a drug or other countermeasure. These provisions previously appeared in section IV, ''Population.'' The previous declaration stated that the population specified in the declaration included:

The populations specified in this declaration are all persons who use a Covered Countermeasure or to whom a Covered Countermeasure is administered in accordance with this declaration, including, but not limited to: (1) Any person conducting research and development of Covered Countermeasures directly for the federal government or pursuant to a contract, grant, or cooperative agreement with the federal government; (2) any person who receives a Covered Countermeasure from persons authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasure, and their officials, agents, employees, contractors, and volunteers following a declaration of an emergency; (3) any person who receives a Covered Countermeasure from a person authorized to prescribe, administer or dispense the countermeasure or who is otherwise authorized to prescribe, administer or dispense the countermeasure under an EUA; (4) any person who receives a Covered Countermeasure as an investigational new drug in human clinical trials being conducted directly by the federal government or pursuant to a contract, grant, or cooperative agreement with the federal government.

[28] 42 U.S.C. 247d–6d(b)(2)(A).

[29] 42 U.S.C. 247d–6d(a).

[30] 42 U.S.C. 247d–6d(b)(2)(C).

We have amended the declaration to provide that the population includes ''any individual who uses or who is administered a Covered Countermeasure in accordance with the declaration.'' We believe this broad statement accurately encompasses all of the previously listed populations given as examples of that phrase and ensures that no populations that use or are administered the Covered Countermeasures in accordance with the terms of the declaration are omitted.

In addition, the PREP Act specifies that liability immunity is afforded: (1) To manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; and (2) to program planners and qualified persons when the countermeasure is either used by or administered to this population or the program planner or qualified person reasonably could have believed the recipient was in this population.[31] We included these statutory conditions in the declaration for clarity.

Section XI, Geographic Area

The Secretary must identify, for each Covered Countermeasure specified in the declaration, the geographic area or areas for which liability immunity is in effect with respect to administration or use of the countermeasure, including, as appropriate, whether the declaration applies only to individuals physically present in the area or, in addition, applies to individuals who have a described connection to the area.[32] This section previously appeared in section V, ''Geographic Area.''

In addition, the PREP Act specifies that liability immunity is afforded: (1) To manufacturers and distributors without regard to whether the countermeasure is used by or administered to individuals in the geographic areas; and (2) to program planners and qualified persons when the countermeasure is either used or administered in the geographic areas or the program planner or qualified person reasonably could have believed the countermeasure was used or administered in the areas.[33] We included these statutory conditions in the declaration for clarity.

Section XII, Effective Time Period

The Secretary must identify, for each Covered Countermeasure, the period or periods during which liability immunity is in effect, designated by dates, milestones, or other description of events, including factors specified in the PREP Act.[34] This section previously appeared as section III, ''Effective Time Period.''

The declaration is amended to clarify when liability takes effect for different means of distribution. These changes are intended to have no legal effect. The declaration is also amended to extend the period for which liability immunity is in effect. The previous declaration was in effect through December 31, 2015. We have extended the effective time period to December 31, 2022.

Section XIII, Additional Time Period of Coverage

The Secretary must specify a date after the ending date of the effective period of the declaration that is reasonable for manufacturers to arrange for disposition of the Covered Countermeasure, including return of the product to the manufacturer, and for other Covered Persons to take appropriate actions to limit administration or use of the Covered Countermeasure.[35] In addition, the PREP Act specifies that for Covered Countermeasures that are subject to a declaration at the time they are obtained for the Strategic National Stockpile (SNS) under 42 U.S.C. 247d-6b(a), the effective period of the declaration extends through the time the countermeasure is used or administered pursuant to a distribution or release from the Stockpile. Liability immunity under the provisions of the PREP Act and the conditions of the declaration continues during these additional time periods. Thus, liability immunity is afforded during the ''Effective Time Period,'' described under XII of the declaration, plus the ''Additional Time Period'' described under section XIII of the declaration.

The provision for additional time periods previously appeared as section VII, ''Additional Time Periods of Coverage After Expiration of the Declaration.'' The provision is amended to clarify the statutory provisions as they apply to manufacturers and to other covered persons, and to clarify that extended coverage applies to any products obtained for the SNS during the effective period of the declaration. We included the statutory provision for clarity.

Section XIV, Countermeasures Injury Compensation Program

Section 319F–4 of the PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to eligible individuals who sustain a serious physical injury or die as a direct result of the administration or use of a Covered Countermeasure.[36] Compensation under the CICP for an injury directly caused by a Covered Countermeasure is based on the requirements set forth in this declaration, the administrative rules for the Program,[37] and the statute.[38] To show direct causation between a Covered Countermeasure and a serious physical injury, the statute requires ''compelling, reliable, valid, medical and scientific evidence.'' [39] The administrative rules for the Program further explain the necessary requirements for eligibility under the CICP. Please note that, by statute, requirements for compensation under the CICP may not always align with the requirements for liability immunity provided under the PREP Act. We have added section XIV, ''Countermeasures Injury Compensation Program'' to explain the types of injury and standard of evidence needed to be considered for compensation under the CICP. We included this information to inform readers of this Program.

Section XV, Amendments

The Secretary may amend any portion of a declaration through publication in the **Federal Register**.[40] This section previously appeared in section VIII, ''Amendments.'' The section has been updated to reflect that the Republished Declaration amends the prior October 10, 2008, declaration.

Deleted Sections

The prior declaration included ''whereas'' clauses as introductory to the declaration. As described above, we have incorporated whereas clauses that made necessary findings under the PREP Act into the text of the declaration itself. We have deleted the remaining whereas clauses. We do not intend this change to have legal effect.

The prior declaration contained a definitions section. These definitions have been incorporated into the relevant sections of the declaration as noted above, and modified or deleted where indicated above.

An appendix appeared in the declaration that listed federal government contracts for research, development, and procurement of Covered Countermeasures. We deleted this appendix to clarify that liability

[31] 42 U.S.C. 247d–6d(a)(4).

[32] 42 U.S.C. 247d–6d(b)(2)(D).

[33] 42 U.S.C. 247d–6d(a)(4).

[34] 42 U.S.C. 246d–6d(b)(2)(B), (b)(6).

[35] 42 U.S.C. 247d–6d(b)(3).

[36] 42 U.S.C. 247d–6e.

[37] 42 CFR part 110.

[38] 42 U.S.C. 247d–6e.

[39] 42 U.S.C. 247d–6e(b)(4).

[40] 42 U.S.C. 247d–6d(b)(4).

immunity under the provisions of the PREP Act and terms of the declaration is not limited to the contracts listed in the appendix. Coverage is available for any award or agreement that meets the description provided in section VII of the declaration. In addition, deleting the appendix relieves the Department of the need to periodically update the appendix.

We made these deletions for clarity and do not intend them to have legal effect.

Republished Declaration

Declaration, as Amended, for Public Readiness and Emergency Preparedness Act Coverage for Botulinum Toxin Countermeasures

This declaration amends and republishes the October 10, 2008, Declaration Under the PREP Act for botulinum toxin countermeasures. To the extent any term of the October 10, 2008, Declaration is inconsistent with any provision of this Republished Declaration, the terms of this Republished Declaration are controlling.

I. Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

42 U.S.C. 247d–6d(b)(1)

I have determined that there is a credible risk that exposure to botulinum toxin(s) and the resulting diseases or conditions from manmade or natural sources may in the future constitute a public health emergency.

II. Factors Considered

42 U.S.C. 247d–6d(b)(6)

I have considered the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the Covered Countermeasures.

III. Recommended Activities

42 U.S.C. 247d–6d(b)(1)

I recommend, under the conditions stated in this declaration, the manufacture, testing, development, distribution, administration, or use of the Covered Countermeasures.

IV. Liability Immunity

42 U.S.C. 247d–6d(a), 247d–6d(b)(1)

Liability immunity as prescribed in the PREP Act and conditions stated in this declaration is in effect for the Recommended Activities described in section III.

V. Covered Persons

42 U.S.C. 247d–6d(i)(2), (3), (4), (6), (8)(A) and (B)

Covered Persons who are afforded liability immunity under this declaration are manufacturers, distributors, program planners, qualified persons, and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States.

In addition, I have determined that the following additional persons are qualified persons: (a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a declaration of an emergency; (b) Any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an EUA in accordance with section 564 of the FD&C Act; (c) Any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act.

VI. Covered Countermeasures

42 U.S.C. 247d–6b(c)(1)(B), 42 U.S.C. 247d–6d(i)(1) and (7)

Covered Countermeasures are any vaccine, including all components and constituent materials of these vaccines, and all devices and their constituent components used in the administration of these vaccines; any antimicrobial/antibiotic; any other drug or antitoxin; any biologic; or any diagnostic or other device to identify, prevent or treat botulinum toxin or adverse events from such countermeasures.

Covered Countermeasures must be ''qualified pandemic or epidemic products,'' or ''security countermeasures,'' or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.

VII. Limitations on Distribution

42 U.S.C. 247d–6d(a)(5) and (b)(2)(E)

I have determined that liability immunity is afforded to Covered Persons only for Recommended Activities involving Covered Countermeasures that are related to:

(a) Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements, or activities directly conducted by the federal government; or

(b) Activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a declaration of an emergency.

i. The Authority Having Jurisdiction means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (*e.g.,* city, county, Tribal, State, or Federal boundary lines) or functional (*e.g.,* law enforcement, public health) range or sphere of authority.

ii. A declaration of emergency means any declaration by any authorized local, regional, State, or Federal official of an emergency specific to events that indicate an immediate need to administer and use the Covered Countermeasures, with the exception of a Federal declaration in support of an Emergency Use Authorization under section 564 of the FD&C Act unless such declaration specifies otherwise;

I have also determined that for governmental program planners only, liability immunity is afforded only to the extent such program planners obtain Covered Countermeasures through voluntary means, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from state, local, or private stockpiles.

VIII. Category of Disease, Health Condition, or Threat

42 U.S.C. 247d–6d(b)(2)(A)

The category of disease, health condition, or threat for which I recommend the administration or use of the Covered Countermeasures is botulinum toxin resulting from exposure to botulinum toxin(s).

IX. Administration of Covered Countermeasures

42 U.S.C. 247d–6d(a)(2)(B)

Administration of the Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations

for purpose of distributing and dispensing countermeasures.

X. Population

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(C)

The populations of individuals include any individual who uses or is administered the Covered Countermeasures in accordance with this declaration.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered to this population or the program planner or qualified person reasonably could have believed the recipient was in this population.

XI. Geographic Area

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(D)

Liability immunity is afforded for the administration or use of a Covered Countermeasure without geographic limitation.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered in these geographic areas; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered in these geographic areas, or the program planner or qualified person reasonably could have believed the recipient was in these geographic areas.

XII. Effective Time Period

42 U.S.C. 247d–6d(b)(2)(B)

Liability immunity for Covered Countermeasures obtained through means of distribution other than in accordance with the public health and medical response of the Authority Having Jurisdiction extends through December 31, 2022.

Liability immunity for Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction begins with a declaration and lasts through (1) the final day the emergency declaration is in effect or (2) December 31, 2022, whichever occurs first.

XIII. Additional Time Period of Coverage

42 U.S.C. 247d–6d(b)(3)(A), (B) and (C)

I have determined that an additional twelve (12) months of liability protection is reasonable to allow for the manufacturer(s) to arrange for disposition of the Covered Countermeasure, including return of the Covered Countermeasures to the manufacturer, and for Covered Persons to take such other actions as are appropriate to limit the administration or use of the Covered Countermeasures.

Covered Countermeasures obtained for the SNS during the effective period of this declaration for Covered Countermeasures obtained through means of distribution other than in accordance with the public health and medical response of the Authority Having Jurisdiction are covered through the date of administration or use pursuant to a distribution or release from the SNS.

XIV. Countermeasures Injury Compensation Program

2 U.S.C. 247d–6e

The PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to certain individuals or estates of individuals who sustain a serious physical covered injury as the direct result of the administration or use of the Covered Countermeasures and/or benefits to certain survivors of individuals who die as a direct result of the administration or use of the Covered Countermeasures. The causal connection between the countermeasure and the serious physical injury must be supported by compelling, reliable, valid, medical and scientific evidence in order for the individual to be considered for compensation. The CICP is administered by the Health Resources and Services Administration, within the Department of Health and Human Services. Information about the CICP is available at 855–266–2427 (toll-free) or *http://www.hrsa.gov/cicp/.*

XV. Amendments

42 U.S.C. 247d–6d(b)(4)

The October 10, 2008, Declaration Under the Public Readiness and Emergency Preparedness Act for botulinum toxin countermeasures was first published on October 17, 2008. This is the first amendment to that declaration.

Any further amendments to this declaration will be published in the **Federal Register**.

Authority: 42 U.S.C. 247d–6d.

Dated: December 1, 2015.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2015–31091 Filed 12–8–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Ebola Virus Disease Therapeutics—Amendment

ACTION: Notice of Amendment to the February 27, 2015, Declaration under the Public Readiness and Emergency Preparedness Act.

SUMMARY: The Secretary is amending the February 27, 2015 Declaration issued pursuant to section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d) (80 FR 22534) to extend the effective time period for an additional twelve (12) months consistent with the terms of the Declaration and republishing the Declaration in its entirety as amended.

DATES: The Amended Declaration is effective as of February 27, 2016.

FOR FURTHER INFORMATION CONTACT: Nicole Lurie, MD, MSPH, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW., Washington, DC 20201; Telephone 202–205–2882.

SUPPLEMENTARY INFORMATION:

Background

The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the administration or use of medical countermeasures (Covered Countermeasures), except for claims that meet the PREP Act's definition of willful misconduct. The Secretary may, though publication in the **Federal Register**, amend any portion of a Declaration. Using this authority, the Secretary is amending the Declaration that provides liability immunity to Covered Persons for activities related to the Covered Countermeasures, Ebola Virus Disease Therapeutics as listed in Section VI of the Declaration to extend the effective time period for an additional twelve (12) months, consistent with the terms of this Declaration.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, Section 2. It amended the Public Health Service (PHS) Act, adding section 319F–3, which addresses liability immunity, and section 319F–4, which creates a compensation program. These sections are codified in the U.S. Code as 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively.

The Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, was enacted on March 13, 2013. Among other things, PAHPRA added sections 564A and 564B to the Federal Food, Drug, and Cosmetic (FD&C) Act to provide authorities for the emergency use of approved products in emergencies and products held for emergency use.

PAHPRA accordingly amended the definitions of ''Covered Countermeasures'' and ''qualified pandemic and epidemic products'' in section 319F–3 of the Public Health Service Act (PREP Act provisions), so that products made available under these new FD&C Act authorities could be covered under PREP Act Declarations. PAHPRA also extended the definition of qualified pandemic and epidemic products that may be covered under a PREP Act Declaration to include products or technologies intended to enhance the use or effect of a drug, biological product, or device used against the pandemic or epidemic or against adverse events from these products.

The Ebola virus causes an acute, serious illness that is often fatal. Since March 2014, West Africa has been experiencing the largest and most complex Ebola outbreak since the virus was first discovered in 1976, affecting populations in multiple West African countries and travelers from West Africa to the United States (U.S.) and other countries. The World Health Organization declared the Ebola Virus Disease Outbreak as a Public Health Emergency of International Concern under the framework of the International Health Regulations (2005).

Unless otherwise noted, all statutory citations below are to the U.S. Code.

Section I, Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

Before issuing a Declaration under the PREP Act, the Secretary is required to determine that a disease or other health condition or threat to health constitutes a public health emergency or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency. This determination is separate and apart from a Declaration issued by the Secretary under section 319 of the PHS Act that a disease or disorder presents a public health emergency or that a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists, or other Declarations or determinations made under other authorities of the Secretary. Accordingly, in Section I, the Secretary determines that there is a credible risk that the spread of Ebola virus and the resulting disease may constitute a public health emergency.

Section II, Factors Considered

In deciding whether and under what circumstances to issue a Declaration with respect to a Covered Countermeasure, the Secretary must consider the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the countermeasure. In Section II, the Secretary states that she has considered these factors.

Section III, Recommended Activities

The Secretary must recommend the activities for which the PREP Act's liability immunity is in effect. These activities may include, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more Covered Countermeasures (''Recommended Activities''). In Section III, the Secretary recommends activities for which the immunity is in effect under the conditions stated in the Declaration, including the condition that the activities relate to clinical trials permitted to proceed after review by the Food and Drug Administration (FDA) that administer or use the Covered Countermeasure under an investigational new drug application (IND) and that are directly supported by the U.S. The Secretary specifies that the term ''directly supported'' in this Declaration means that the United States has provided some form of tangible support such as supplies, funds, products, technical assistance, or staffing. This condition is intended to afford liability immunity only to activities related to clinical trials using the Covered Countermeasure being conducted in the U.S. and West Africa that are directly supported by the U.S.

Section IV, Liability Immunity

The Secretary must also state that liability protections available under the PREP Act are in effect with respect to the Recommended Activities. These liability protections provide that, ''[s]ubject to other provisions of [the PREP Act], a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered countermeasure if a Declaration . . . has been issued with respect to such countermeasure.'' In Section IV, the Secretary states that liability protections are in effect with respect to the Recommended Activities.

Section V, Covered Persons

The PREP Act's liability immunity applies to Covered Persons with respect to administration or use of a Covered Countermeasure. The term ''Covered Persons'' has a specific meaning and is defined in the PREP Act to include manufacturers, distributors, program planners, and qualified persons, and their officials, agents, and employees, and the U.S. The PREP Act further defines the terms ''manufacturer,'' ''distributor,'' ''program planner,'' and ''qualified person'' as described below.

A manufacturer includes a contractor or subcontractor of a manufacturer; a supplier or licenser of any product, intellectual property, service, research tool or component or other article used in the design, development, clinical testing, investigation or manufacturing of a Covered Countermeasure; and any or all of the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer.

A distributor means a person or entity engaged in the distribution of drug, biologics, or devices, including but not limited to: manufacturers; repackers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; warehouses and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies.

A program planner means a state or local government, including an Indian tribe; a person employed by the state or local government; or other person who supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a Covered Countermeasure, including a person who establishes requirements, provides policy guidance, or supplies technical or scientific advice or assistance or provides a facility to administer or use a Covered Countermeasure in accordance with the Secretary's Declaration. Under this definition, a private-sector employer or community group or other ''person'' can

be a program planner when it carries out the described activities.

A qualified person means a licensed health professional or other individual authorized to prescribe, administer, or dispense Covered Countermeasures under the law of the state in which the countermeasure was prescribed, administered, or dispensed; or a person within a category of persons identified as qualified in the Secretary's Declaration. Under this definition, the Secretary can describe in the Declaration other qualified persons, such as volunteers, who are Covered Persons. Section V describes other qualified persons covered by this Declaration.

The PREP Act also defines the word ''person'' as used in the Act: A person includes an individual, partnership, corporation, association, entity, or public or private corporation, including a federal, State, or local government agency or department. Section V describes Covered Persons under the Declaration, including Qualified Persons.

Section VI, Covered Countermeasures

As noted above, section III describes the Secretary's Recommended Activities for which liability immunity is in effect. Section VI identifies the countermeasures for which the Secretary has recommended such activities. The PREP Act states that a Covered Countermeasure must be: A ''qualified pandemic or epidemic product,'' or a ''security countermeasure,'' as described immediately below; or a drug, biological product or device authorized for emergency use in accordance with sections 564, 564A, or 564B of the FD&C Act.

A qualified pandemic or epidemic product means a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act that is: (i) Manufactured, used, designed, developed, modified, licensed or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm such a pandemic or epidemic might otherwise cause; (ii) manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by such a drug, biological product, or device; (iii) or a product or technology intended to enhance the use or effect of such a drug, biological product, or device.

A security countermeasure is a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act that: (i)(a) The Secretary determines to be a priority to diagnose, mitigate, prevent, or treat harm from any biological, chemical, radiological, or nuclear agent identified as a material threat by the Secretary of Homeland Security, or (b) to diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent; and (ii) is determined by the Secretary of Health and Human Services to be a necessary countermeasure to protect public health.

To be a Covered Countermeasure, qualified pandemic or epidemic products or security countermeasures also must be approved or cleared under the FD&C Act; licensed under the PHS Act; or authorized for emergency use under sections 564, 564A, or 564B of the FD&C Act.

A qualified pandemic or epidemic product also may be a Covered Countermeasure when it is subject to an exemption (that is, it is permitted to be used under an Investigational Drug Application or an Investigational Device Exemption) under the FD&C Act and is the object of research for possible use for diagnosis, mitigation, prevention, treatment, or cure, or to limit harm of a pandemic or epidemic or serious or life-threatening condition caused by such a drug or device. A security countermeasure also may be a Covered Countermeasure if it may reasonably be determined to qualify for approval or licensing within 10 years after the Department's determination that procurement of the countermeasure is appropriate.

Section VI lists the Ebola Virus Disease Therapeutics that are Covered Countermeasures. Section VI also refers to the statutory definitions of Covered Countermeasures to make clear that these statutory definitions limit the scope of Covered Countermeasures. Specifically, the Declaration notes that Covered Countermeasures must be ''qualified pandemic or epidemic products, or security countermeasures, or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.''

Section VII, Limitations on Distribution

The Secretary may specify that liability immunity is in effect only to Covered Countermeasures obtained through a particular means of distribution. The Declaration states that liability immunity is afforded to Covered Persons for Recommended Activities related to clinical trials permitted to proceed after FDA review, that administer or use the Covered Countermeasure under an IND, and directly supported by the U.S., as described in Section III of this Declaration, through present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, or memoranda of understanding or other federal agreements or arrangements.

This limitation is intended to afford liability immunity to activities that are related to clinical trials permitted to proceed after FDA review that administer or use the Covered Countermeasure under an IND and that are directly supported by the U.S. As stated in Section III of the Declaration, the term ''directly support'' means that the U.S. has provided some form of tangible support such as supplies, funds, products, technical assistance, or staffing. As of the date of this Declaration, activities primarily are those with a direct connection to the conduct of clinical trials in the U.S. and West Africa, but this Declaration also would apply to use in qualifying clinical trials outside those areas.

For governmental program planners only, liability immunity is afforded only to the extent they obtain Covered Countermeasures through voluntary means, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from State, local, or private stockpiles.

This last limitation on distribution is intended to deter program planners that are government entities from seizing privately held stockpiles of Covered Countermeasures. It does not apply to any other Covered Persons, including other program planners who are not government entities.

Section VIII, Category of Disease, Health Condition, or Threat

The Secretary must identify, for each Covered Countermeasure, the categories of diseases, health conditions, or threats to health for which the Secretary recommends the administration or use of the countermeasure. In Section VIII, the Secretary states that the disease threat for which she recommends administration or use of the Covered Countermeasures is Ebola virus disease.

Section IX, Administration of Covered Countermeasures

The PREP Act does not explicitly define the term ''administration'' but

does assign the Secretary the responsibility to provide relevant conditions in the Declaration. In Section IX, the Secretary defines ''Administration of a Covered Countermeasure:''

Administration of a Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution, and dispensing of the countermeasures to recipients; management and operation of countermeasure programs; or management and operation of locations for purpose of distributing and dispensing countermeasures.

The definition of ''administration'' extends only to physical provision of a countermeasure to a recipient, such as vaccination or handing drugs to patients, and to activities related to management and operation of programs and locations for providing countermeasures to recipients, such as decisions and actions involving security and queuing, but only insofar as those activities directly relate to the countermeasure activities. Claims for which Covered Persons are provided immunity under the Act are losses caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a Covered Countermeasure consistent with the terms of a Declaration issued under the Act. Under the Secretary's definition, these liability claims are precluded if the claims allege an injury caused by physical provision of a countermeasure to a recipient, or if the claims are directly due to conditions of delivery, distribution, dispensing, or management and operation of countermeasure programs at distribution and dispensing sites.

Thus, it is the Secretary's interpretation that, when a Declaration is in effect, the Act precludes, for example, liability claims alleging negligence by a manufacturer in creating a therapeutic, or negligence by a health care provider in prescribing the wrong dose, absent willful misconduct. Likewise, the Act precludes a liability claim relating to the management and operation of a countermeasure distribution program or site, such as a slip-and-fall injury or vehicle collision by a recipient receiving a countermeasure at a retail store serving as an administration or dispensing location that alleges, for example, lax security or chaotic crowd control. However, a liability claim alleging an injury occurring at the site that was not directly related to the countermeasure activities is not covered, such as a slip-and-fall with no direct connection to the countermeasure's administration or use. In each case, whether immunity is applicable will depend on the particular facts and circumstances.

Section X, Population

The Secretary must identify, for each Covered Countermeasure specified in a Declaration, the population or populations of individuals for which liability immunity is in effect with respect to administration or use of the countermeasure. This section explains which individuals should use the countermeasure or to whom the countermeasure should be administered—in short, those who should be vaccinated or take a drug or other countermeasure. Section X provides that the population includes ''any individual who uses or who is administered a Covered Countermeasure in accordance with the Declaration.''

In addition, the PREP Act specifies that liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to this Population and to program planners and qualified persons when the countermeasure is either used by or administered to this population or the program planner or qualified person reasonably could have believed the recipient was in this population. Section X includes these statutory conditions in the Declaration for clarity.

Section XI, Geographic Area

The Secretary must identify, for each Covered Countermeasure specified in the Declaration, the geographic area or areas for which liability immunity is in effect with respect to administration or use of the countermeasure, including, as appropriate, whether the Declaration applies only to individuals physically present in the area or, in addition, applies to individuals who have a described connection to the area. Section XI provides that liability immunity is afforded for the administration or use of a Covered Countermeasure without geographic limitation. This could include claims related to administration or use in West Africa. It is possible that claims may arise in regard to administration or use of the Covered Countermeasures outside the U.S. that may be resolved under U.S. law.

In addition, the PREP Act specifies that liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to individuals in the geographic areas and to program planners and qualified persons when the countermeasure is either used or administered in the geographic areas or the program planner or qualified person reasonably could have believed the countermeasure was used or administered in the areas. Section XI includes these statutory conditions in the Declaration for clarity.

Section XII, Effective Time Period

The Secretary must identify for each Covered Countermeasure the period or periods during which liability immunity is in effect, designated by dates, milestones, or other description of events, including factors specified in the PREP Act. Section XII identifies the effective time period. The effective time period commences at the start of clinical trials permitted to proceed after FDA review that administer or use the Covered Countermeasure under an IND and that are directly supported by the U.S., as described in Section III of the Declaration. Liability immunity is afforded to claims arising from such administration or use of the Covered Countermeasures after that date that have a causal relationship with any of the Recommended Activities stated in this Declaration. Section XII is amended to extend the effective time period an additional twelve (12) months.

Section XIII, Additional Time Period of Coverage

The Secretary must specify a date after the ending date of the effective period of the Declaration that is reasonable for manufacturers to arrange for disposition of the Covered Countermeasure, including return of the product to the manufacturer, and for other Covered Persons to take appropriate actions to limit administration or use of the Covered Countermeasure. In addition, the PREP Act specifies that for Covered Countermeasures that are subject to a Declaration at the time they are obtained for the Strategic National Stockpile (SNS) under 42 U.S.C. 247d–6b(a), the effective period of the Declaration extends through the time the countermeasure is used or administered pursuant to a distribution or release from the SNS. Liability immunity under the provisions of the PREP Act and the conditions of the Declaration continues during these additional time periods. Thus, liability immunity is afforded during the ''Effective Time Period,'' described under XII of the Declaration, plus the ''Additional Time Period'' described under section XIII of the Declaration.

Section XIII provides for twelve (12) months as the additional time period of coverage after expiration of the

Declaration. Section XIII also explains the extended coverage that applies to products obtained for the SNS during the effective period of the Declaration.

Section XIV, Countermeasures Injury Compensation Program

Section 319F–4 of the PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to eligible individuals who sustain a serious physical injury or die as a direct result of the administration or use of a Covered Countermeasure. Compensation under the CICP for an injury directly caused by a Covered Countermeasure is based on the requirements set forth in this Declaration, the administrative rules for the Program, and the statute. To show direct causation between a Covered Countermeasure and a serious physical injury, the statute requires ''compelling, reliable, valid, medical and scientific evidence.''

The administrative rules for the Program further explain the necessary requirements for eligibility under the CICP. Please note that, by statute, requirements for compensation under the CICP may not always align with the requirements for liability immunity provided under the PREP Act. Section XIV, Countermeasures Injury Compensation Program explains the types of injury and standard of evidence needed to be considered for compensation under the CICP.

Further, the administrative rules for the CICP specify if countermeasures are administered or used outside the U.S., only otherwise eligible individuals at American embassies, military installations abroad (such as military bases, ships, and camps) or at North Atlantic Treaty Organization (NATO) installations (subject to the NATO Status of Forces Agreement) where American servicemen and servicewomen are stationed may be considered for CICP benefits. Other individuals outside the U.S. may not be eligible for CICP benefits.

Section XV, Amendments

This is the first amendment to the February 27, 2015, Declaration (80 FR 73314). The Secretary may amend any portion of a Declaration through publication in the **Federal Register**.

Republished Declaration

Declaration, as Amended, Public Readiness and Emergency Preparedness Act Coverage for Ebola Virus Disease Therapeutics

This Declaration amends and republishes the February 27, 2015 for coverage under the Public Readiness and Emergency Preparedness (PREP) Act for Ebola Virus Disease Therapeutics. To the extent any term of the February 27, 2015, Declaration is inconsistent with any provision of this Republished Declaration, the terms of this Republished Declaration are controlling.

I. Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

42 U.S.C. 247d–6d(b)(1)

I have determined that there is a credible risk that the spread of Ebola virus and the resulting disease or conditions may in the future constitute a public health emergency.

II. Factors Considered

42 U.S.C. 247d–6d(b)(6)

I have considered the desirability of encouraging the design, development, clinical testing, or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the Covered Countermeasures.

III. Recommended Activities

42 U.S.C. 247d–6d(b)(1)

I recommend the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures under the conditions stated in this Declaration, including the condition that the activities relate to clinical trials permitted to proceed after review by the Food and Drug Administration (FDA) that administer or use the Covered Countermeasure under an IND application and that are directly supported by the U.S. The term ''directly supported'' in this Declaration means that the U.S. has provided some form of tangible support such as supplies, funds, products, technical assistance, or staffing.

IV. Liability Immunity

42 U.S.C. 247d–6d(a), 247d–6d(b)(1)

Liability immunity as prescribed in the PREP Act and conditions stated in this Declaration is in effect for the Recommended Activities described in section III.

V. Covered Persons

42 U.S.C. 247d–6d(i)(2), (3), (4), (6), (8)(A) and (B)

Covered Persons who are afforded liability immunity under this Declaration are manufacturers, distributors, program planners, qualified persons, and their officials, agents, and employees, as those terms are defined in the PREP Act, and the U.S. In addition, I have determined that the following additional persons are qualified persons: Any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity to carry out clinical trials permitted to proceed after FDA review that administer or use the Covered Countermeasure under an IND and that are directly supported by the United States, as described in Section III of this Declaration.

VI. Covered Countermeasures

42 U.S.C. 247d–6b(c)(1)(B), 42 U.S.C. 247d–6d(i)(1) and (7)

Covered Countermeasures are the following Ebola Virus Disease Therapeutics: ZMapp monoclonal antibody therapeutic.

Covered Countermeasures must be ''qualified pandemic or epidemic products,'' or ''security countermeasures,'' or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.

VII. Limitations on Distribution

42 U.S.C. 247d–6d(a)(5) and (b)(2)(E)

I have determined that liability immunity is afforded to Covered Persons only for Recommended Activities involving Covered Countermeasures that are related to clinical trials permitted to proceed after FDA review that administer or use the Covered Countermeasure under an IND and that are directly supported by the United States, as described in Section III of this Declaration, through present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements or arrangements.

I have also determined that for governmental program planners only, liability immunity is afforded only to the extent such program planners obtain Covered Countermeasures through voluntary means, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from State, local, or private stockpiles.

VIII. Category of Disease, Health Condition, or Threat

42 U.S.C. 247d–6d(b)(2)(A)

The category of disease, health condition, or threat for which I recommend the administration or use of the Covered Countermeasures is Ebola virus disease.

IX. Administration of Covered Countermeasures

42 U.S.C. 247d–6d(a)(2)(B)

Administration of the Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for purpose of distributing and dispensing countermeasures.

X. Population

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(C)

The populations of individuals include any individual who uses or is administered the Covered Countermeasures in accordance with this Declaration.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered to this population, or the program planner or qualified person reasonably could have believed the recipient was in this population.

XI. Geographic Area

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(D)

Liability immunity is afforded for the administration or use of a Covered Countermeasure without geographic limitation.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered in any designated geographic area; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered in any designated geographic area, or the program planner or qualified person reasonably could have believed the recipient was in that geographic area.

XII. Effective Time Period

42 U.S.C. 247d–6d(b)(2)(B)

Liability immunity for Covered Countermeasures began on February 27, 2015, and extends for twenty-four (24) months.

XIII. Additional Time Period of Coverage

42 U.S.C. 247d–6d(b)(3)(B) and (C)

I have determined that an additional twelve (12) months of liability protection is reasonable to allow for the manufacturer(s) to arrange for disposition of the Covered Countermeasure, including return of the Covered Countermeasures to the manufacturer, and for Covered Persons to take such other actions as are appropriate to limit the administration or use of the Covered Countermeasures.

Covered Countermeasures obtained for the SNS during the effective period of this Declaration are covered through the date of administration or use pursuant to a distribution or release from the SNS.

XIV. Countermeasures Injury Compensation Program

42 U.S.C 247d–6e

The PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of the Covered Countermeasures, and benefits to certain survivors of individuals who die as a direct result of the administration or use of the Covered Countermeasures. The causal connection between the countermeasure and the serious physical injury must be supported by compelling, reliable, valid, medical and scientific evidence in order for the individual to be considered for compensation. The CICP is administered by the Health Resources and Services Administration, within the Department of Health and Human Services. Information about the CICP is available by telephone at 855–266–2427 (toll-free) or *http://www.hrsa.gov/cicp/.*

XV. Amendments

42 U.S.C. 247d–6d(b)(4)

Any amendments to this Declaration will be published in the **Federal Register**.

Authority: 42 U.S.C. 247d–6d.

Dated: December 1, 2015.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2015–31089 Filed 12–8–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Ebola Virus Disease Vaccines—Amendment

ACTION: Notice of Amendment to the December 3, 2014 Declaration under the Public Readiness and Emergency Preparedness Act.

SUMMARY: The Secretary is amending the Declaration issued pursuant to section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d) on December 3, 2014 (79 FR 73314) to extend the effective time period for an additional twelve (12 months) to clarify the list of Covered Countermeasures, and to clarify Covered Persons consistent with the terms of the declaration and republishing the Declaration in its entirety as amended.

DATES: The Amended Declaration is effective as of December 3, 2015.

FOR FURTHER INFORMATION CONTACT: Nicole Lurie, MD, MSPH, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW., Washington, DC 20201, Telephone 202–205–2882.

SUPPLEMENTARY INFORMATION:

Background

The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a Declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the administration or use of medical countermeasures (Covered Countermeasures), except for claims that meet the PREP Act's definition of willful misconduct. The Secretary may, though publication in the **Federal Register**, amend any portion of a Declaration. Using this authority, the Secretary is amending the Declaration that provides liability immunity to Covered Persons for activities related to the Covered Countermeasures, Ebola Virus Disease Vaccines listed in Section VI of the Declaration, to extend the effective time period for an additional

twelve (12) months; to clarify the identification of Covered Countermeasures, and clarify Covered Persons, consistent with the terms of this Declaration.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, Section 2. It amended the Public Health Service (PHS) Act, adding section 319F–3, which addresses liability immunity, and section 319F–4, which creates a compensation program. These sections are codified in the U.S. Code as 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively.

The Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, was enacted on March 13, 2013. Among other things, PAHPRA added sections 564A and 564B to the Federal Food, Drug, & Cosmetic (FD&C) Act to provide new authorities for the emergency use of approved products in emergencies and products held for emergency use. PAHPRA accordingly amended the definitions of ''Covered Countermeasures'' and ''qualified pandemic and epidemic products'' in section 319F–3 of the Public Health Service Act (PREP Act provisions), so that products made available under these new FD&C Act authorities could be covered under PREP Act Declarations. PAHPRA also extended the definition of qualified pandemic and epidemic products that may be covered under a PREP Act Declaration to include products or technologies intended to enhance the use or effect of a drug, biological product, or device used against the pandemic or epidemic or against adverse events from these products.

The Ebola virus causes an acute, serious illness that is often fatal. Since March 2014, West Africa has experienced the largest and most complex Ebola outbreak since the virus was discovered in 1976, affecting populations in West African countries and travelers who leave West Africa. The World Health Organization declared the Ebola Virus Disease Outbreak as a Public Health Emergency of International Concern under the framework of the International Health Regulations (2005).

Unless otherwise noted, all statutory citations below are to the U.S. Code.

Section I, Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

Before issuing a Declaration under the PREP Act, the Secretary is required to determine that a disease or other health condition or threat to health constitutes a public health emergency or that there is a credible risk that the disease, condition, or threat may constitute such an emergency. This determination is separate and apart from a Declaration issued by the Secretary under section 319 of the PHS Act that a disease or disorder presents a public health emergency or that a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists, or other Declarations or determinations made under other authorities of the Secretary. Accordingly, in Section I, the Secretary determines that there is a credible risk that the spread of Ebola virus and the resulting disease may constitute a public health emergency.

Section II, Factors Considered

In deciding whether and under what circumstances to issue a Declaration with respect to a Covered Countermeasure, the Secretary must consider the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the countermeasure. In Section II, the Secretary states that she has considered these factors.

Section III, Recommended Activities

The Secretary must recommend the activities for which the PREP Act's liability immunity is in effect. These activities may include, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more Covered Countermeasures (Recommended Activities). In Section III, the Secretary recommends activities for which the immunity is in effect.

Section IV, Liability Immunity

The Secretary must also state that liability protections available under the PREP Act are in effect with respect to the Recommended Activities. These liability protections provide that, ''[s]ubject to other provisions of [the PREP Act], a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered countermeasure if a Declaration . . . has been issued with respect to such countermeasure.'' In Section IV, the Secretary states that liability protections are in effect with respect to the Recommended Activities.

Section V, Covered Persons

The PREP Act's liability immunity applies to ''Covered Persons'' with respect to administration or use of a Covered Countermeasure. The term ''Covered Persons'' has a specific meaning and is defined in the PREP Act to include manufacturers, distributors, program planners, and qualified persons, and their officials, agents, and employees, and the United States. The PREP Act further defines the terms ''manufacturer,'' ''distributor,'' ''program planner,'' and ''qualified person'' as described below.

A manufacturer includes a contractor or subcontractor of a manufacturer; a supplier or licenser of any product, intellectual property, service, research tool or component or other article used in the design, development, clinical testing, investigation or manufacturing of a Covered Countermeasure; and any or all of the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer.

A distributor means a person or entity engaged in the distribution of drug, biologics, or devices, including but not limited to: Manufacturers; repackers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; warehouses and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies.

A program planner means a state or local government, including an Indian tribe; a person employed by the state or local government; or other person who supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a Covered Countermeasure, including a person who establishes requirements, provides policy guidance, or supplies technical or scientific advice or assistance or provides a facility to administer or use a Covered Countermeasure in accordance with the Secretary's Declaration. Under this definition, a private sector employer or community group or other ''person'' can be a program planner when it carries out the described activities.

A qualified person means a licensed health professional or other individual authorized to prescribe, administer, or dispense Covered Countermeasures under the law of the state in which the countermeasure was prescribed, administered, or dispensed; or a person within a category of persons identified as qualified in the Secretary's Declaration. Under this definition, the Secretary can describe in the Declaration other qualified persons, such as volunteers, who are Covered

Persons. Section V describes other qualified persons covered by this Declaration.

The PREP Act also defines the word ''person'' as used in the Act: A person includes an individual, partnership, corporation, association, entity, or public or private corporation, including a Federal, State, or local government agency or department.

Section V describes Covered Persons under the Declaration, including Qualified Persons. We have revised the last category to remove the specific references to emergency use instructions and orders issued under section 564A of the FD&C Act, to clarify that any activities in accordance with that section are covered.

Section VI, Covered Countermeasures

As noted above, section III describes the Secretary's Recommended Activities for which liability immunity is in effect. This section identifies the countermeasures for which the Secretary has recommended such activities. The PREP Act states that a ''Covered Countermeasure'' must be: A ''qualified pandemic or epidemic product,'' or a ''security countermeasure,'' as described immediately below; or a drug, biological product or device authorized for emergency use in accordance with sections 564, 564A, or 564B of the FD&C Act.

A qualified pandemic or epidemic product means a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act that is: (i) Manufactured, used, designed, developed, modified, licensed or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm such a pandemic or epidemic might otherwise cause; (ii) manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by such a drug, biological product, or device; (iii) or a product or technology intended to enhance the use or effect of such a drug, biological product, or device.

A security countermeasure is a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act that: (i) (a) The Secretary determines to be a priority to diagnose, mitigate, prevent, or treat harm from any biological, chemical, radiological, or nuclear agent identified as a material threat by the Secretary of Homeland Security, or (b) to diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent; and (ii) is determined by the Secretary of Health and Human Services to be a necessary countermeasure to protect public health.

To be a Covered Countermeasure, qualified pandemic or epidemic products or security countermeasures also must be approved or cleared under the FD&C Act; licensed under the PHS Act; or authorized for emergency use under sections 564, 564A, or 564B of the FD&C Act.

A qualified pandemic or epidemic product also may be a Covered Countermeasure when it is subject to an exemption (that is, it is permitted to be used under an Investigational Drug Application or an Investigational Device Exemption) under the FD&C Act and is the object of research for possible use for diagnosis, mitigation, prevention, treatment, or cure, or to limit harm of a pandemic or epidemic or serious or life-threatening condition caused by such a drug or device. A security countermeasure also may be a Covered Countermeasure if it may reasonably be determined to qualify for approval or licensing within 10 years after the Department's determination that procurement of the countermeasure is appropriate.

Section VI lists the Ebola Virus Disease Vaccines that are Covered Countermeasures. The Secretary is amending the list to identify the vaccines without names of manufacturers. This change is intended to clarify that the listed vaccines are Covered Countermeasures regardless of the arrangements made by manufactures for production of the vaccine. The change is intended to clarify existing coverage; it is not intended to be a substantive legal change. In addition, the Secretary changed ''BPSC1001 (rVSV–ZEBOV–GP)'' to the current name for the same vaccine, ''Recombinant Vesicular Stomatitis Virus-vectored vaccine expressing EBOV-Zaire glycoprotein (rVSV–ZEBOV–GP),'' for accuracy.

Section VI also refers to the statutory definitions of Covered Countermeasures to make clear that these statutory definitions limit the scope of Covered Countermeasures. Specifically, the Declaration notes that Covered Countermeasures must be ''qualified pandemic or epidemic products,'' or ''security countermeasures,'' or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.

Section VII, Limitations on Distribution

The Secretary may specify that liability immunity is in effect only to Covered Countermeasures obtained through a particular means of distribution. The Declaration states that liability immunity is afforded to Covered Persons for Recommended Activities related to: (a) Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, or memoranda of understanding or other federal agreements; or (b) Activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasures following a Declaration of an emergency.

Section VII defines the terms ''Authority Having Jurisdiction'' and ''Declaration of an emergency.'' We have specified in the definition that Authorities having jurisdiction include federal, state, local, and tribal authorities and institutions or organizations acting on behalf of those governmental entities.

For governmental program planners only, liability immunity is afforded only to the extent they obtain Covered Countermeasures through voluntary means, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from Federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from State, local, or private stockpiles. This last limitation on distribution is intended to deter program planners that are government entities from seizing privately held stockpiles of Covered Countermeasures. It does not apply to any other Covered Persons, including other program planners who are not government entities.

Section VIII, Category of Disease, Health Condition, or Threat

The Secretary must identify, for each Covered Countermeasure, the categories of diseases, health conditions, or threats to health for which the Secretary recommends the administration or use of the countermeasure. In Section VIII, the Secretary states that the disease threat for which she recommends administration or use of the Covered Countermeasures is Ebola virus disease.

Section IX, Administration of Covered Countermeasures

The PREP Act does not explicitly define the term ''administration'' but

does assign the Secretary the responsibility to provide relevant conditions in the Declaration. In Section IX, the Secretary defines ''Administration of a Covered Countermeasure:''

Administration of a Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution, and dispensing of the countermeasures to recipients; management and operation of countermeasure programs; or management and operation of locations for purpose of distributing and dispensing countermeasures.

The definition of ''administration'' extends only to physical provision of a countermeasure to a recipient, such as vaccination or handing drugs to patients, and to activities related to management and operation of programs and locations for providing countermeasures to recipients, such as decisions and actions involving security and queuing, but only insofar as those activities directly relate to the countermeasure activities. Claims for which Covered Persons are provided immunity under the Act are losses caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a Covered Countermeasure consistent with the terms of a Declaration issued under the Act. Under the Secretary's definition, these liability claims are precluded if they allege an injury caused by physical provision of a countermeasure to a recipient, or if the claims are directly due to conditions of delivery, distribution, dispensing, or management and operation of countermeasure programs at distribution and dispensing sites.

Thus, it is the Secretary's interpretation that, when a Declaration is in effect, the Act precludes, for example, liability claims alleging negligence by a manufacturer in creating a vaccine, or negligence by a health care provider in prescribing the wrong dose, absent willful misconduct. Likewise, the Act precludes a liability claim relating to the management and operation of a countermeasure distribution program or site, such as a slip-and-fall injury or vehicle collision by a recipient receiving a countermeasure at a retail store serving as an administration or dispensing location that alleges, for example, lax security or chaotic crowd control. However, a liability claim alleging an injury occurring at the site that was not directly related to the countermeasure activities is not covered, such as a slip and fall with no direct connection to the countermeasure's administration or use. In each case, whether immunity is applicable will depend on the particular facts and circumstances.

Section X, Population

The Secretary must identify, for each Covered Countermeasure specified in a Declaration, the population or populations of individuals for which liability immunity is in effect with respect to administration or use of the countermeasure. This section explains which individuals should use the countermeasure or to whom the countermeasure should be administered—in short, those who should be vaccinated or take a drug or other countermeasure. Section X provides that the population includes ''any individual who uses or who is administered a Covered Countermeasure in accordance with the Declaration.''

In addition, the PREP Act specifies that liability immunity is afforded: (1) To manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; and (2) to program planners and qualified persons when the countermeasure is either used by or administered to this population or the program planner or qualified person reasonably could have believed the recipient was in this population. Section X includes these statutory conditions in the Declaration for clarity.

Section XI, Geographic Area

The Secretary must identify, for each Covered Countermeasure specified in the Declaration, the geographic area or areas for which liability immunity is in effect with respect to administration or use of the countermeasure, including, as appropriate, whether the Declaration applies only to individuals physically present in the area or, in addition, applies to individuals who have a described connection to the area. Section XI provides that liability immunity is afforded for the administration or use of a Covered Countermeasure without geographic limitation. This could include claims related to administration or use in West Africa. It is possible that claims may arise in regard to administration or use of the Covered Countermeasures outside the U.S. that may be resolved under U.S. law.

In addition, the PREP Act specifies that liability immunity is afforded: (1) To manufacturers and distributors without regard to whether the countermeasure is used by or administered to individuals in the geographic areas; and (2) to program planners and qualified persons when the countermeasure is either used or administered in the geographic areas or the program planner or qualified person reasonably could have believed the countermeasure was used or administered in the areas. Section XI includes these statutory conditions in the Declaration for clarity.

Section XII, Effective Time Period

The Secretary must identify, for each Covered Countermeasure, the period or periods during which liability immunity is in effect, designated by dates, milestones, or other description of events, including factors specified in the PREP Act. Section XII is amended to extend the effective time period for different means of distribution of Covered Countermeasures up to an additional twelve (12) months.

Section XIII, Additional Time Period of Coverage

The Secretary must specify a date after the ending date of the effective period of the Declaration that is reasonable for manufacturers to arrange for disposition of the Covered Countermeasure, including return of the product to the manufacturer, and for other Covered Persons to take appropriate actions to limit administration or use of the Covered Countermeasure. In addition, the PREP Act specifies that for Covered Countermeasures that are subject to a Declaration at the time they are obtained for the Strategic National Stockpile (SNS) under 42 U.S.C. 247d–6b(a), the effective period of the Declaration extends through the time the countermeasure is used or administered pursuant to a distribution or release from the Stockpile. Liability immunity under the provisions of the PREP Act and the conditions of the Declaration continues during these additional time periods. Thus, liability immunity is afforded during the ''Effective Time Period,'' described under XII of the Declaration, plus the ''Additional Time Period'' described under section XIII of the Declaration.

Section XIII provides for twelve (12) months as the additional time period of coverage after expiration of the Declaration.' Section XIII also explains the extended coverage that applies to any products obtained for the Strategic National Stockpile during the effective period of the Declaration.

Section XIV, Countermeasures Injury Compensation Program

Section 319F–4 of the PREP Act authorizes the Countermeasures Injury

Compensation Program (CICP) to provide benefits to eligible individuals who sustain a serious physical injury or die as a direct result of the administration or use of a Covered Countermeasure. Compensation under the CICP for an injury directly caused by a Covered Countermeasure is based on the requirements set forth in this Declaration, the administrative rules for the Program, and the statute. To show direct causation between a Covered Countermeasure and a serious physical injury, the statute requires ''compelling, reliable, valid, medical and scientific evidence.'' The administrative rules for the Program further explain the necessary requirements for eligibility under the CICP. Please note that, by statute, requirements for compensation under the CICP may not align with the requirements for liability immunity provided under the PREP Act. Section XIV, ''Countermeasures Injury Compensation Program'' explains the types of injury and standard of evidence needed to be considered for compensation under the CICP.

Further, the administrative rules for the CICP specify if countermeasures are administered or used outside the United States, only otherwise eligible individuals at American embassies, military installations abroad (such as military bases, ships, and camps) or at North Atlantic Treaty Organization (NATO) installations (subject to the NATO Status of Forces Agreement) where American servicemen and servicewomen are stationed may be considered for CICP benefits. Other individuals outside the United States may not be eligible for CICP benefits.

Section XV, Amendments

This is the first amendment to the Declaration issued December 3, 2014 (79 FR 73314). The Secretary may amend any portion of this Declaration through publication in the **Federal Register**.

Republished Declaration

Declaration, as Amended, for Public Readiness and Emergency Preparedness Act Coverage for Ebola Virus Disease Vaccines.

This Declaration amends and republishes the December 3, 2014, Declaration for coverage under the Public Readiness and Emergency Preparedness (''PREP'') Act for Ebola Virus Disease Vaccines. To the extent any term of the December 3, 2014, Declaration is inconsistent with any provision of this Republished Declaration, the terms of this Republished Declaration are controlling.

I. Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

42 U.S.C. 247d–6d(b)(1)

I have determined that there is a credible risk that the spread of Ebola virus and the resulting disease or conditions may in the future constitute a public health emergency.

II. Factors Considered

42 U.S.C. 247d–6d(b)(6)

I have considered the desirability of encouraging the design, development, clinical testing, or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the Covered Countermeasures.

III. Recommended Activities

42 U.S.C. 247d–6d(b)(1)

I recommend, under the conditions stated in this Declaration, the manufacture, testing, development, distribution, administration, and use of the Covered Countermeasures.

IV. Liability Immunity

42 U.S.C. 247d–6d(a), 247d–6d(b)(1)

Liability immunity as prescribed in the PREP Act and conditions stated in this Declaration is in effect for the Recommended Activities described in section III.

V. Covered Persons

42 U.S.C. 247d–6d(i)(2), (3), (4), (6), (8)(A) and (B)

Covered Persons who are afforded liability immunity under this Declaration are ''manufacturers,'' ''distributors,'' ''program planners,'' ''qualified persons,'' and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States.

In addition, I have determined that the following additional persons are qualified persons: (a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a Declaration of an emergency; (b) any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with section 564 of the FD&C Act; (c) any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act.

VI. Covered Countermeasures

42 U.S.C. 247d–6b(c)(1)(B), 42 U.S.C. 247d–6d(i)(1) and (7)

Covered Countermeasures are the following Ebola Virus Disease Vaccines:

(1) Recombinant Replication Deficient Chimpanzee Adenovirus Type 3-Vectored Ebola Zaire Vaccine (ChAd3–EBO–Z);

(2) Recombinant Vesicular Stomatitis Virus-vectored vaccine expressing EBOV-Zaire glycoprotein (rVSV–ZEBOV–GP), and;

(3) Ad26.ZEBOV/MVA–BN-Filo (MVA–mBN226B).

Covered Countermeasures must be ''qualified pandemic or epidemic products,'' or ''security countermeasures,'' or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.

VII. Limitations on Distribution

42 U.S.C. 247d–6d(a)(5) and (b)(2)(E)

I have determined that liability immunity is afforded to Covered Persons only for Recommended Activities involving Covered Countermeasures that are related to:

(a) Present or future Federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements; or,

(b) Activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a Declaration of an emergency.

i. The Authority Having Jurisdiction means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (*e.g.,* city, county, tribal, state, or federal boundary lines) or functional (*e.g.,* law enforcement, public health) range or sphere of authority.

ii. A Declaration of emergency means any Declaration by any authorized local, regional, state, or federal official of an emergency specific to events that indicate an immediate need to administer and use the Covered Countermeasures, with the exception of

a federal Declaration in support of an Emergency Use Authorization under section 564 of the FD&C Act unless such Declaration specifies otherwise;

I have also determined that for governmental program planners only, liability immunity is afforded only to the extent such program planners obtain Covered Countermeasures through voluntary means, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from state, local, or private stockpiles.

VIII. Category of Disease, Health Condition, or Threat

42 U.S.C. 247d–6d(b)(2)(A)

The category of disease, health condition, or threat for which I recommend the administration or use of the Covered Countermeasures is Ebola virus disease.

IX. Administration of Covered Countermeasures

42 U.S.C. 247d–6d(a)(2)(B)

Administration of the Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for purpose of distributing and dispensing countermeasures.

X. Population

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(C)

The populations of individuals include any individual who uses or is administered the Covered Countermeasures in accordance with this Declaration.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered to this population, or the program planner or qualified person reasonably could have believed the recipient was in this population.

XI. Geographic Area

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(D)

Liability immunity is afforded for the administration or use of a Covered Countermeasure without geographic limitation.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered in any designated geographic area; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered in any designated geographic area, or the program planner or qualified person reasonably could have believed the recipient was in that geographic area.

XII. Effective Time Period

42 U.S.C. 247d–6d(b)(2)(B)

Liability immunity for Covered Countermeasures through means of distribution, as identified in Section VII(a) of this Declaration, other than in accordance with the public health and medical response of the Authority Having Jurisdiction began on December 3, 2014, and extends for twenty-four (24) months from that date.

Liability immunity for Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction begins with a Declaration and lasts through (1) the final day the emergency Declaration is in effect or (2) twenty-four (24) months from December 3, 2014, whichever occurs first.

XIII. Additional Time Period of Coverage

42 U.S.C. 247d–6d(b)(3)(B) and (C)

I have determined that an additional twelve (12) months of liability protection is reasonable to allow for the manufacturer(s) to arrange for disposition of the Covered Countermeasure, including return of the Covered Countermeasures to the manufacturer, and for Covered Persons to take such other actions as are appropriate to limit the administration or use of the Covered Countermeasures.

Covered Countermeasures obtained for the SNS during the effective period of this Declaration are covered through the date of administration or use pursuant to a distribution or release from the SNS.

XIV. Countermeasures Injury Compensation Program

42 U.S.C 247d–6e

The PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to certain individuals or estates of individuals who sustain a covered serious physical injury as the direct result of the administration or use of the Covered Countermeasures, and benefits to certain survivors of individuals who die as a direct result of the administration or use of the Covered Countermeasures. The causal connection between the countermeasure and the serious physical injury must be supported by compelling, reliable, valid, medical and scientific evidence in order for the individual to be considered for compensation. The CICP is administered by the Health Resources and Services Administration, within the Department of Health and Human Services. Information about the CICP is available at the toll-free number 1–855–266–2427 or *http://www.hrsa.gov/cicp/.*

XV. Amendments

42 U.S.C. 247d–6d(b)(4)

Amendments to this Declaration will be published in the **Federal Register**.

Authority: 42 U.S.C. 247d–6d.

Dated: December 1, 2015.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2015–31088 Filed 12–8–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Smallpox Medical Countermeasures—Amendment

ACTION: Notice of Amendment to the October 10, 2008 Declaration under the Public Readiness and Emergency Preparedness Act.

SUMMARY: The Secretary is amending the declaration issued on October 10, 2008, (73 FR 61869) pursuant to section 319F–3 of the Public Health Service Act (42 U.S.C. 247d–6d) to: Include countermeasures authorized for use under sections 564A and 564B of the Federal Food, Drug, and Cosmetic (FD&C) Act (21 U.S.C. 360bbb–3a and 360bbb–3b); clarify the description of covered countermeasures; extend the effective time period of the declaration; reformat the declaration; modify or clarify terms of the declaration; and

republish the declaration in its entirety, as amended.

DATES: The amendment of the October 10, 2008, declaration is effective as of January 1, 2016.

FOR FURTHER INFORMATION CONTACT: Nicole Lurie, MD, MSPH, Assistant Secretary for Preparedness and Response, Office of the Secretary, Department of Health and Human Services, 200 Independence Avenue SW., Washington, DC 20201, Telephone 202–205–2882.

SUPPLEMENTARY INFORMATION:

Background

The Public Readiness and Emergency Preparedness Act (PREP Act) authorizes the Secretary of Health and Human Services (the Secretary) to issue a declaration to provide liability immunity to certain individuals and entities (Covered Persons) against any claim of loss caused by, arising out of, relating to, or resulting from the administration or use of medical countermeasures (Covered Countermeasures), except for claims that meet the PREP Act's definition of willful misconduct. The Secretary may, though publication in the **Federal Register**, amend any portion of a declaration. Using this authority, the Secretary issued a declaration for smallpox countermeasures against variola virus or other orthopoxviruses on October 10, 2008, and is amending this declaration.[1]

The major actions taken by this amendment to the smallpox countermeasures declaration include are the following: (1) Updating the description of covered countermeasures to include countermeasures authorized for use under sections 564A and 564B of the FD&C Act;[2] (2) revising the description of covered countermeasures to clarify that coverage for vaccines includes all components and constituent materials of the vaccines and all devices and their constituent components used in the administration of the vaccines, and to add biologics; (3) changing the description of qualified persons to include persons authorized to prescribe, administer, or dispense covered countermeasures in accordance with Section 564A of the FD&C Act; (4) clarifying that liability immunity extends to other transactions and to activities related to any federal agreements including clinical trials agreements by adding the terms ''other transactions'' and ''other Federal agreements'' to the clause describing the types of federal agreements for which immunity is in effect; (5) deleting references to specific federal contracts to clarify that immunity is not limited to activities conducted under listed contracts; (6) clarifying that liability immunity extends to activities directly conducted by the federal government by adding the phrase ''or directly conducted by the Federal Government'' to the section describing methods of distribution for which liability immunity is in effect; (7) narrowing the definition of ''administration'' to cover ''slip-and-fall'' claims only to the extent they are directly tied to the operation of a countermeasure program; (8) extending the time period for which liability immunity is in effect for the Covered Countermeasures to December 31, 2022, and (9) changing the entire declaration to the new format that was first used with the February 29, 2012, amendment to the declaration for pandemic influenza to make the declaration easier for readers to follow. Other minor modifications and clarifications are also made, as fully explained below.

The declaration is republished in full. We explain both the substantive and format changes in this supplementary section.

The PREP Act was enacted on December 30, 2005, as Public Law 109–148, Division C, Section 2. It amended the Public Health Service (PHS) Act, adding section 319F–3, which addresses liability immunity, and section 319F–4, which creates a compensation program. These sections are codified in the U.S. Code as 42 U.S.C. 247d–6d and 42 U.S.C. 247d–6e, respectively.

The Pandemic and All-Hazards Preparedness Reauthorization Act (PAHPRA), Public Law 113–5, was enacted on March 13, 2013. Among other things, PAHPRA added sections 564A and 564B to the FD&C Act to provide new authorities for the emergency use of approved products in emergencies and products held for emergency use. PAHPRA accordingly amended the definitions of ''Covered Countermeasures'' and ''qualified pandemic and epidemic products'' in section 319F–3 of the Public Health Service Act (the PREP Act provisions), so that products made available under these new FD&C Act authorities could be covered under PREP Act declarations. PAHPRA also extended the definition of qualified pandemic and epidemic products to include products or technologies intended to enhance the use or effect of a drug, biological product, or device used against the pandemic or epidemic or against adverse events from these products.

Unless otherwise noted, all statutory citations below are to the U.S. Code.

Section I, Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

Before issuing a declaration under the PREP Act, the Secretary is required to determine that a disease or other health condition or threat to health constitutes a public health emergency or that there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency.[3] This determination is separate and apart from a declaration issued by the Secretary under section 319 of the PHS Act[4] that a disease or disorder presents a public health emergency or that a public health emergency, including significant outbreaks of infectious diseases or bioterrorist attacks, otherwise exists, or other declarations or determinations made under other authorities of the Secretary. In the previous PREP Act declaration for smallpox countermeasures (''declaration''), this determination appeared in the declaration's introduction as the conclusion to the ''whereas'' clauses. The determination is stated in the first section of the declaration. This change was made to improve readability and is not intended to have any substantive legal effect.

In addition, we made a substantive change to the determination. The determination made in the ''whereas'' clauses in the October 10, 2008, declaration stated that the Secretary ''determined there is a credible risk that the exposure to variola virus or other orthopoxvirus disease and the resulting disease constitutes a public health emergency.'' The Secretary is amending this determination to state that the threat may be ''in the future,'' to refer to release of variola virus or orthopox virus rather than exposure, and to refer to both diseases and conditions, to more accurately describe the risk and to be consistent with the language used in the PREP Act.[5] Thus, in this amended declaration, the Secretary determines ''that there is a credible risk that the release of variola virus or other orthopoxvirus and the resulting disease or conditions may in the future constitute a public health emergency.'' This change is provided for clarification.

Section II, Factors Considered

In deciding whether and under what circumstances to issue a declaration

[1] 73 FR 61869.

[2] 21 U.S.C. 360bbb–3a and 360bbb–3b.

[3] 42 U.S.C. 247d–6d(b)(1).

[4] 42 U.S.C. 247d.

[5] See 42 U.S.C. 247d–6d(b)(1).

with respect to a Covered Countermeasure, the Secretary must consider the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the countermeasure.[6] We previously stated these considerations in the introductory ''whereas'' clauses to the declaration. The declaration now states these considerations in section II. We made this change to improve readability and do not intend that it have any substantive legal effect.

Section III, Recommended Activities

The Secretary must recommend the activities for which the PREP Act's liability immunity is in effect. These activities may include, under conditions as the Secretary may specify, the manufacture, testing, development, distribution, administration, or use of one or more Covered Countermeasures (''Recommended Activities'').[7] In the previous declaration, we included the Recommended Activities in section I of the declaration, ''Covered Countermeasures.'' The declaration now states them in section III. We made this change to improve readability and do not intend that it have any substantive legal effect. In addition, we deleted the phrases ''as defined in section IX below'' and ''with respect to the category of disease and population described in sections II and IV below'' for consistency with formatting changes, and changed ''and usage'' to ''or use'' for consistency with the statute. These changes are not intended to have any substantive legal effect.

Section IV, Liability Immunity

The Secretary must also state that liability protections available under the PREP Act are in effect with respect to the Recommended Activities.[8] These liability protections provide that, ''[s]ubject to other provisions of [the PREP Act], a covered person shall be immune from suit and liability under Federal and State law with respect to all claims for loss caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a covered countermeasure if a declaration . . . has been issued with respect to such countermeasure.'' [9] In the previous declaration, we included a statement referring to liability immunity specified under the PREP Act in section I of the declaration, ''Covered Countermeasures.'' The declaration now includes the statement that liability immunity is in effect for Recommended Activities in a separate section IV. We made this change to improve readability and do not intend that it have any substantive legal effect.

Section V, Covered Persons

The PREP Act's liability immunity applies to ''Covered Persons'' with respect to administration or use of a Covered Countermeasure. The term ''Covered Persons'' has a specific meaning, and is defined in the PREP Act to include manufacturers, distributors, program planners, and qualified persons, and their officials, agents, and employees, and the United States.[10] The PREP Act further defines the terms ''manufacturer,'' ''distributor,'' ''program planner,'' and ''qualified person'' as described below.[11]

A *manufacturer* includes a contractor or subcontractor of a manufacturer; a supplier or licenser of any product, intellectual property, service, research tool or component or other article used in the design, development, clinical testing, investigation or manufacturing of a Covered Countermeasure; and any or all of the parents, subsidiaries, affiliates, successors, and assigns of a manufacturer; [12]

A *distributor* means a person or entity engaged in the distribution of drug, biologics, or devices, including but not limited to: manufacturers; repackers; common carriers; contract carriers; air carriers; own-label distributors; private-label distributors; jobbers; brokers; warehouses and wholesale drug warehouses; independent wholesale drug traders; and retail pharmacies; [13]

A *program planner* means a state or local government, including an Indian tribe; a person employed by the state or local government; or other person who supervises or administers a program with respect to the administration, dispensing, distribution, provision, or use of a Covered Countermeasure, including a person who establishes requirements, provides policy guidance, or supplies technical or scientific advice or assistance or provides a facility to administer or use a Covered Countermeasure in accordance with the Secretary's declaration; [14] Under this definition, a private sector employer or community group or other person can be a program planner when it carries out the described activities.

A *qualified person* means a licensed health professional or other individual who is authorized to prescribe, administer, or dispense Covered Countermeasures under the law of the state in which the countermeasure was prescribed, administered, or dispensed; or a person within a category of persons identified as qualified in the Secretary's declaration.[15] Under this definition, the Secretary can describe in the declaration other qualified persons, such as volunteers, who are Covered Persons. Section V describes other qualified persons covered by this declaration. The PREP Act also defines ''person'' as used in the Act: A *person* includes an individual, partnership, corporation, association, entity, or public or private corporation, including a federal, state, or local government agency or department.[16]

The provisions regarding Covered Persons previously appeared in the declaration as a definition in section IX, ''Definitions'' and in section VI, ''Qualified Persons.'' We combined these two provisions into a new section V, ''Covered Persons'' and added ''to perform an activity'' to the description of ''Other Qualified Persons'' authorized under an Emergency Use Authorization (EUA) for clarity. We made these changes to improve readability and clarity and do not intend them to have any substantive legal effect.

We also modified the description of Covered Persons to include a new category of qualified persons: ''Any person authorized to prescribe, administer, or dispense covered countermeasures in accordance with Section 564A of the FD&C Act.'' This change ensures that persons who prescribe, administer, or dispense covered countermeasures in accordance with section 564A of the FD&C Act are Covered Persons under the declaration.

Section VI, Covered Countermeasures

As noted above, section III describes the Secretary's Recommended Activities for which liability immunity is in effect. This section identifies the countermeasures for which the Secretary has recommended such activities. The PREP Act states that a ''Covered Countermeasure'' must be: A ''qualified pandemic or epidemic product,'' or a ''security countermeasure,'' as described immediately below; or a drug, biological product or device authorized for emergency use in accordance with

[6] 42 U.S.C. 247d–6d(b)(6).

[7] 42 U.S.C. 247d–6d(b)(1).

[8] 42 U.S.C. 247d–6d(b)(1).

[9] 42 U.S.C. 247d–6d(a)(1).

[10] 42 U.S.C. 247d–6d (i)(2).

[11] 42 U.S.C. 247d–6d(i).

[12] 42 U.S.C. 247d–6d(i)(4).

[13] 42 U.S.C. 247d–6d(i)(3).

[14] 42 U.S.C. 247d–6d(i)(6).

[15] 42 U.S.C. 247d–6d(i)(8).

[16] 42 U.S.C. 247d–6d(i)(5).

section 564, 564A, or 564B of the FD&C Act.[17]

A *qualified pandemic or epidemic product* means a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act[18] that is: (i) Manufactured, used, designed, developed, modified, licensed or procured to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic or limit the harm such a pandemic or epidemic might otherwise cause; (ii) manufactured, used, designed, developed, modified, licensed, or procured to diagnose, mitigate, prevent, treat, or cure a serious or life-threatening disease or condition caused by such a drug, biological product or device; (iii) or a product or technology intended to enhance the use or effect of such a drug, biological product, or device.[19]

A *security countermeasure* is a drug or device, as defined in the FD&C Act or a biological product, as defined in the PHS Act[20] that: (i) (a) the Secretary determines to be a priority to diagnose, mitigate, prevent or treat harm from any biological, chemical, radiological, or nuclear agent identified as a material threat by the Secretary of Homeland Security, or (b) to diagnose, mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, biological product, or device against such an agent; and (ii) is determined by the Secretary of Health and Human Services to be a necessary countermeasure to protect public health.[21]

To be a Covered Countermeasure, qualified pandemic or epidemic products and security countermeasures also must be approved or cleared under the FD&C Act;[22] licensed under the PHS Act;[23] authorized for emergency use under sections 564, 564A, or 564B of the FD&C Act.[24]

A qualified pandemic or epidemic product also may be a Covered Countermeasure when it is subject to an exemption (that is, it is permitted to be used under an Investigational Drug Application or an Investigational Device Exemption) under the FD&C Act[25] and is the object of research for possible use for diagnosis, mitigation, prevention, treatment, cure or limit harm of a pandemic or epidemic or serious or life-threatening condition caused by such a drug or device. A security countermeasure also may be a Covered Countermeasure if it may reasonably be determined to qualify for approval or licensing within 10 years after the Department's determination that procurement of the countermeasure is appropriate.

Provisions regarding Covered Countermeasures appeared in section I of the declaration, ''Covered Countermeasures'' and section IX of the declaration, ''Definitions.'' Section I included not only a description of the Covered Countermeasure but also the Secretary's recommendation, statement regarding liability immunity, and additional conditions characterizing countermeasures. We have combined sections I and IX and simplified the language so that it now only identifies the Covered Countermeasures. We have relocated the other conditions included in the ''Covered Countermeasure'' section to new sections, ''Recommended Activities,'' ''Liability Immunity,'' and ''Limitations on Distribution,'' to improve readability. We do not intend for this change to have any substantive legal effect.

Section I of the declaration also stated that the declaration applied to Covered Countermeasures administered or used during the effective time period of the declaration. We have deleted this language as it is redundant of the provisions stated in sections XII, ''Effective Time Period,'' and XIII, ''Additional Time Period of Coverage.''

We also revised the description and definition of the Covered Countermeasure that previously appeared in sections I, ''Covered Countermeasures'' and IX, ''Definitions.'' Section I referred to the Act for the definition of ''Covered Countermeasures,'' and section IX defined the term ''Smallpox Countermeasure'' as ''Any vaccine; antiviral, other drug; or diagnostic or device to identify, prevent or treat smallpox or orthopoxvirus or adverse events from such countermeasures (1) Licensed under section 351 of the Public Health Service Act; (2) approved under section 505 or section 515 of the Federal Food, Drug, and Cosmetic Act (FDCA); (3) cleared under section 510(k) of the FDCA; (4) authorized for emergency use under section 564 of the FDCA ; (5) used under section 505(i) of the FDCA or section 351(a)(3) of the PHS Act, and 21 CFR part 312; or (6) used under section 520(g) of the FDCA and 21 CFR part 812.''

We revised the description of smallpox countermeasures to clarify that coverage for vaccines includes components and constituent materials of the vaccines and device and constituent components used in administration of the vaccines. We also added the term ''biologic'' to more accurately describe the types of countermeasures used against smallpox and added ''other'' before ''drug'' and ''device'' for accuracy. The definition now reads: ''any vaccine, including all components and constituent materials of these vaccines, and all devices and their constituent components used in the administration of these vaccines; any antiviral; any other drug; any biologic; or any diagnostic or other device to identify, prevent or treat smallpox or orthopoxvirus or adverse events from such countermeasures.'' These changes are intended as clarification.

We also added a statement referencing the statutory definitions of Covered Countermeasures to make clear that these statutory definitions limit the scope of Covered Countermeasures. Specifically, we noted that they must be ''qualified pandemic or epidemic products,'' or ''security countermeasures,'' or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.'' By referencing the statutory provisions, the revised definition also incorporates changes to the PREP Act definitions of covered countermeasure and qualified pandemic or epidemic product made by PAHPRA.

Section VII, Limitations on Distribution

The Secretary may specify that liability immunity is in effect only to Covered Countermeasures obtained through a particular means of distribution.[26] These limitations on distribution previously appeared in section I, ''Covered Countermeasures,'' and section IX, ''Definitions.'' We now state the limitations in a separate section and combine them with relevant definitions for improved readability.

The declaration now states that liability immunity is afforded to Covered Persons for Recommended Activities related to:

(a) Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, or memoranda of understanding or other federal agreements or activities directly conducted by the federal government; or

[17] 42 U.S.C. 247d–6d(i)(1). Sections 564, 564A, and 564B of the FD&C Act may be found at 21 U.S.C. 360bbb–3, 360bbb–3a, and 360bbb–3b.

[18] 21 U.S.C. 321(g)(1), (h); 42 U.S.C. 262(i).

[19] 42 U.S.C. 247d–6d(i)(1)(A), (i)(7).

[20] 21 U.S.C. 321(g)(1), (h);42 U.S.C. 262(i).

[21] 42 U.S.C. 247d–6d(i)(1)(B),(c)(1)(B).

[22] 21 U.S.C. 301 *et seq.*

[23] 42 U.S.C. 262.

[24] 21 U.S.C. 360bbb–3, 360bbb–3a, 360bbb–3b.

[25] 21 U.S.C. 355(i), 360j(g).

[26] 42 U.S.C. 247d–6d(a)(5), (b)(2)(E).

(b) Activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures following a declaration of an emergency.

For governmental program planners only, liability immunity is afforded only to the extent they obtain Covered Countermeasures through voluntary means, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from Federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from State, local, or private stockpiles.

In regard to (a), we, added the phrase ''other transactions,'' which may be used for some Covered Countermeasure activities,[27] added the phrase ''or other Federal agreements'' to clarify that the provision is intended to cover all types of Federal agreements, and added the phrase ''or activities directly conducted by the Federal Government'' to clarify that activities such as manufacture of vaccines for clinical trials by the HHS National Institutes of Health Vaccine Research Center or distribution of countermeasures by federal employees are covered. We changed the conjunction ''and'' to ''or'' between (a) and (b) to clarify that immunity is available under either of these circumstances; the activities do not have to both relate to a Federal award or agreement and be used in a public health and medical response in order for immunity to apply. The conjunction ''and'' used in the previous declaration was a drafting error; the Secretary's intent in that previous declarations has been the meaning conferred by the term ''or.'' Provisions (a) and (b) are intended to afford immunity to Federal government conducted and supported activities that precede a public health emergency and to activities in accordance with all Authorities Having Jurisdiction during a declared public health emergency. These changes are intended as clarifications and to improve readability, and are not intended as substantive changes.

In regard to (b), the meaning of the terms ''Authority Having Jurisdiction'' and ''Declaration of an Emergency'' are unchanged.

Finally, we slightly modified the last limitation by deleting extraneous statutory references and other language and by replacing the final sentence with the word ''only'' after ''planners'' to improve readability. We do not intend for the changes to this provision to alter its substantive legal effect. As stated in the ''whereas'' clauses of the prior declaration, this limitation on distribution is intended to deter program planners that are government entities from seizing privately held stockpiles of Covered Countermeasures. It does not apply to any other Covered Persons, including other program planners who are not government entities.

Section VIII, Category of Disease, Health Condition, or Threat

The Secretary must identify, for each Covered Countermeasure, the categories of diseases, health conditions, or threats to health for which the Secretary recommends the administration or use of the countermeasure.[28] This information previously appeared in section II, ''Category of Disease.''

Section IX, Administration of Covered Countermeasures

The PREP Act does not explicitly define the term ''administration'' but does assign the Secretary the responsibility to provide relevant conditions in the declaration. This definition previously appeared in section IX, ''Definitions.'' We have moved it to a separate section to improve readability. The Secretary has also narrowed the definition of ''administration'' that was previously provided in the declaration. The declaration previously defined the term ''administration'' to include physical provision of a Covered Countermeasure, as well as management and operation of systems and locations at which Covered Countermeasures may be provided to recipients:

Administration of a Covered Countermeasure: As used in section 319F–3(a)(2)(B) of the Act includes, but is not limited to, public and private delivery, distribution, and dispensing activities relating to physical administration of the countermeasures to patients/recipients, management and operation of delivery systems, and management and operation of distribution and dispensing locations.

The definition has been revised as follows:

Administration of a Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients; management and operation of countermeasure programs; or management and operation of locations for purpose of distributing and dispensing countermeasures.

As clarified, *administration* extends only to physical provision of a countermeasure to a recipient, such as vaccination or handing drugs to patients, and to activities related to management and operation of programs and locations for providing countermeasures to recipients, such as decisions and actions involving security and queuing, but only insofar as those activities directly relate to the countermeasure activities. Claims for which Covered Persons are provided immunity under the Act are losses caused by, arising out of, relating to, or resulting from the administration to or use by an individual of a Covered Countermeasure consistent with the terms of a declaration issued under the Act.[29] Under the Secretary's definition, these liability claims are precluded if the claims allege an injury caused by physical provision of a countermeasure to a recipient, or if the claims are directly due to conditions of delivery, distribution, dispensing, or management and operation of countermeasure programs at distribution and dispensing sites.

Thus, it is the Secretary's interpretation that, when a declaration is in effect, the Act precludes, for example, liability claims alleging negligence by a manufacturer in creating a vaccine, or negligence by a health care provider in prescribing the wrong dose, absent willful misconduct. Likewise, the Act precludes a liability claim relating to the management and operation of a countermeasure distribution program or site, such as a ''slip-and-fall'' injury or vehicle collision by a recipient receiving a countermeasure at a retail store serving as an administration or dispensing location that alleges, for example, lax security or chaotic crowd control. However, a liability claim alleging an injury occurring at the site that was not directly related to the countermeasure activities is not covered, such as a slip and fall with no direct connection to the countermeasure's administration or use. In each case, whether immunity is applicable will depend on the particular facts and circumstances.

Section X, Population

The Secretary must identify, for each Covered Countermeasure specified in a declaration, the population or populations of individuals for which liability immunity is in effect with respect to administration or use of the

[27] See, *e.g.,* 42 U.S.C. 247d–7d(c)(5).

[28] 42 U.S.C. 247d–6d(b)(2)(A).

[29] 42 U.S.C. 247d–6d(a).

countermeasure.[30] This section explains which individuals should use the countermeasure or to whom the countermeasure should be administered—in short, those who should be vaccinated or take a drug or other countermeasure. These provisions previously appeared in section IV, ''Population.'' The previous declaration stated that the population specified in the declaration included:

The populations specified in this declaration are all persons who use a Covered Countermeasure or to whom a Covered Countermeasure is administered in accordance with this declaration, including, but not limited to: (1) Any person conducting research and development of Covered Countermeasures directly for the federal government or pursuant to a contract, grant, or cooperative agreement with the federal government; (2) any person who receives a Covered Countermeasure from persons authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute, or dispense the Covered Countermeasure, and their officials, agents, employees, contractors, and volunteers following a declaration of an emergency; (3) any person who receives a Covered Countermeasure from a person authorized to prescribe, administer or dispense the countermeasure or who is otherwise authorized to prescribe, administer or dispense the countermeasure under an Emergency Use Authorization; (4) any person who receives a Covered Countermeasure as an investigational new drug in human clinical trials being conducted directly by the federal government or pursuant to a contract, grant, or cooperative agreement with the federal government.

We have amended the declaration to provide that the population includes ''any individual who uses or who is administered a Covered Countermeasure in accordance with the declaration.'' We believe this broad statement accurately encompasses all of the previously listed populations given as examples of that phrase and ensures that no populations that use or are administered the Covered Countermeasures in accordance with the terms of the declaration are omitted.

In addition, the PREP Act specifies that liability immunity is afforded: (1) To manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; and (2) to program planners and qualified persons when the countermeasure is either used by or administered to this population or the program planner or qualified person reasonably could have believed the recipient was in this population.[31] We included these statutory conditions in the declaration for clarity.

Section XI, Geographic Area

The Secretary must identify, for each Covered Countermeasure specified in the declaration, the geographic area or areas for which liability immunity is in effect with respect to administration or use of the countermeasure, including, as appropriate, whether the declaration applies only to individuals physically present in the area or, in addition, applies to individuals who have a described connection to the area.[32] This section appeared in section V, ''Geographic Area.''

In addition, the PREP Act specifies that liability immunity is afforded: (1) To manufacturers and distributors without regard to whether the countermeasure is used by or administered to individuals in the geographic areas; and (2) to program planners and qualified persons when the countermeasure is either used or administered in the geographic areas or the program planner or qualified person reasonably could have believed the countermeasure was used or administered in the areas.[33] We included these statutory conditions in the declaration for clarity.

Section XII, Effective Time Period

The Secretary must identify, for each Covered Countermeasure, the period or periods during which liability immunity is in effect, designated by dates, milestones, or other description of events, including factors specified in the PREP Act.[34] This section appeared as section III, ''Effective Time Period.''

The declaration is amended to clarify when liability takes effect for different means of distribution and to delete language referring to the Smallpox Emergency Personnel Protection Act (SEPPA) of 2003. These changes are intended to have no legal effect. The time frame for filing claims under the Secretary's SEPPA declaration expired in January 2010. The declaration is also amended to extend the period for which liability immunity is in effect. The previous declaration was in effect through December 31, 2015. We have extended the effective time period to December 31, 2022.

Section XIII, Additional Time Period of Coverage

The Secretary must specify a date after the ending date of the effective period of the declaration that is reasonable for manufacturers to arrange for disposition of the Covered Countermeasure, including return of the product to the manufacturer, and for other Covered Persons to take appropriate actions to limit administration or use of the Covered Countermeasure.[35] In addition, the PREP Act specifies that for Covered Countermeasures that are subject to a declaration at the time they are obtained for the Strategic National Stockpile (SNS) under 42 U.S.C. 247d–6b(a), the effective period of the declaration extends through the time the countermeasure is used or administered pursuant to a distribution or release from the SNS. Liability immunity under the provisions of the PREP Act and the conditions of the declaration continues during these additional time periods. Thus, liability immunity is afforded during the ''Effective Time Period,'' described under XII of the declaration, plus the ''Additional Time Period'' described under section XIII of the declaration.

The provision for additional time periods previously appeared as section VII, ''Additional Time Periods of Coverage After Expiration of the Declaration.'' The provision is amended to clarify the statutory provisions as they apply to manufacturers and to other covered persons, and to clarify that extended coverage applies to any products obtained for the Strategic National Stockpile during the effective period of the declaration. We included the statutory provision for clarity.

Section XIV, Countermeasures Injury Compensation Program

Section 319F–4 of the PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to eligible individuals who sustain a serious physical injury or die as a direct result of the administration or use of a Covered Countermeasure.[36] Compensation under the CICP for an injury directly caused by a Covered Countermeasure is based on the requirements set forth in this declaration, the administrative rules for the Program,[37] and the statute.[38] To show direct causation between a Covered Countermeasure and a serious physical injury, the statute requires

[30] 42 U.S.C. 247d–6d(b)(2)(C).

[31] 42 U.S.C. 247d–6d(a)(4).

[32] 42 U.S.C. 247d–6d(b)(2)(D).

[33] 42 U.S.C. 247d–6d(a)(4).

[34] 42 U.S.C. 246d–6d(b)(2)(B), (b)(6).

[35] 42 U.S.C. 247d–6d(b)(3).

[36] 42 U.S.C. 247d–6e.

[37] 42 CFR part 110.

[38] 42 U.S.C. 247d–6e.

''compelling, reliable, valid, medical and scientific evidence.'' [39] The administrative rules for the Program further explain the necessary requirements for eligibility under the CICP. Please note that, by statute, requirements for compensation under the CICP may not always align with the requirements for liability immunity provided under the PREP Act. We have added section XIV, ''Countermeasures Injury Compensation Program'' to explain the types of injury and standard of evidence needed to be considered for compensation under the CICP. We included this information to inform readers of this Program.

Section XV, Amendments

The Secretary may amend any portion of a declaration through publication in the **Federal Register**.[40] This section appeared in section VIII, ''Amendments.'' It has been updated to reflect that the Republished Declaration amends the prior October 10, 2008, declaration.

Deleted Sections

The prior declaration included a number of ''whereas'' clauses as introductory to the declaration. As described above, we have incorporated ''whereas'' clauses that made necessary findings under the PREP Act into the text of the declaration itself. We have deleted the remaining ''whereas'' clauses. We do not intend this change to have legal effect.

The prior declaration contained a definitions section. These definitions have been incorporated into the relevant sections of the declaration as noted above, and modified or deleted where indicated above.

An appendix previously appeared in the declaration that listed federal government contracts for research, development, and procurement of Covered Countermeasures. We deleted this appendix to clarify that liability immunity under the provisions of the PREP Act and terms of the declaration is not limited to the contracts listed in the appendix. Coverage is available for any award or agreement that meets the description provided in section VII of the declaration. In addition, deleting the appendix relieves the Department of the need to periodically update the appendix.

We made these deletions for clarity and do not intend them to have legal effect.

[39] 42 U.S.C. 247d–6e(b)(4).

[40] 42 U.S.C. 247d–6d(b)(4).

Republished Declaration

Declaration, as Amended, for Public Readiness and Emergency Preparedness Act Coverage for Smallpox Countermeasures

This declaration amends and republishes the October 10, 2008, Declaration Under the Public Readiness and Emergency Preparedness Act (''PREP Act'') for smallpox countermeasures. To the extent any term of the October 10, 2008, Declaration is inconsistent with any provision of this Republished Declaration, the terms of this Republished Declaration are controlling.

I. Determination of Public Health Emergency or Credible Risk of Future Public Health Emergency

42 U.S.C. 247d–6d(b)(1)

I have determined that there is a credible risk the release of variola virus or other orthopoxvirus and the resulting disease or conditions may in the future constitute a public health emergency.

II. Factors Considered

42 U.S.C. 247d–6d(b)(6)

I have considered the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing, and use of the Covered Countermeasures.

III. Recommended Activities

42 U.S.C. 247d–6d(b)(1)

I recommend, under the conditions stated in this declaration, the manufacture, testing, development, distribution, administration, or use of the Covered Countermeasures.

IV. Liability Immunity

42 U.S.C. 247d–6d(a), 247d–6d(b)(1)

Liability immunity as prescribed in the PREP Act and conditions stated in this declaration is in effect for the Recommended Activities described in section III.

V. Covered Persons

42 U.S.C. 247d–6d(i)(2),(3),(4),(6),(8)(A) and (B)

Covered Persons who are afforded liability immunity under this declaration are ''manufacturers,'' distributors, program planners, qualified persons, and their officials, agents, and employees, as those terms are defined in the PREP Act, and the United States.

In addition, I have determined that the following additional persons are qualified persons: (a) Any person authorized in accordance with the public health and medical emergency response of the Authority Having Jurisdiction, as described in section VII below, to prescribe, administer, deliver, distribute or dispense the Covered Countermeasures, and their officials, agents, employees, contractors and volunteers, following a declaration of an emergency; (b) Any person authorized to prescribe, administer, or dispense the Covered Countermeasures or who is otherwise authorized to perform an activity under an Emergency Use Authorization in accordance with section 564 of the FD&C Act; (c) any person authorized to prescribe, administer, or dispense Covered Countermeasures in accordance with Section 564A of the FD&C Act.

VI. Covered Countermeasures

42 U.S.C. 247d–6b(c)(1)(B), 42 U.S.C. 247d–6d(i)(1) and (7)

Covered Countermeasures are any vaccine, including all components and constituent materials of these vaccines, and all devices and their constituent components used in the administration of these vaccines; any antiviral; any other drug; any biologic; or any diagnostic or other device to identify, prevent or treat smallpox or orthopoxvirus or adverse events from such countermeasures.

Covered Countermeasures must be ''qualified pandemic or epidemic products,'' or ''security countermeasures,'' or drugs, biological products, or devices authorized for investigational or emergency use, as those terms are defined in the PREP Act, the FD&C Act, and the Public Health Service Act.

VII. Limitations on Distribution

42 U.S.C. 247d–6d(a)(5) and (b)(2)(E)

I have determined that liability immunity is afforded to Covered Persons only for Recommended Activities involving Covered Countermeasures that are related to:

(a) Present or future federal contracts, cooperative agreements, grants, other transactions, interagency agreements, memoranda of understanding, or other federal agreements, or activities directly conducted by the federal government; or

(b) Activities authorized in accordance with the public health and medical response of the Authority Having Jurisdiction to prescribe, administer, deliver, distribute or

dispense the Covered Countermeasures following a declaration of an emergency.

i. The Authority Having Jurisdiction means the public agency or its delegate that has legal responsibility and authority for responding to an incident, based on political or geographical (*e.g.,* city, county, tribal, state, or federal boundary lines) or functional (*e.g.,* law enforcement, public health) range or sphere of authority.

ii. A declaration of emergency means any declaration by any authorized local, regional, state, or federal official of an emergency specific to events that indicate an immediate need to administer and use the Covered Countermeasures, with the exception of a federal declaration in support of an Emergency Use Authorization under section 564 of the FD&C Act unless such declaration specifies otherwise;

I have also determined that for governmental program planners only, liability immunity is afforded only to the extent such program planners obtain Covered Countermeasures through voluntary means, such as (1) donation; (2) commercial sale; (3) deployment of Covered Countermeasures from federal stockpiles; or (4) deployment of donated, purchased, or otherwise voluntarily obtained Covered Countermeasures from State, local, or private stockpiles.

VIII. Category of Disease, Health Condition, or Threat

42 U.S.C. 247d–6d(b)(2)(A)

The category of disease, health condition, or threat for which I recommend the administration or use of the Covered Countermeasures is smallpox resulting from exposure to variola virus and the threat of disease resulting from exposure to other orthodox viruses.

IX. Administration of Covered Countermeasures

42 U.S.C. 247d–6d(a)(2)(B)

Administration of the Covered Countermeasure means physical provision of the countermeasures to recipients, or activities and decisions directly relating to public and private delivery, distribution and dispensing of the countermeasures to recipients, management and operation of countermeasure programs, or management and operation of locations for purpose of distributing and dispensing countermeasures.

X. Population

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(C)

The populations of individuals include any individual who uses or is administered the Covered Countermeasures in accordance with this declaration.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered to this population; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered to this population or the program planner or qualified person reasonably could have believed the recipient was in this population.

XI. Geographic Area

42 U.S.C. 247d–6d(a)(4), 247d–6d(b)(2)(D)

Liability immunity is afforded for the administration or use of a Covered Countermeasure without geographic limitation.

Liability immunity is afforded to manufacturers and distributors without regard to whether the countermeasure is used by or administered in these geographic areas; liability immunity is afforded to program planners and qualified persons when the countermeasure is used by or administered in these geographic areas, or the program planner or qualified person reasonably could have believed the recipient was in these geographic areas.

XII. Effective Time Period

42 U.S.C. 247d–6d(b)(2)(B)

Liability immunity for Covered Countermeasures obtained through means of distribution other than in accordance with the public health and medical response of the Authority Having Jurisdiction extends through December 31, 2022.

Liability immunity for Covered Countermeasures administered and used in accordance with the public health and medical response of the Authority Having Jurisdiction begins with a declaration and lasts through (1) the final day the emergency declaration is in effect or (2) December 31, 2022, whichever occurs first.

XIII. Additional Time Period of Coverage

42 U.S.C. 247d–6d(b)(3)(A), (B) and (C)

I have determined that an additional twelve (12) months of liability protection is reasonable to allow for the manufacturer(s) to arrange for disposition of the Covered Countermeasure, including return of the Covered Countermeasures to the manufacturer, and for Covered Persons to take such other actions as are appropriate to limit the administration or use of the Covered Countermeasures.

Covered Countermeasures obtained for the SNS during the effective period of this declaration for Covered Countermeasures obtained through means of distribution other than in accordance with the public health and medical response of the Authority Having Jurisdiction are covered through the date of administration or use pursuant to a distribution or release from the SNS.

XIV. Countermeasures Injury Compensation Program

42 U.S.C. 247d–6e

The PREP Act authorizes the Countermeasures Injury Compensation Program (CICP) to provide benefits to certain individuals or estates of individuals who sustain a serious physical covered injury as the direct result of the administration or use of the Covered Countermeasures and/or benefits to certain survivors of individuals who die as a direct result of the administration or use of the Covered Countermeasures. The causal connection between the countermeasure and the serious physical injury must be supported by compelling, reliable, valid, medical and scientific evidence in order for the individual to be considered for compensation. The CICP is administered by the Health Resources and Services Administration, within the Department of Health and Human Services. Information about the CICP is available at 855–266–2427 (toll-free) or *http://www.hrsa.gov/cicp/.*

XV. Amendments

42 U.S.C. 247d–6d(b)(4)

The October 10, 2008 Declaration Under the Public Readiness and Emergency Preparedness Act for smallpox countermeasures was first published on October 17, 2008. This is the first amendment to that declaration.

Any further amendments to this declaration will be published in the **Federal Register**.

Authority: 42 U.S.C. 247d–6d.

Dated: December 1, 2015.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2015–31092 Filed 12–8–15; 8:45 am]

BILLING CODE P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Allergy And Infectious Diseases; 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 Allergy and Infectious Diseases Special Emphasis Panel, NIAID Resource-Related Research Projects (R24) and NIAID Investigator Initiated Program Project Applications (P01).

Date: January 12, 2016.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Room 4H100, 5601 Fishers Lane, Rockville, MD 20892 (Telephone Conference Call).

Contact Person: B. Duane Price, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, RM 3G50, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, 240–669–5074, *pricebd@niaid.nih.gov*.

Name of Committee: National Institute of Allergy and Infectious Diseases Special Emphasis Panel, NIAID Investigator Initiated Program Project Applications (P01).

Date: January 14, 2016.

Time: 8:00 a.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health/NIAID, Room 3C100, 5601 Fishers Lane, Rockville, MD 20852, (Telephone Conference Call).

Contact Person: B. Duane Price, Ph.D., Scientific Review Officer, Scientific Review Program, Division of Extramural Activities, RM 3G50, National Institutes of Health, NIAID, 5601 Fishers Lane, MSC 9823, Bethesda, MD 20892–9823, 240–669–5074, *pricebd@niaid.nih.gov*.

(Catalogue of Federal Domestic Assistance Program Nos. 93.855, Allergy, Immunology, and Transplantation Research; 93.856, Microbiology and Infectious Diseases Research, National Institutes of Health, HHS)

Dated: December 3, 2015.

Natasha Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–31026 Filed 12–8–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Eye Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Eye Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Eye Council.

Date: January 21, 2016.

Open: 8:30 a.m. to 1:00 p.m.

Agenda: Following opening remarks by the Director, NEI, there will be presentations by the staff of the Institute and discussions concerning Institute programs.

Place: National Institutes of Health Terrace Level Conference Rooms; 5635 Fishers Lane; Bethesda, MD 20892.

Closed: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health Terrace Level Conference Rooms; 5635 Fishers Lane; Bethesda, MD 20892.

Contact Person: Anne E. Schaffner, Ph.D.; Chief, Scientific Review Branch; Division of Extramural Research National Eye Institute; National Institutes of Health; 5635 Fishers Lane, Suite 1300, MSC 9300; Bethesda, MD 20892–9300; (301) 451–2020; *aes@nei.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *www.nei.nih.gov,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.867, Vision Research, National Institutes of Health, HHS)

Dated: December 2, 2015.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–31027 Filed 12–8–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center For Scientific Review; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Center for Scientific Review Special Emphasis Panel, December 02, 2015, 01:00 p.m. to December 02, 2015, 02:00 p.m., National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 which was published in the **Federal Register** on November 12, 2015, 80 FR 69972–69973.

The meeting is now being held on December 15, 2015 from 01:00 p.m. to 02:00 p.m. at the location listed above. The meeting is closed to the public.

Dated: December 1, 2015.

Natasha M. Copeland,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015–31028 Filed 12–8–15; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Transformation Accountability Reporting System—(OMB No. 0930–0285)—Revision

The Transformation Accountability (TRAC) Reporting System is a real-time, performance management system that captures information on the substance abuse treatment and mental health services delivered in the United States. A wide range of client and program information is captured through TRAC for approximately 700 grantees. This request includes an extension of the currently approved data collection effort.

This information collection will allow SAMHSA to continue to meet the Government Performance and Results Act (GPRA) of 1993 reporting requirements that quantify the effects and accomplishments of its programs, which are consistent with OMB guidance. In order to carry out section 1105(a)(29) of GPRA, SAMHSA is required to prepare a performance plan for its major programs of activity. This plan must:

- Establish performance goals to define the level of performance to be achieved by a program activity;
- Express such goals in an objective, quantifiable, and measurable form;
- Briefly describe the operational processes, skills and technology, and the human, capital, information, or other resources required to meet the performance goals;
- Establish performance indicators to be used in measuring or assessing the relevant outputs, service levels, and outcomes of each program activity;
- Provide a basis for comparing actual program results with the established performance goals; and
- Describe the means to be used to verify and validate measured values.

In addition, this data collection supports the GPRA Modernization Act of 2010 which requires overall organization management to improve agency performance and achieve the mission and goals of the agency through the use of strategic and performance planning, measurement, analysis, regular assessment of progress, and use of performance information to improve the results achieved. Specifically, this data collection will allow CMHS to have the capacity to report on a consistent set of performance measures across its various grant programs that conduct each of these activities. SAMHSA's legislative mandate is to increase access to high quality substance abuse and mental health prevention and treatment services and to improve outcomes. Its mission is to improve the quality and availability of treatment and prevention services for substance abuse and mental illness. To support this mission, the Agency's overarching goals are:

- Accountability—Establish systems to ensure program performance measurement and accountability
- Capacity—Build, maintain, and enhance mental health and substance abuse infrastructure and capacity
- Effectiveness—Enable all communities and providers to deliver effective services

Each of these key goals complements SAMHSA's legislative mandate. All of SAMHSA's programs and activities are geared toward the achievement of these goals and performance monitoring is a collaborative and cooperative aspect of this process. SAMHSA will strive to coordinate the development of these goals with other ongoing performance measurement development activities.

The total annual burden estimate is shown below:

ESTIMATES OF ANNUALIZED HOUR BURDEN

[CMHS Client outcome measures for discretionary programs]

Type of response	Number of respondents	Responses per respondent	Total responses	Hours per response	Total hour burden
Client-level baseline interview	35,845	1	35,854	0.45	16,130
Client-level 6-month reassessment interview[1]	23,658	1	23,658	0.45	10,646
Client-level discharge interview[2]	10,753	1	10,753	0.45	4,838
PBHCI- Section H Form Only Baseline	14,000	1	14,000	.08	1,120
PBHCI- Section H Form Only Follow-Up[3]	9,240	1	9,240	.08	739
PBHCI—Section H Form Only Discharge[4]	4,200	1	4,200	.08	336
HIV Continuum of Care Specific Form Baseline	200	1	200	0.33	66
HIV Continuum of Care Follow-Up[5]	148	1	148	.033	49
HIV Continuum of Care Discharge[6]	104	1	104	0.33	34
Infrastructure development, prevention, and mental health promotion quarterly record abstraction[7]	982	4.0	3928	2.0	7,856
Total	36,827		102,139		48,814

Note: Numbers may not add to the totals due to rounding and some individual participants completing more than one form.
[1] It is estimated that 66% of baseline clients will complete this interview.
[2] It is estimated that 30% of baseline clients will complete this interview.
[3] It is estimated that 74% of baseline clients will complete this interview.
[4] It is estimated that 52% of baseline clients will complete this interview.
[5] It is estimated that 52% of baseline clients will complete this interview.
[6] It is estimated that 30% of baseline clients will complete this interview.
[7] Grantees are required to report this information as a condition of their grant. No attrition is estimated.

Written comments and recommendations concerning the proposed information collection should be sent by January 8, 2016 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov.* Although commenters are encouraged to send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory

Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,

Statistician.

[FR Doc. 2015–31024 Filed 12–8–15; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Substance Abuse and Mental Health Services Administration

Agency Information Collection Activities: Submission for OMB Review; Comment Request

Periodically, the Substance Abuse and Mental Health Services Administration (SAMHSA) will publish a summary of information collection requests under OMB review, in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these documents, call the SAMHSA Reports Clearance Officer on (240) 276–1243.

Project: Services Accountability Improvement System—(OMB No. 0930–0208)—Revision

The Services Accountability Improvement System (SAIS) is a real-time, performance management system that captures information on the substance abuse treatment and mental health services delivered in the United States. A wide range of client and program information is captured through SAIS for approximately 650 grantees. Continued approval of this information collection will allow SAMHSA to continue to meet Government Performance and Results Act of 1993 (GPRA) reporting requirements that quantify the effects and accomplishments of its discretionary grant programs which are consistent with OMB guidance.

Based on current funding and planned fiscal year 2015 notice of funding announcements (NOFA), the CSAT programs that will use these measures in fiscal years 2015 through 2017 include: Access to Recovery 3 (ATR3); Adult Treatment Court Collaboratives (ATCC); Enhancing Adult Drug Court Services, Coordination and Treatment (EADCS); Offender Reentry Program (ORP); Treatment Drug Court (TDC); Office of Juvenile Justice and Delinquency Prevention—Juvenile Drug Courts (OJJDP–JDC); Teen Court Program (TCP); HIV/AIDS Outreach Program; Targeted Capacity Expansion Program for Substance Abuse Treatment and HIV/AIDS Services (TCE–HIV); Addictions Treatment for the Homeless (AT–HM); Cooperative Agreements to Benefit Homeless Individuals (CABHI); Cooperative Agreements to Benefit Homeless Individuals—States (CABHI—States); Recovery-Oriented Systems of Care (ROSC); Targeted Capacity Expansion—Peer to Peer (TCE—PTP); Pregnant and Postpartum Women (PPW); Screening, Brief Intervention and Referral to Treatment (SBIRT); Targeted Capacity Expansion (TCE); Targeted Capacity Expansion—Health Information Technology (TCE–HIT); Targeted Capacity Expansion Technology Assisted Care (TCE–TAC); Addiction Technology Transfer Centers (ATTC); International Addiction Technology Transfer Centers (I–ATTC); State Adolescent Treatment Enhancement and Dissemination (SAT–ED); Grants to Expand Substance Abuse Treatment Capacity in Adult Tribal Healing to Wellness Courts and Juvenile Drug Courts; and Grants for the Benefit of Homeless Individuals—Services in Supportive Housing (GBHI). Grantees in the Adult Treatment Court Collaborative program (ATCC) will also provide program-level data using the CSAT Aggregate Instrument

SAMHSA and its Centers will use the data for annual reporting required by GPRA and for NOMs comparing baseline with discharge and follow-up data. GPRA requires that SAMHSA's report for each fiscal year include actual results of performance monitoring for the three preceding fiscal years. The additional information collected through this process will allow SAMHSA to report on the results of these performance outcomes as well as be consistent with the specific performance domains that SAMHSA is implementing as the NOMs, to assess the accountability and performance of its discretionary and formula grant programs.

Note that there are no changes to the instrument from the previous OMB submission.

ESTIMATES OF ANNUALIZED HOUR BURDEN

[CSAT GPRA Client Outcome Measures for Discretionary Programs]

SAMHSA program title	Number of respondents	Responses per respondent	Total number of responses	Burden hours per response	Total burden hours
Baseline Interview Includes SBIRT Brief TX and Referral to TX	182,153	1	182,153	0.47	85,612
Follow-Up Interview [1]	134,793	1	134,793	0.47	63,353
Discharge Interview [2]	94,720	1	94,720	0.47	44,518
SBIRT Program –Screening Only [3]	594,192	1	594,192	0.13	77,244
SBIRT Program—Brief Intervention Only [4] Baseline	111,411	1	111,411	.20	22,282
SBIRT Program—Brief Intervention Only Follow-Up [1]	82,444	1	82,444	.20	16,489
SBIRT Program—Brief Intervention Only Discharge [2]	57,934	1	57,934	.20	11,587
CSAT Total	887,756		1,257,647		321,085

* **Notes:**

1. It is estimated that 74% of baseline clients will complete this interview.
2. It is estimated that 52% of baseline clients will complete this interview.
3. The estimated number of SBIRT respondents receiving screening services is 80% of the total number SBIRT participants. No further data is collected from these participants.
4. The estimated number of SBIRT respondents receiving brief intervention services is 15% of the total number SBIRT participants.

Written comments and recommendations concerning the proposed information collection should be sent by January 8, 2016 to the SAMHSA Desk Officer at the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB). To ensure timely receipt of comments, and to avoid potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, commenters are encouraged to submit their comments to OMB via email to: *OIRA_Submission@omb.eop.gov.* Although commenters are encouraged to

send their comments via email, commenters may also fax their comments to: 202–395–7285. Commenters may also mail them to: Office of Management and Budget, Office of Information and Regulatory Affairs, New Executive Office Building, Room 10102, Washington, DC 20503.

Summer King,

Statistician.

[FR Doc. 2015–31023 Filed 12–8–15; 8:45 am]

BILLING CODE 4162–20–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2015–0001; Internal Agency Docket No. FEMA–B–1551]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Title 44, Part 65 of the Code of Federal Regulations (44 CFR part 65). The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will become effective on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov*; or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.*, and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: November 18, 2015.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Effective date of modification	Community No.
Illinois:						
Cook	Village of Alsip (15–05–5016P).	The Honorable Patrick E. Kitching, Village President, Village of Alsip, 4500 West 123rd Street, Alsip, IL 60803.	Village Office, 4500 West 123rd Street, Alsip, IL 60803.	*http://www.msc.fema.gov/lomc.*	Jan. 8, 2016	170055
McHenry	Village of Johnsburg (15–05–6182X).	The Honorable Edwin P. Hettermann, Village President, Village of Johnsburg, 1515 Channel Beach Avenue, Johnsburg, IL 60051.	Village Hall, 1515 West Channel Beach Avenue, Johnsburg, IL 60051.	*http://www.msc.fema.gov/lomc.*	Feb. 4, 2016	170486

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Effective date of modification	Community No.
Peoria	City of Peoria (15–05–2741P).	The Honorable Jim Ardis, Mayor, City of Peoria, 419 Fulton Street, Suite 401, Peoria, IL 61602.	Public Works Department, 3505 North Dries Lane, Peoria, IL 61604.	*http://www.msc.fema.gov/lomc.*	Jan. 27, 2016	170536
Peoria	Unincorporated areas of Peoria County (15–05–2741P).	The Honorable Thomas O'Neill, Chairman, Peoria County Board, County Courthouse, Room 502, 324 Main Street, Peoria, IL 61602.	County Courthouse, 324 Main Street, Peoria, IL 61602.	*http://www.msc.fema.gov/lomc.*	Jan. 27, 2016	170533
Michigan: Wayne	City of Romulus (15–05–1538P).	The Honorable LeRoy Burcroff, Mayor, City of Romulus, 11111 Wayne Road, Romulus, MI 48174.	11111 Wayne Road, Romulus, MI 48174.	*http://www.msc.fema.gov/lomc.*	Jan. 8, 2016	260381
Missouri: Jackson	City of Kansas City (15–07–1558P).	The Honorable Sly James, Mayor, City of Kansas City, 414 E 12th Street, 29th Floor, Kansas City, MO 64106.	414 E. 12th Street, 25th Floor, c/o City Clerk Marilyn Sanders, Kansas City, MO 64106.	*http://www.msc.fema.gov/lomc.*	Jan. 15, 2016	290173
Ohio:						
Hocking	City of Logan (15–05–6391X).	The Honorable J. Martin Irvine, Mayor, City of Logan, 10 South Mulberry Street, Logan, OH 43138.	10 S. Mulberry Street, Logan, OH 43138.	*http://www.msc.fema.gov/lomc.*	Jan. 9, 2016	390274
Hocking	Unincorporated areas of Hocking County (15–05–6391X).	Mr. Larry Dicken, County Commissioner, Hocking County, 1 East Main Street, Logan, OH 43138.	93 W. Hunter Street, Logan, OH 43138.	*http://www.msc.fema.gov/lomc.*	Jan. 9, 2016	390272
Oregon:						
Lane	City of Creswell (15–10–1143P).	The Honorable Dave Stram, Mayor, City of Creswell, P.O. Box 276, Creswell, OR 97426.	City Hall, 13 South 1st Street, Creswell, OR 97426.	*http://www.msc.fema.gov/lomc.*	Jan. 15, 2016	410121
Lane	Unincorporated areas of Lane County (15–10–1143P).	The Honorable Faye Stewart, Commissioner, East Lane County, Lane County Public Service Building, 125 East 8th Street, Eugene, OR 97401.	Lane County Planning Department, Public Service Building, 125 East 8th Street, Eugene, OR 97401.	*http://www.msc.fema.gov/lomc.*	Jan. 15, 2016	415591
Texas:						
Tarrant	City of Fort Worth (15–06–2612P).	The Honorable Betsy Price, Mayor, City of Fort Worth, 1000 Throckmorton Street, Fort Worth, TX 76102.	Department of Transportation and Public Works, 1000 Throckmorton Street, Fort Worth, TX 76102.	*http://www.msc.fema.gov/lomc.*	Jan. 8, 2016	480596
Tarrant	City of Haltom City (15–06–2612P).	The Honorable David Averitt, Mayor, City of Haltom City, 5024 Broadway Avenue, Haltom City, TX 76117.	City Hall, 5024 Broadway Avenue, Haltom City, TX 76117.	*http://www.msc.fema.gov/lomc.*	Jan. 8, 2016	480599
Virginia: Roanoke	City of Roanoke (14–03–3119P).	The Honorable David A. Bowers, Mayor, City of Roanoke, 215 Church Avenue Southwest Room 452, Roanoke, VA 24011.	215 Church Avenue, Roanoke, VA 24011.	*http://www.msc.fema.gov/lomc.*	Dec. 30, 2015	510130
Wisconsin: Calumet.	Unincorporated areas of Calumet County (15–05–1737P).	Mr. Todd Romenesko, Calumet County Administrator, 206 Court Street, Chilton, WI 53014.	City Hall, 206 Court Street, Chilton, WI 53014.	*http://www.msc.fema.gov/lomc.*	Jan. 8, 2016	550035

[FR Doc. 2015–31030 Filed 12–8–15; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2015–0001]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports

have been made final for the communities listed in the table below.

The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

DATES: The effective date of March 2, 2016 which has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *www.msc.fema.gov* by the effective date indicated above.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov.*

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Date: November 18, 2015.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

Community	Community map repository address
Navajo County, Arizona, and Incorporated Areas Docket No.: FEMA–B–1445	
City of Winslow	Community Development Department, 21 North Williamson Avenue, Winslow, AZ 86047.
Unincorporated Areas of Navajo County	Navajo County Flood Control, 100 East Code Talkers Drive, Holbrook, AZ 86025.

[FR Doc. 2015–31009 Filed 12–8–15; 8:45 am]
BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2015–0001]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below.

The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

DATES: The effective date of February 3, 2016 which has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *www.msc.fema.gov* by the effective date indicated above.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov*; or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone

areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov.*

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: November 18, 2015.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

I. Watershed-Based Studies:

Community	Community map repository address
Lower Wisconsin River Watershed	
Grant County, Wisconsin, and Incorporated Areas Docket No.: FEMA–B–1434	
City of Boscobel	City Hall, 1006 Wisconsin Avenue, Boscobel, WI 53805.
City of Lancaster	City Hall, 206 South Madison Street, Lancaster, WI 53813.
City of Platteville	City Hall, 75 North Bonson Street, Platteville, WI 53818.
Village of Bagley	Village Hall, 400 South Jackley Lane, Bagley, WI 53801.
Village of Bloomington	Village Hall, 453 Canal Street , Bloomington, WI 53804.
Village of Blue River	Village Hall, 201 Clinton Street, Blue River, WI 53518.
Village of Mount Hope	Village Hall, 127 East Main Street, Mount Hope, WI 53816.
Village of Muscoda	Village Hall, 206 North Wisconsin Avenue, Muscoda, WI 53573.
Unincorporated Areas of Grant County	Tax Listers Office, 111 South Jefferson Street, Lancaster, WI 53813.

II. Non-Watershed-Based Studies:

Community	Community map repository address
Cochise County, Arizona, and Incorporated Areas Docket No.: FEMA–B–1413	
City of Benson	Planning & Zoning, 120 West 6th Street, Benson, AZ 85602.
Unincorporated Areas of Cochise County	Cochise County Flood Control District, 1415 Melody Lane, Building F, Bisbee, AZ 85603.
Hamilton County, Tennessee, and Incorporated Areas Docket No.: FEMA–B–1445	
City of Chattanooga	City of Chattanooga Planning Department, 1250 Market Street, Suite 1000, Chattanooga, TN 37402.
City of Collegedale	Collegedale City Hall, 4910 Swinyar Drive, Collegedale, TN 37315.
City of East Ridge	East Ridge City Hall, Inspections Department, 1517 Tombras Avenue, East Ridge, TN 37412.
Unincorporated Areas of Hamilton County	Hamilton County Regional Planning Department, 1250 Market Street, Suite 3050, Chattanooga, TN 37402.

[FR Doc. 2015–31010 Filed 12–8–15; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2015–0001]

Final Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Final Notice.

SUMMARY: Flood hazard determinations, which may include additions or modifications of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or regulatory floodways on the Flood Insurance Rate Maps (FIRMs) and where applicable, in the supporting Flood Insurance Study (FIS) reports have been made final for the communities listed in the table below.

The FIRM and FIS report are the basis of the floodplain management measures that a community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the Federal Emergency Management Agency's (FEMA's) National Flood Insurance Program (NFIP). In addition, the FIRM and FIS report are used by insurance agents and others to calculate appropriate flood insurance premium rates for buildings and the contents of those buildings.

DATES: The effective date of February 17, 2016 which has been established for the FIRM and, where applicable, the supporting FIS report showing the new or modified flood hazard information for each community.

ADDRESSES: The FIRM, and if applicable, the FIS report containing the final flood hazard information for each community is available for inspection at the respective Community Map Repository address listed in the tables below and will be available online through the FEMA Map Service Center at *www.msc.fema.gov* by the effective date indicated above.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov*; or visit the FEMA Map Information eXchange

(FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The Federal Emergency Management Agency (FEMA) makes the final determinations listed below for the new or modified flood hazard information for each community listed. Notification of these changes has been published in newspapers of local circulation and 90 days have elapsed since that publication. The Deputy Associate Administrator for Mitigation has resolved any appeals resulting from this notification.

This final notice is issued in accordance with section 110 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4104, and 44 CFR part 67. FEMA has developed criteria for floodplain management in floodprone areas in accordance with 44 CFR part 60.

Interested lessees and owners of real property are encouraged to review the new or revised FIRM and FIS report available at the address cited below for each community or online through the FEMA Map Service Center at *www.msc.fema.gov.*

The flood hazard determinations are made final in the watersheds and/or communities listed in the table below.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Date: November 18, 2015.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

I. Watershed-Based Studies:

SQUAW CREEK WATERSHED

Community	Community map repository address
Lake County, Illinois, and Incorporated Areas Docket No.: FEMA–B–1404	
Unincorporated Areas of Lake County	Central Permit Facility, 500 West Winchester Road, Unit 101, Libertyville, IL 60048.
Village of Grayslake	Village Hall, 10 South Seymour Avenue, Grayslake, IL 60030.
Village of Hainesville	Village Hall, 100 North Hainesville Road, Hainesville, IL 60030.
Village of Hawthorn Woods	Village Hall, 2 Lagoon Drive, Hawthorn Woods, IL 60047.
Village of Mundelein	Village Hall, 300 Plaza Circle, Mundelein, IL 60060.
Village of Round Lake	Village Hall, 442 North Cedar Lake Road, Round Lake, IL 60073.
Village of Round Lake Park	Village Hall, 203 East Lake Shore Drive, Round Lake Park, IL 60073.
Village of Volo	Village Hall, 500 South Fish Lake Road, Volo, IL 60073.
Village of Wauconda	Village Hall, 101 North Main Street, Wauconda, IL 60084.

II. Non-Watershed-Based Studies:

Community	Community map repository address
Winnebago County, Illinois, and Incorporated Areas Docket No.: FEMA–B–1452	
City of Loves Park	Public Works Department, 100 Heart Boulevard, Loves Park, IL 61111.
City of Rockford	City Hall, 425 East State Street, Rockford, IL 61104.
City of South Beloit	City Hall, 519 Blackhawk Boulevard, South Beloit, IL 61080.
Unincorporated Areas of Winnebago County	County Courthouse, 404 Elm Street, Rockford, IL 61101.
Village of Machesney Park	Planning & Zoning Department, 300 Roosevelt Road, Machesney Park, IL 61115.
Village of Pecatonica	Village Hall, 405 Main Street, Pecatonica, IL 61063.
Village of Rockton	Village Hall, 110 East Main Street, Rockton, IL 61072.
Village of Roscoe	Village Hall, 10631 Main Street, Roscoe, IL 61073.
Delaware County, Ohio, and Incorporated Areas Docket No.: FEMA–B–1270	
City of Delaware	City Building, 1 South Sandusky Street, 2nd Floor, Delaware, OH 43015.
Unincorporated Areas of Delaware County	Code Compliance Building, 50 Channing Street, South Wing, Delaware, OH 43015.
Armstrong County, Pennsylvania (All Jurisdictions) Docket No.: FEMA–B–1443	
Borough of Apollo	Borough Municipal Office, 616 First Street, Apollo, PA 15613.
Borough of Applewold	Applewold Borough Building, 8 Hickory Street, Kittanning, PA 16201.
Borough of Atwood	Atwood Borough Hall, 225 Atwood Sugar Run Road, Creekside, PA 15732.
Borough of Dayton	Borough Office, 207 Mechanic Street, Dayton, PA 16222.
Borough of Ford City	Borough Municipal Building, 1000 4th Avenue, Ford City, PA 16226.
Borough of Freeport	Borough Municipal Office, 414 Market Street, Freeport, PA 16229.
Borough of Kittanning	Borough Building, 300 South McKean Street, Kittanning, PA 16201
Borough of Leechburg	Borough Office, 260 Market Street, Leechburg, PA 15656.
Borough of Manorville	Borough Building, 600 Center Lane, Manorville, PA 16238.
Borough of North Apollo	Borough Building, 1421 Leonard Avenue, North Apollo, PA 15673.

Community	Community map repository address
Borough of Rural Valley	Borough Building, 300 Parkwood Drive, Rural Valley, PA 16249.
Borough of South Bethlehem	South Bethlehem Borough Building, 217 West Broad Street, New Bethlehem, PA 16242.
Borough of Worthington	Borough Municipal Building, 206 Church Street, Worthington, PA 16262.
City of Parker	City Hall, 210 North Cooper Avenue, Parker, PA 16049.
Township of Bethel	Bethel Township Hall, 3218 Ridge Road, Ford City, PA 16226.
Township of Boggs	Boggs Township Building, 292 Mountain Trails Road, Templeton, PA 16259.
Township of Brady's Bend	Brady's Bend Township Municipal Building, 1004 State Route 68, East Brady, PA 16028.
Township of Burrell	Burrell Township Municipal Building, 110 Cochran's Mill Road, Ford City, PA 16226.
Township of Cadogan	Township Office, 333 1st Avenue, Cadogan, PA 16212.
Township of Cowanshannock	Cowanshannock Township Municipal Building, 4033 Second Street, NuMine, PA 16244.
Township of East Franklin	East Franklin Township Municipal Building, 106 Cherry Orchard Avenue, Kittanning, PA 16201.
Township of Gilpin	Gilpin Township Municipal Building, 589 State Route 66, Leechburg, PA 15656.
Township of Hovey	Hovey Township Building, 600 North Riverview Drive, Parker, PA 16049.
Township of Kiskiminetas	Kiskiminetas Township Building, 1222A Old State Road, Apollo, PA 15613.
Township of Kittanning	Township Municipal Building, 395 Township Shed Road , Kittanning, PA 16201
Township of Madison	Madison Township Building, 107 Lawsonham Road, Templeton, PA 16259.
Township of Mahoning	Mahoning Township Office, 2237 Madison Road, Distant, PA 16223.
Township of Manor	Manor Township Municipal Building, 306 Byron Street, McGrann, PA 16236.
Township of North Buffalo	North Buffalo Township Municipal Building, 149 McHaddon Road, Kittanning, PA 16201.
Township of Parks	Parks Township Community Building, 26 Jackson Street, North Vandergrift, PA 15690.
Township of Perry	Perry Township Building, 758 Queenstown Road, Karns City, PA 16041.
Township of Pine	Pine Township Building, 115 Fifth Street, Templeton, PA 16259.
Township of Plumcreek	Plumcreek Township Building, 849 State Route 210, Shelocta, PA 15774.
Township of Rayburn	Rayburn Township Building, 105 McGregor Road, Kittanning, PA 16201.
Township of Redbank	Redbank Township Office, 135 Sugar Valley Road, Mayport, PA 16240.
Township of South Bend	South Bend Township Municipal Building, 219 Girty Road, Spring Church, PA 15686.
Township of South Buffalo	South Buffalo Township Municipal Building, 384 Iron Bridge Road, Freeport, PA 16229.
Township of Sugarcreek	Sugarcreek Township Municipal Building, 1807 State Route 268, East Brady, PA 16028.
Township of Valley	Valley Township Municipal Building, 321 Harris Road, Kittanning, PA 16201.
Township of Washington	Washington Township Office, 357 Adrian Sherrett Road, Adrian, PA 16210.
Township of Wayne	Wayne Township Building, 1381 State Route 1018, Dayton, PA 16222.
Township of West Franklin	West Franklin Township Municipal Building, 1473 Butler Road, Worthington, PA 16262.
Aransas County, Texas, and Incorporated Areas Docket No.: FEMA–B–1443	
City of Aransas Pass	City Hall, 600 West Cleveland Boulevard, Aransas Pass, TX 78336.
City of Port Aransas	City Hall, 710 West Avenue A, Port Aransas, TX 78373.
City of Rockport	Public Works Service Center, 2751 State Highway 35 Bypass, Rockport, TX 78382.
Town of Fulton	Town Hall, 201 North 7th Street, Fulton, TX 78358.
Unincorporated Areas of Aransas County	Aransas County Environmental Health Department, 870 Airport Road, Rockport, TX 78382.

[FR Doc. 2015–31011 Filed 12–8–15; 8:45 am]
BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

[Docket ID FEMA–2015–0001; Internal Agency Docket No. FEMA–B–1552]

Changes in Flood Hazard Determinations

AGENCY: Federal Emergency Management Agency, DHS.

ACTION: Notice.

SUMMARY: This notice lists communities where the addition or modification of Base Flood Elevations (BFEs), base flood depths, Special Flood Hazard Area (SFHA) boundaries or zone designations, or the regulatory floodway (hereinafter referred to as flood hazard determinations), as shown on the Flood Insurance Rate Maps (FIRMs), and where applicable, in the supporting Flood Insurance Study (FIS) reports, prepared by the Federal Emergency Management Agency (FEMA) for each community, is appropriate because of new scientific or technical data. The FIRM, and where applicable, portions of the FIS report, have been revised to reflect these flood hazard determinations through issuance of a Letter of Map Revision (LOMR), in accordance with Title 44, Part 65 of the Code of Federal Regulations (44 CFR part 65). The LOMR will be used by insurance agents and others to calculate appropriate flood insurance premium rates for new buildings and the contents of those buildings. For rating purposes, the currently effective community number is shown in the table below and must be used for all new policies and renewals.

DATES: These flood hazard determinations will become effective on the dates listed in the table below and revise the FIRM panels and FIS report in effect prior to this determination for the listed communities.

From the date of the second publication of notification of these changes in a newspaper of local circulation, any person has 90 days in which to request through the community that the Deputy Associate Administrator for Mitigation reconsider the changes. The flood hazard determination information may be changed during the 90-day period.

ADDRESSES: The affected communities are listed in the table below. Revised flood hazard information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

Submit comments and/or appeals to the Chief Executive Officer of the community as listed in the table below.

FOR FURTHER INFORMATION CONTACT: Luis Rodriguez, Chief, Engineering Management Branch, Federal Insurance and Mitigation Administration, FEMA, 500 C Street SW., Washington, DC 20472, (202) 646–4064, or (email) *Luis.Rodriguez3@fema.dhs.gov;* or visit the FEMA Map Information eXchange (FMIX) online at *www.floodmaps.fema.gov/fhm/fmx_main.html.*

SUPPLEMENTARY INFORMATION: The specific flood hazard determinations are not described for each community in this notice. However, the online location and local community map repository address where the flood hazard determination information is available for inspection is provided.

Any request for reconsideration of flood hazard determinations must be submitted to the Chief Executive Officer of the community as listed in the table below.

The modifications are made pursuant to section 201 of the Flood Disaster Protection Act of 1973, 42 U.S.C. 4105, and are in accordance with the National Flood Insurance Act of 1968, 42 U.S.C. 4001 *et seq.,* and with 44 CFR part 65.

The FIRM and FIS report are the basis of the floodplain management measures that the community is required either to adopt or to show evidence of having in effect in order to qualify or remain qualified for participation in the National Flood Insurance Program (NFIP).

These flood hazard determinations, together with the floodplain management criteria required by 44 CFR 60.3, are the minimum that are required. They should not be construed to mean that the community must change any existing ordinances that are more stringent in their floodplain management requirements. The community may at any time enact stricter requirements of its own or pursuant to policies established by other Federal, State, or regional entities. The flood hazard determinations are in accordance with 44 CFR 65.4.

The affected communities are listed in the following table. Flood hazard determination information for each community is available for inspection at both the online location and the respective community map repository address listed in the table below. Additionally, the current effective FIRM and FIS report for each community are accessible online through the FEMA Map Service Center at *www.msc.fema.gov* for comparison.

(Catalog of Federal Domestic Assistance No. 97.022, ''Flood Insurance.'')

Dated: November 18, 2015.

Roy E. Wright,

Deputy Associate Administrator for Insurance and Mitigation, Department of Homeland Security, Federal Emergency Management Agency.

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Effective date of modification	Community No.
Arizona:						
Maricopa	City of Peoria (15–09–1335P).	The Honorable Cathy Carlat, Mayor, City of Peoria, 8401 West Monroe Street, Peoria, AZ 85345.	City Hall, 8401 West Monroe Street, Peoria, AZ 85345.	*http://www.msc.fema.gov/lomc.*	Dec. 11, 2015	040050
Maricopa	City of Tempe (15–09–2580P).	The Honorable Mark Mitchell, Mayor, City of Tempe, P. O. Box 5002, Tempe, AZ 85280.	Engineering Department, City Hall, 31 East Fifth Street, Tempe, AZ 85281.	*http://www.msc.fema.gov/lomc.*	Feb. 5, 2016	040054
Maricopa	City of Scottsdale (15–09–2058P).	The Honorable W.J. Jim Lane, Mayor, City of Scottsdale, 3939 North Drinkwater Boulevard, Scottsdale, AZ 85251.	Scottsdale City Hall, 3939 North Drinkwater Boulevard, Scottsdale, AZ 85251.	*http://www.msc.fema.gov/lomc.*	Jan. 8, 2016	045012
Maricopa	Town of Queen Creek (15–09–0910P).	The Honorable Gail Barney, Mayor, Town of Queen Creek, 22350 South Ellsworth Road, Queen Creek, AZ 85142.	Town Hall, 22350 South Ellsworth Road, Queen Creek, AZ 85142.	*http://www.msc.fema.gov/lomc.*	Dec. 28, 2015	040132

State and county	Location and case No.	Chief executive officer of community	Community map repository	Online location of letter of map revision	Effective date of modification	Community No.
Maricopa	Unincorporated Areas of Maricopa County (15–09–0910P).	The Honorable Steve Chucri, Chairman, Maricopa County, Board of Supervisors, 301 West Jefferson Street, 10th Floor, Phoenix, AZ 85003.	Flood Control District of Maricopa County, 2801 West Durango Street, Phoenix, AZ 85009.	*http://www.msc.fema.gov/lomc.*	Dec. 28, 2015	040037
Pima	Unincorporated Areas of Pima County (14–09–4178P).	The Honorable Sharon Bronson, Chair, Pima County, Board of Supervisors, 130 W. Congress Street, 11th Floor, Tucson, AZ 85701.	Pima County Flood Control District, 97 East Congress Street, 3rd Floor, Tucson, AZ 85701.	*http://www.msc.fema.gov/lomc.*	Jan. 25, 2016	040073
Pinal	Unincorporated Areas of Pinal County (15–09–0910P).	The Honorable Cheryl Chase, Chair, Pinal County, Board of Supervisors, 135 North Pinal Street, Florence, AZ 85132.	Pinal County Engineering Department, 135 North Pinal Street, Florence, AZ 85132.	*http://www.msc.fema.gov/lomc.*	Dec. 28, 2015	040077
Yavapai	Town of Prescott Valley (15–09–1138P).	The Honorable Harvey Skoog, Mayor, Town of Prescott Valley, 7501 East Civic Circle, Prescott Valley, AZ 86314.	Engineering Division, 7501 East Civic Circle, Prescott Valley, AZ 86314.	*http://www.msc.fema.gov/lomc.*	Jan. 8, 2016	040121
California:						
Alameda	City of Alameda (15–09–1763X).	The Honorable Trish Herrera Spencer, Mayor, City of Alameda, City Hall, 2263 Santa Clara Avenue, Alameda, CA 94501.	950 West Mall Square, Alameda, CA 94501.	*http://www.msc.fema.gov/lomc.*	Dec. 11, 2015	060002
San Diego	City of Santee (14–09–3827P).	The Honorable Randy Voepel, Mayor, City of Santee, 10601 Magnolia Ave., Santee, CA 92071.	City Hall, 10601 Magnolia Drive, Santee, CA 92071.	*http://www.msc.fema.gov/lomc.*	Jan. 29, 2016	060703
San Diego	Unincorporated Areas of San Diego County (14–09–3827P).	The Honorable Bill Horn, Chairman, Board of Supervisors San Diego County, 1600 Pacific Highway, San Diego, CA 92101.	Department of Public Works, Flood Control, 5201 Ruffin Road, Suite P, San Diego, CA 92123.	*http://www.msc.fema.gov/lomc.*	Jan. 29, 2016	060284
San Diego	Unincorporated Areas of San Diego County (14–09–3829P).	The Honorable Bill Horn, Chairman, Board of Supervisors San Diego County, 1600 Pacific Highway, San Diego, CA 92101.	Department of Public Works, Flood Control, 5201 Ruffin Road, Suite P, San Diego, CA 92101.	*http://www.msc.fema.gov/lomc.*	Jan. 29, 2016	060284
Santa Clara	City of Morgan Hill (15–09–1137P).	The Honorable Steve Tate, Mayor, City of Morgan Hill, 17555 Peak Avenue, Morgan Hill, CA 95037.	Public Works Department, 17555 Peak avenue, Morgan Hill, CA 95037.	*http://www.msc.fema.gov/lomc.*	Dec. 14, 2015	060346
Nevada:						
Clark	City of Henderson (15–09–1109P).	The Honorable Andy A. Hafen, Mayor, City of Henderson, 240 Water Street, Henderson, NV 89015.	Public Works Department, 240 Water Street, Henderson, NV 89015.	*http://www.msc.fema.gov/lomc.*	Feb. 5, 2016	320005
Clark	Unincorporated Areas of Clark County (15–09–1539P).	The Honorable Steve Sisolak, Chairman, Board of Supervisors Clark County, 500 South Grand Central Parkway, 6th Floor, Las Vegas, NV 89155.	Office of the Director of Public Works, 500 South Grand Central Parkway, Las Vegas, NV 89155.	*http://www.msc.fema.gov/lomc.*	Feb. 11, 2016	320003

[FR Doc. 2015–31029 Filed 12–8–15; 8:45 am]

BILLING CODE 9110–12–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0050]

Agency Information Collection Activities: Request for Hearing on a Decision in Naturalization Proceedings (Under Section 336 of the INA), Form N–336; Revision of a Currently Approved Collection

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting 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. The information collection notice was previously published in the **Federal Register** on July 13, 2015, at 80 FR 40083, allowing for a 60-day public comment period. USCIS did receive 2 comments in connection with the 60-day notice.

DATES: The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until January 8, 2016. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be directed to the OMB USCIS Desk Officer via email at *oira_submission@omb.eop.gov.* Comments may also be submitted via fax at (202) 395–5806 (This is not a toll-free number). All submissions received must include the agency name and the OMB Control Number 1615–0050.

You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make. For additional information please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy,

Regulatory Coordination Division, Laura Dawkins, Chief, 20 Massachusetts Avenue NW., Washington, DC 20529–2140, Telephone number (202) 272–8377 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at *http://www.uscis.gov*, or call the USCIS National Customer Service Center at (800) 375–5283; TTY (800) 767–1833.

SUPPLEMENTARY INFORMATION:

Comments: You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2007–0020 in the search box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection Request:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Request for Hearing on a Decision in Naturalization Proceedings (Under Section 336 of the INA).

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* N–336; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. Form N–336 provides a method for applicants, whose applications for naturalization are denied, to request a new hearing by an Immigration Officer of the same or higher rank as the denying officer, within 30 days of the original decision.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection N–336 is 5,253 and the estimated hour burden per response is 2.75 hours for paper submissions and 2.4 hours for MyUSCIS submissions.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 12,706 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $1,313,250.

Dated: December 3, 2015.

Samantha Deshommes,

Deputy Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2015–30951 Filed 12–8–15; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0056]

Agency Information Collection Activities: Application To Preserve Residence for Naturalization, Form N–470; Revision of a Currently Approved Collection

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 30-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration Services (USCIS) will be submitting 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. The information collection notice was previously published in the **Federal Register** on July 13, 2015, at 80 FR 40083, allowing for a 60-day public comment period. USCIS did not receive any comments in connection with the 60-day notice.

DATES: The purpose of this notice is to allow an additional 30 days for public comments. Comments are encouraged and will be accepted until January 8, 2016. This process is conducted in accordance with 5 CFR 1320.10.

ADDRESSES: Written comments and/or suggestions regarding the item(s) contained in this notice, especially regarding the estimated public burden and associated response time, must be directed to the OMB USCIS Desk Officer via email at *oira_submission@omb.eop.gov.* Comments may also be submitted via fax at (202) 395–5806 (This is not a toll-free number). All submissions received must include the agency name and the OMB Control Number 1615–0056.

You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make. For additional information please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Laura Dawkins, Chief, 20 Massachusetts Avenue NW., Washington, DC 20529–2140, Telephone number (202) 272–8377 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at *http://www.uscis.gov,* or call the USCIS National Customer Service Center at (800) 375–5283; TTY (800) 767–1833.

SUPPLEMENTARY INFORMATION:

Comments: You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2006–0030 in the search box. Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Overview of This Information Collection

(1) *Type of Information Collection Request:* Revision of a Currently Approved Collection.

(2) *Title of the Form/Collection:* Application to Preserve Residence for Naturalization.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* N–470; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. The information collected on Form N–470 will be used to determine whether an alien who intends to be absent from the United States for a period of one year or more is eligible to preserve residence for naturalization purposes.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection N–470 is 625 and the estimated hour burden per response is .6 hour for respondents via paper and .4 hour for respondents via MyUSCIS.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 263 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* The estimated total annual cost burden associated with this collection of information is $76,563.

Dated: December 3, 2015.

Samantha Deshommes,

Deputy Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2015–30952 Filed 12–8–15; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF HOMELAND SECURITY

U.S. Citizenship and Immigration Services

[OMB Control Number 1615–0113]

Agency Information Collection Activities: InfoPass, No Form; Extension, Without Change, of a Currently Approved Collection

AGENCY: U.S. Citizenship and Immigration Services, Department of Homeland Security.

ACTION: 60-Day notice.

SUMMARY: The Department of Homeland Security (DHS), U.S. Citizenship and Immigration (USCIS) invites the general public and other Federal agencies to comment upon this proposed extension of a currently approved collection of information. In accordance with the Paperwork Reduction Act (PRA) of 1995, the information collection notice is published in the **Federal Register** to obtain comments regarding the nature of the information collection, the categories of respondents, the estimated burden (*i.e.*, the time, effort, and resources used by the respondents to respond), the estimated cost to the respondent, and the actual information collection instruments.

DATES: Comments are encouraged and will be accepted for 60 days until February 8, 2016.

ADDRESSES: All submissions received must include the OMB Control Number 1615–0113 in the subject box, the agency name and Docket ID USCIS–2009–0024. To avoid duplicate submissions, please use only *one* of the following methods to submit comments:

(1) *Online.* Submit comments via the Federal eRulemaking Portal Web site at *http://www.regulations.gov* under e-Docket ID number USCIS–2009–0024;

(2) *Email.* Submit comments to *USCISFRComment@uscis.dhs.gov*;

(3) *Mail.* Submit written comments to DHS, USCIS, Office of Policy and Strategy, Chief, Regulatory Coordination Division, 20 Massachusetts Avenue NW., Washington, DC 20529–2140.

FOR FURTHER INFORMATION CONTACT: USCIS, Office of Policy and Strategy, Regulatory Coordination Division, Laura Dawkins, Chief, 20 Massachusetts Avenue NW., Washington, DC 20529–2140, telephone number 202–272–8377 (This is not a toll-free number. Comments are not accepted via telephone message). Please note contact information provided here is solely for questions regarding this notice. It is not for individual case status inquiries. Applicants seeking information about the status of their individual cases can check Case Status Online, available at the USCIS Web site at *http://www.uscis.gov*, or call the USCIS National Customer Service Center at 800–375–5283 (TTY 800–767–1833).

SUPPLEMENTARY INFORMATION:

Comments:

You may access the information collection instrument with instructions, or additional information by visiting the Federal eRulemaking Portal site at: *http://www.regulations.gov* and enter USCIS–2009–0024 in the search box. Regardless of the method used for submitting comments or material, all submissions will be posted, without change, to the Federal eRulemaking Portal at *http://www.regulations.gov*, and will include any personal information you provide. Therefore, submitting this information makes it public. You may wish to consider limiting the amount of personal information that you provide in any voluntary submission you make to DHS. DHS may withhold information provided in comments from public viewing that it determines may impact the privacy of an individual or is offensive. For additional information, please read the Privacy Act notice that is available via the link in the footer of *http://www.regulations.gov.*

Written comments and suggestions from the public and affected agencies should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(3) Enhance the quality, utility, and clarity of the information to be collected; and

(4) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

Overview of this information collection:

(1) *Type of Information Collection:* Extension, Without Change, of a Currently Approved Collection.

(2) *Title of the Form/Collection:* InfoPass.

(3) *Agency form number, if any, and the applicable component of the DHS sponsoring the collection:* No Agency Form Number; USCIS.

(4) *Affected public who will be asked or required to respond, as well as a brief abstract: Primary:* Individuals or households. The InfoPass system allows an applicant or petitioner to schedule an interview appointment with USCIS through USCIS' Internet Web site.

(5) *An estimate of the total number of respondents and the amount of time estimated for an average respondent to respond:* The estimated total number of respondents for the information collection is 1,043,319 and the estimated hour burden per response is .1 hours.

(6) *An estimate of the total public burden (in hours) associated with the collection:* The total estimated annual hour burden associated with this collection is 104,332 hours.

(7) *An estimate of the total public burden (in cost) associated with the collection:* There is no estimated total annual cost burden associated with this collection of information.

Dated: December 3, 2015.

Samantha Deshommes,

Deputy Chief, Regulatory Coordination Division, Office of Policy and Strategy, U.S. Citizenship and Immigration Services, Department of Homeland Security.

[FR Doc. 2015–30950 Filed 12–8–15; 8:45 am]

BILLING CODE 9111–97–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[FWS–R1–ES–2015–0026; FXES11120100000–167–FF01E00000]

Programmatic Draft Environmental Impact Statement for Invasive Rodent and Mongoose Control and Eradication on U.S. Pacific Islands Within the National Wildlife Refuge System and in Native Ecosystems in Hawaii

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of intent; reopening of public scoping and comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), in coordination with the State of Hawaii Department of Land and Natural Resources (DLNR), Division of Forestry and Wildlife (DOFAW), announce the reopening of the public scoping process and comment period for the preparation of a Programmatic Draft Environmental Impact Statement for Invasive Rodent and Mongoose Control and Eradication on U.S. Pacific Islands within the National Wildlife Refuge System and in Native Ecosystems in Hawaii (PDEIS). We are reopening the public scoping process and comment period for an additional 120 days.

DATES: *Written Comments:* To ensure consideration, we must receive your written comments on or before April 7, 2016 to ensure all relevant information and recommendations are considered during the PDEIS process. Public scoping meetings will be held at a later date. Meeting dates, locations, and times will be announced in a future notice and on the Service's Web site at *http://www.fws.gov/pacificislands/nativerestoration/.*

ADDRESSES: Send your comments regarding the proposed action and the proposed PDEIS by one of the following methods:

- *Electronically: www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–R1–ES–2015–0026.
- *U.S. Mail:* Public Comments Processing, Attn: FWS–R1–ES–2015–0026; Division of Policy and Directives Management; U.S. Fish and Wildlife Service, MS: BPHC; 5275 Leesburg Pike, Falls Church, VA 22041–3803.

FOR FURTHER INFORMATION CONTACT: Mary Abrams, Field Supervisor, U.S. Fish and Wildlife Service, Pacific Islands Fish and Wildlife Office, 300 Ala Moana Boulevard, Room 3–122, Honolulu, HI 96850; telephone 808–792–9400). If you use a telecommunications device for the deaf, please call the Federal Information Relay Service at 800–877–8339.

SUPPLEMENTARY INFORMATION: On June 30, 2015, we published a **Federal Register** notice (80 FR 37286), in coordination with the State of Hawaii DLNR, DOFAW, announcing our intent to prepare a PDEIS. We originally opened a 120-day comment period from June 30, 2015, to October 28, 2015 (80 FR 37286). For background and more information, please see that notice. We are reopening the public comment period for an additional 120 days to be able to hold public scoping meetings in partnership with the DOFAW. At a later date, the DOFAW will be publishing their Environmental Impact Statement preparation notice, as defined by chapters 201N and 343 of the Hawaii Revised Statutes and title 11, chapter 200 of the Hawaii Administrative Rules, in *The Environmental Bulletin* published by the Hawaii State Office of Environmental Quality Control. We are seeking comments, information, and suggestions from the public, interested government agencies, Native Hawaiian organizations, the scientific community, and other interested parties regarding the objectives, proposed action, and alternatives identified and described. If you have previously submitted comments, please do not resubmit them. We have already incorporated them in the public record and will fully consider them in the development of the PDEIS.

Public Availability of Comments

All comments and materials we receive become part of the public record associated with this action. Before including your address, phone number, email address, or other personally identifiable information in your comments, you should be aware that your entire comment—including your personally identifiable information—may be made publicly available at any time. While you can ask us in your comment to withhold your personally identifiable information from public review, we cannot guarantee that we will be able to do so. Comments and materials we receive, as well as supporting documentation we use in preparing the PDEIS, will be available for public inspection by appointment, during normal business hours, at our Pacific Islands Fish and Wildlife Office (see **ADDRESSES**).

Authority

The environmental review of this project will be conducted in accordance with the requirements of NEPA of 1969, as amended (42 U.S.C. 4321 *et seq.*), Council on Environmental Quality Regulations (40 CFR parts 1500–1508), and other applicable Federal laws and regulations. This notice is being furnished in accordance with 40 CFR 1501.7 of the NEPA regulations to obtain suggestions and information from other agencies and the public on the scope of issues and alternatives to be addressed in the PDEIS.

Dated: November 13, 2015.

Theresa E. Rabot,

Acting Deputy Regional Director, Pacific Region, U.S. Fish and Wildlife Service, Portland, Oregon.

[FR Doc. 2015–30976 Filed 12–8–15; 8:45 am]

BILLING CODE 4333–15–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

[Docket No. FWS–HQ–IA–2015–0175; FXIA16710900000–156–FF09A30000]

Endangered Species; Receipt of Applications for Permit

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of receipt of applications for permit.

SUMMARY: We, the U.S. Fish and Wildlife Service, invite the public to comment on the following applications to conduct certain activities with endangered species. With some exceptions, the Endangered Species Act (ESA) prohibits activities with listed species unless Federal authorization is acquired that allows such activities.

DATES: We must receive comments or requests for documents on or before January 8, 2016.

ADDRESSES: *Submitting Comments:* You may submit comments by one of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments on Docket No. FWS–HQ–IA–2015–0175.
- *U.S. mail or hand-delivery:* Public Comments Processing, Attn: Docket No. FWS–HQ–IA–2015–0175; U.S. Fish and Wildlife Service Headquarters, MS: BPHC; 5275 Leesburg Pike, Falls Church, VA 22041–3803.

When submitting comments, please indicate the name of the applicant and the PRT# you are commenting on. We will post all comments on *http://www.regulations.gov.* This generally means that we will post any personal information you provide us (see the Public Comments section below for more information).

Viewing Comments: Comments and materials we receive will be available for public inspection on *http://www.regulations.gov,* or by appointment, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays, at the U.S. Fish and Wildlife Service, Division of Management Authority, 5275 Leesburg Pike, Falls Church, VA 22041–3803; telephone 703–358–2095.

FOR FURTHER INFORMATION CONTACT: Brenda Tapia, (703) 358–2104 (telephone); (703) 358–2281 (fax); *DMAFR@fws.gov* (email).

SUPPLEMENTARY INFORMATION:

I. Public Comment Procedures

A. How do I request copies of applications or comment on submitted applications?

Send your request for copies of applications or comments and materials concerning any of the applications to the contact listed under **ADDRESSES**. Please include the **Federal Register** notice publication date, the PRT-number, and the name of the applicant in your request or submission. We will not consider requests or comments sent to an email or address not listed under **ADDRESSES**. If you provide an email address in your request for copies of applications, we will attempt to respond to your request electronically.

Please make your requests or comments as specific as possible. Please confine your comments to issues for which we seek comments in this notice, and explain the basis for your comments. Include sufficient information with your comments to allow us to authenticate any scientific or commercial data you include.

The comments and recommendations that will be most useful and likely to influence agency decisions are: (1) Those supported by quantitative information or studies; and (2) Those that include citations to, and analyses of, the applicable laws and regulations. We will not consider or include in our administrative record comments we receive after the close of the comment period (see **DATES**) or comments delivered to an address other than those listed above (see **ADDRESSES**).

B. May I review comments submitted by others?

Comments, including names and street addresses of respondents, will be available for public review at the street address listed under **ADDRESSES**. The public may review documents and other information applicants have sent in support of the application unless our allowing viewing would violate the Privacy Act or Freedom of Information Act. Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

II. Background

To help us carry out our conservation responsibilities for affected species, and in consideration of section 10(a)(1)(A) of the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*), along with Executive Order 13576, ''Delivering an Efficient, Effective, and Accountable Government,'' and the President's Memorandum for the Heads of Executive Departments and Agencies of January 21, 2009—Transparency and Open Government (74 FR 4685; January 26, 2009), which call on all Federal agencies to promote openness and transparency in Government by disclosing information to the public, we invite public comment on these permit applications before final action is taken.

III. Permit Applications

Endangered Species

Applicant: The Ohio State University, Columbus, OH; PRT–73358B

The applicant requests a permit to import seven skeletons and seven crania of sooty mangabey (*Cercocebus atys*) for the purpose of scientific research. This notification covers activities to be conducted by the applicant over a 1-year period.

Applicant: Columbia University, New York, NY; PRT–79276B

The applicant requests a permit to import biological samples from wild specimens of Mexican long-nosed bat (*Leptonycteris nivalis*) for the purpose of scientific research.

Applicant: Ho, Shawn, Chino, CA; PRT–68844B

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the following species to enhance species propagation or survival: Radiated tortoise (*Astrochelys radiata*). This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Nickel City Reptiles & Exotics, North Tonawanda, NY; PRT–60987B

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the following species to enhance species propagation or survival: Radiated tortoise (*Astrochelys radiata*), spotted pond turtle (*Geoclemys hamiltonii*), Nile crocodile, (*Crocodylus niloticus*), dwarf crocodile (*Osteolaemus tetraspis*), Grand Cayman iguana (*Cyclura lewisi*), Moluccan cockatoo (*Cacatua moluccensis*), brush-tailed bettong (*Bettongia penicillata*), ring-tailed lemur (*Lemur catta*), black and white ruffed lemur (*Varecia variegata*), red ruffed lemur (*Varecia rubra*), cotton-topped tamarin (*Saguinus oedipus*) lar gibbon (*Hylobates lar*), and clouded leopard (*Neofelis nebulosa*). This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Serpentarium Magic, Mills River, NC; PRT–64789B

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the following species to enhance species propagation or survival: Radiated tortoise (*Astrochelys radiata*), Cuban rock iguana (*Cyclura nubila nubila*), Grand Cayman iguana (*Cyclura lewisi*)), Cayman Brac ground iguana (*Cyclura nubila caymanensis*), San Esteban Island chuckwalla

(*Sauromalus varius*), Jamaican boa (*Epicrates subflavus*), Indian python (*Python molurus molurus*), and Aruba Island rattlesnake (*Crotalus unicolor*). This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: Meyer, Victoria, Great Falls, MT; PRT–73515B

The applicant requests a captive-bred wildlife registration under 50 CFR 17.21(g) for the following species to enhance species propagation or survival: Golden conure (*Guarouba guarouba*). This notification covers activities to be conducted by the applicant over a 5-year period.

Applicant: West Coast Game Park, Inc., Bandon, OR; PRT–667821

The applicant requests an amendment to his captive-bred wildlife registration under 50 CFR 17.21(g) to add the following species to enhance species propagation or survival: Chimpanzee (*Pan troglodytes*). This notification covers activities to be conducted by the applicant over a 5-year period.

Multiple Applicants

The following applicants each request a permit to import the sport-hunted trophy of one male bontebok (*Damaliscus pygargus pygargus*) culled from a captive herd maintained under the management program of the Republic of South Africa, for the purpose of enhancement of the survival of the species.

Applicant: Erhardt Steinborn, Sherwood, OR; PRT–81224B

Applicant: Gregory Fowler, Lookout, CA; PRT–81679B

Applicant: David Twiss, Richardson, TX; PRT–80817B

Applicant: Kevin Wilbanks, Artesia, NM; PRT–81946B

Brenda Tapia,

Program Analyst/Data Administrator, Branch of Permits, Division of Management Authority.

[FR Doc. 2015–30967 Filed 12–8–15; 8:45 am]

BILLING CODE 4310–15–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NERO–ACAD–19758; PPNEACADSO, PPMPSPDIZ.YM0000]

Notice of Meetings of the Acadia National Park Advisory Commission

AGENCY: National Park Service, Interior.

ACTION: Meeting notice.

SUMMARY: This notice sets the dates of the next three meetings of the Acadia National Park Advisory Commission occurring in 2016. The Commission meeting locations may change based on inclement weather or exceptional circumstances. If a meeting location is changed, the Superintendent will issue a press release and use local newspapers to announce the meeting.

DATES: All meetings will begin at 1:00 p.m. (EASTERN). The schedule for the public meetings of the Commission will be held as follows: Monday, February 1, 2016; Monday, June 6, 2016; and Monday, September 12, 2016.

ADDRESSES: For the February 1, 2016, and June 6, 2016, meetings, the Commission will meet at the Acadia National Park headquarters conference room, Acadia National Park, 20 McFarland Hill Drive, Bar Harbor, Maine 04609. For the September 12, 2016, meeting, the Commission will meet at Schoodic Education and Research Center, Winter Harbor, Maine 04693.

Agenda

Each Commission meeting will consist of the following proposed agenda items:

1. Committee Reports:
   - Land Conservation
   - Park Use
   - Science and Education
   - Historic
2. Old Business
3. Superintendent's Report
4. Chairman's Report
5. Public Comments
6. Adjournment

FOR FURTHER INFORMATION CONTACT: R. Michael Madell, Deputy Superintendent, Acadia National Park, P.O. Box 177, Bar Harbor, Maine 04609, telephone (207) 288–8701.

SUPPLEMENTARY INFORMATION: The meeting is open to the public. Interested persons may make oral or written presentations to the Commission or file written statements. Such requests should be made to the Deputy Superintendent at least seven days prior to the meeting. Before including your address, telephone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: December 1, 2015.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2015–30919 Filed 12–8–15; 8:45 am]

BILLING CODE 4310–EE–P

DEPARTMENT OF THE INTERIOR

National Park Service

[NPS–NERO–PAGR–19767; PX.PR166532I.00.1]

Notice of 2016 Meetings for the Paterson Great Falls National Historical Park Advisory Commission

AGENCY: National Park Service, Interior.

ACTION: Notice of meetings.

SUMMARY: As required by the Federal Advisory Committee Act (5 U.S.C. Appendix 1–16), the National Park Service is hereby giving notice for the 2016 schedule of meetings for the Paterson Great Falls National Historical Park Advisory Commission. The Commission is authorized by the Omnibus Public Land Management Act, (16 U.S.C. 410lll), ''to advise the Secretary in the development and implementation of the management plan.'' Agendas for these meetings will be provided on the Commission Web site at *http://www.nps.gov/pagr/parkmgmt/federal-advisory-commission.htm.*

DATES: The Commission will meet on the following dates in 2016:

Thursday, January 7, 2016, 2:00–5:00 p.m. (snow date: January 14, 2016, 2:00 p.m.–5:00 p.m.) (EASTERN);

Thursday, April 7, 2016, 2:00–5:00 p.m. (EASTERN);

Thursday, July 7, 2016, 2:00–5:00 p.m. (EASTERN); and

Thursday, October 20, 2016; 2:00–5:00 p.m. (EASTERN).

ADDRESSES: The January and July meetings will be held at the Rogers Meeting Center, 32 Spruce Street, Paterson, NJ 07501. The April and October meetings will be held at the Paterson Museum, 2 Market Street, Paterson, NJ 07501.

FOR FURTHER INFORMATION CONTACT: Darren Boch, Superintendent and Designated Federal Officer, Paterson Great Falls National Historical Park, 72 McBride Avenue, Paterson, NJ 07501, (973) 523–2630.

SUPPLEMENTARY INFORMATION: Topics to be discussed include updates on the status of the Paterson Great Falls National Historical Park General Management Plan.

The meetings will be open to the public and time will be reserved during

each meeting for public comment. Oral comments will be summarized for the record. If individuals wish to have their comments recorded verbatim, they must submit them in writing. Written comments and requests for agenda items may be sent to: Federal Advisory Commission, Paterson Great Falls National Historical Park, 72 McBride Avenue, Paterson, NJ 07501.

Before including your address, telephone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you may ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so. All comments will be made part of the public record and will be electronically distributed to all Commission members.

Dated: December 1, 2015.

Alma Ripps,

Chief, Office of Policy.

[FR Doc. 2015–30921 Filed 12–8–15; 8:45 am]

BILLING CODE 4310–EE–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000 167S180110; S2D2S SS08011000 SX064A000 16XS501520]

Notice of Proposed Information Collection; Request for Comments for 1029–0119

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSMRE) is announcing that the information collection request for contractor eligibility, and the Abandoned Mine Land Contractor Information Form, has been forwarded to the Office of Management and Budget (OMB) for review and approval. The information collection request describes the nature of the information collection and the expected burden and cost. This information collection activity was previously approved by OMB and assigned control number 1029–0119.

DATES: Comments must be submitted on or before January 8, 2016, to be assured of consideration.

ADDRESSES: Submit comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Department of the Interior Desk Officer, via email at *OIRA_submission@omb.eop.gov,* or by facsimile to (202) 395–5806. Also, please send a copy of your comments to John Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave. NW., Room 203–SIB, Washington, DC 20240, or electronically to *jtrelease@osmre.gov.* Please reference 1029–0119 in your correspondence.

FOR FURTHER INFORMATION CONTACT: To receive a copy of the information collection request contact John Trelease at (202) 208–2783, or electronically at *jtrelease@osmre.gov.* You may also review this information collection request on the Internet by going to *http://www.reginfo.gov* (Information Collection Review, Currently Under Review, Agency is Department of the Interior, DOI–OSMRE).

SUPPLEMENTARY INFORMATION: The Office of Management and Budget (OMB) regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8(d)]. OSMRE has submitted a request to OMB to renew its approval for the collection of information for 30 CFR 874.16, and the AML Contractor Information Form which is found in the Applicant/Violator System (AVS) handbook. OSMRE is requesting a 3-year term of approval for this collection.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this collection of information is 1029–0119.

As required by 5 CFR 1320.8(d), a **Federal Register** notice soliciting comments on this collection of information was published on August 17, 2015 (80 FR 49267). No comments were received. This notice provides the public with an additional 30 days in which to comment on the following information collection activity:

Title: 30 CFR 874.16—Contractor Eligibility and the Abandoned Mine Land Contractor Information Form.

OMB Control Number: 1029–0119.

Summary: 30 CFR 874.16 requires that every successful bidder for an AML contract must be eligible under 30 CFR 773.15(b)(1) at the time of contract award to receive a permit or conditional permit to conduct surface coal mining operations. Further, the regulation requires the eligibility to be confirmed by OSMRE's automated Applicant/Violator System (AVS) and the contractor must be eligible under the regulations implementing section 510(c) of the Surface Mining Act to receive permits to conduct mining operations. This form provides a tool for OSMRE and the States/Indian tribes to help them prevent persons with outstanding violations from conducting further mining or AML reclamation activities in the State.

Bureau Form Title: AML Contractor Information Form (No form number).

Frequency of Collection: Once per contract.

Description of Respondents: AML contract applicants and State and Tribal regulatory authorities.

Total Annual Responses: 247 bidders and 93 State/Tribal responses.

Total Annual Burden Hours: 205.

Obligation to Respond: Required in order to obtain or retain benefits.

Send comments on the need for the collection of information for the performance of the functions of the agency; the accuracy of the agency's burden estimates; ways to enhance the quality, utility and clarity of the information collection; and ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information, to the offices listed in the **ADDRESSES** section. Please refer to the appropriate OMB control number in all correspondence.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: December 4, 2015.

John A. Trelease,

Acting Chief, Division of Regulatory Support.

[FR Doc. 2015–30988 Filed 12–8–15; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000 167S180110; S2D2S SS08011000 SX064A000 16XS501520]

Notice of Proposed Information Collection; Request for Comments for 1029–0098

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSMRE) is announcing that the information collection request for the Petition process for designation of Federal lands as unsuitable for all or certain types of surface coal mining operations and for termination of previous designations, has been submitted to the Office of Management and Budget (OMB) for review and approval. The information collection request describes the nature of the information collection and its expected burden and cost. This information collection activity was previously approved by OMB and assigned control number 1029–0098.

DATES: OMB has up to 60 days to approve or disapprove the information collection request but may respond after 30 days. Therefore, public comments should be submitted to OMB by January 8, 2016, in order to be assured of consideration.

ADDRESSES: Submit comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Department of the Interior Desk Officer, by telefax at (202) 395–5806 or via email to *OIRA_Submission@omb.eop.gov.* Also, please send a copy of your comments to John Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave. NW., Room 203–SIB, Washington, DC 20240, or electronically to *jtrelease@osmre.gov.* Please reference 1029–0098 in your correspondence.

FOR FURTHER INFORMATION CONTACT: To receive a copy of the information collection request contact John Trelease at (202) 208–2783, or electronically at *jtrelease@OSMREre.gov.* You may also review this information collection request on the Internet by going to *http://www.reginfo.gov* (Information Collection Review, Currently Under Review, Agency is Department of the Interior, DOI–OSMRE).

SUPPLEMENTARY INFORMATION: OMB regulations at 5 CFR part 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8(d)]. OSMRE has submitted a request to OMB to renew its approval for the collection of information found at 30 CFR part 769—Petition process for designation of Federal lands as unsuitable for all or certain types of surface coal mining operations and for termination of previous designations. OSMRE is requesting a 3-year term of approval for this collection.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this collection of information is 1029–0098.

As required under 5 CFR 1320.8(d), a **Federal Register** notice soliciting comments on this collection of information was published on August 5, 2015 (80 FR 46602). No comments were received. This notice provides the public with an additional 30 days in which to comment on the following information collection activity:

Title: 30 CFR part 769—Petition process for designation of Federal lands as unsuitable for all or certain types of surface coal mining operations and for termination of previous designations.

OMB Control Number: 1029–0098.

Summary: This part establishes the minimum procedures and standards for designating Federal lands unsuitable for certain types of surface mining operations and for terminating designations pursuant to a petition. The information requested will aid the regulatory authority in the decision making process to approve or disapprove a request.

Bureau Form Number: None.

Frequency of Collection: Once.

Description of Respondents: People who may be adversely affected by surface mining on Federal lands.

Total Annual Responses: 1.

Total Annual Burden Hours: 1,000.

Obligation to Respond: Required in order to obtain or retain benefits.

Send comments on the need for the collection of information for the performance of the functions of the agency; the accuracy of the agency's burden estimates; ways to enhance the quality, utility and clarity of the information collection; and ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information, to the offices listed in the **ADDRESSES** section. Please reference OMB control number 1029–0098 in all correspondence.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: December 4, 2015.

John A. Trelease,

Acting Chief, Division of Regulatory Support.

[FR Doc. 2015–30985 Filed 12–8–15; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000 167S180110; S2D2S SS08011000 SX064A000 16XS501520]

Notice of Proposed Information Collection for 1029–0115

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSMRE) is announcing its intention to seek renewed approval for the collection of information for permits and permit processing. This information collection will also seek approval to collect permit processing fees approved under OSMRE regulations. This information collection activity was previously approved by OMB and assigned control number 1029–0115.

DATES: Comments on the proposed information collection must be received by February 8, 2016, to be assured of consideration.

ADDRESSES: Comments may be mailed to John A. Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave. NW., Room 203–SIB, Washington, DC 20240. Comments may also be submitted electronically to *jtrelease@osmre.gov.*

FOR FURTHER INFORMATION CONTACT: To receive a copy of the information collection request contact John A.

Trelease, at (202) 208–2783 or at the email address listed in **ADDRESSES.**

SUPPLEMENTARY INFORMATION: The Office of Management and Budget (OMB) regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8(d)]. This notice identifies an information collection that OSMRE will be submitting to OMB for extension. This collection is contained in 30 CFR part 773—Requirements for permits and permit processing. OSMRE is including in this collection a request for OMB approval to collect processing fees for new permits in Federal program states and on Indian lands codified in 30 CFR 736.25 and 750.25.

OSMRE has revised burden estimates, where appropriate, to reflect current reporting levels or adjustments based on reestimates of burden or respondents. OSMRE will request a 3-year term of approval for the information collection activity.

Comments are invited on: (1) The need for the collection of information for the performance of the functions of the agency; (2) the accuracy of the agency's burden estimates; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information. A summary of the public comments will be included in OSMRE's submissions of the information collection requests to OMB.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Title: 30 CFR part 773—Requirements for Permits and Permit Processing.

OMB Control Number: 1029–0115.

Summary: The collection activities for this Part ensure that the public has the opportunity to review permit applications prior to their approval, and that applicants for permanent program permits or their associates who are in violation of the Surface Mining Control and Reclamation Act do not receive surface coal mining permits pending resolution of their violations. This collection request includes the submission of processing fees authorized by 30 CFR 736.25 and 750.25 in Federal program states and on Indian lands, respectively.

Bureau Form Number: None.

Frequency of Collection: Once.

Description of Respondents: Applicants for surface coal mining and reclamation permits and State governments and Indian Tribes.

Total Annual Respondents: 892 coal mining applicants and 24 regulatory authorities.

Total Annual Burden Hours: 38,442.

Total Annual Non-Wage Cost Burden: $85,600.

Obligation to Respond: Required in order to obtain or retain benefits.

Dated: December 4, 2015.

John A. Trelease,

Acting Chief, Division of Regulatory Support.

[FR Doc. 2015–30991 Filed 12–8–15; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000 167S180110; S2D2S SS08011000 SX064A000 16XS501520]

Notice of Proposed Information Collection for 1029–0051

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSMRE) is announcing its intention to request approval to continue the collection of information for its Permanent Program Inspection and Enforcement Procedures. This information collection activity was previously approved by the Office of Management and Budget (OMB), and assigned control number 1029–0051.

DATES: Comments on the proposed information collection activities must be received by February 8, 2016, to be assured of consideration.

ADDRESSES: Comments may be mailed to John Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave. NW., Room 203–SIB, Washington, DC 20240. Comments may also be submitted electronically to *jtrelease@osmre.gov.* Please reference control number 1029–0051 in your correspondence.

FOR FURTHER INFORMATION CONTACT: To request additional information about this collection of information, contact John Trelease, at (202) 208–2783 or by email listed in **ADDRESSES**.

SUPPLEMENTARY INFORMATION: OMB regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8(d)]. This notice identifies an information collection that OSMRE will be submitting to OMB for renewed approval. The collection is contained in 30 CFR part 840—Permanent Program Inspection and Enforcement Procedures. OSMRE will request a 3-year term of approval for each information collection activity.

Comments are invited on: (1) The need for the collection of information for the performance of the functions of the agency; (2) the accuracy of the agency's burden estimates; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information. A summary of the public comments will accompany OSMRE's submission of the information collection request to OMB.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment–including your personal identifying information–may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Title: 30 CFR part 840—Permanent Program Inspection and Enforcement Procedures.

OMB Control Number: 1029–0051.

Abstract: This provision requires the regulatory authority to conduct periodic inspections of coal mining activities, and prepare and maintain inspection reports and other related documents for OSMRE and public review. This information is necessary to meet the requirements of the Surface Mining Control and Reclamation Act of 1977 and its public participation provisions. Public review assures the public that the State is meeting the requirements of the Act and approved State regulatory program.

Bureau Form Number: None.

Frequency of Collection: Once and annually.

Description of Respondents: State Regulatory Authorities.

Total Annual Responses: 106,382.
Total Annual Burden Hours: 748,140.
Total Non-Wage Costs: $1,440.
Obligation To Respond: Required in order to obtain or retain benefits.

Dated: *December 4, 2015.*

John A. Trelease,

Acting Chief, Division of Regulatory Support.

[FR Doc. 2015–30990 Filed 12–8–15; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000 167S180110; S2D2S SS08011000 SX064A000 16XS501520]

Notice of Proposed Information Collection; Request for Comments for 1029–0027

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSMRE) is announcing its intention to seek renewed authority to collect information for surface coal mining and reclamation operations on Federal lands. This collection request has been forwarded to the Office of Management and Budget (OMB) for review and approval. The information collection request describes the nature of the information collection and the expected burden and cost.

DATES: OMB has up to 60 days to approve or disapprove the information collection request but may respond after 30 days. Therefore, public comments should be submitted to OMB by January 8, 2016, in order to be assured of consideration.

ADDRESSES: Submit comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Attention: Department of the Interior Desk Officer, by telefax at (202) 395–5806 or via email to *OIRA__Submission@omb.eop.gov*. Also, please send a copy of your comments to John Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave. NW., Room 203–SIB, Washington, DC 20240, or electronically to *jtrelease@osmre.gov*. Please reference 1029–0027 in your correspondence.

FOR FURTHER INFORMATION CONTACT: To receive a copy of the information collection request contact John Trelease at (202) 208-2783, or electronically at *jtrelease@osmre.gov*. You may also review this information collection request on the Internet by going to *http://www.reginfo.gov* (Information Collection Review, Currently Under Review, Agency is Department of the Interior, DOI–OSMRE).

SUPPLEMENTARY INFORMATION: OMB regulations at 5 CFR part 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [*see* 5 CFR 1320.8(d)]. OSMRE has submitted a request to OMB to renew its approval for the collections of information contained in 30 CFR part 740, Surface Coal Mining and Reclamation Operations on Federal Lands. OSMRE is requesting a 3-year term of approval for this information collection activity.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this collection of information is 1029-0027.

As required under 5 CFR 1320.8(d), a **Federal Register** notice soliciting comments on this collection of information was published on August 5, 2015 (80 FR 46601). No comments were received. This notice provides the public with an additional 30 days in which to comment on the following information collection activity:

Title: 30 CFR part 740—General Requirements for Surface Coal Mining and Reclamation Operations on Federal Lands.

OMB Control Number: 1029–0027.

Summary: Section 523 of the Surface Mining Control and Reclamation Act of 1977 requires that a Federal lands program be established to govern surface coal mining and reclamation operations on Federal lands. The information requested is needed to assist the regulatory authority to determine the eligibility of an applicant to conduct surface coal mining operations on Federal lands.

Frequency of Collection: Once.

Description of Respondents: Applicants for surface coal mine permits on Federal lands, and State Regulatory Authorities.

Total Annual Responses: 12.

Total Annual Burden Hours for Applicants: 780.

Total Annual Burden Hours for States: 1,425.

Total Annual Burden for All Respondents: 2,205.

Obligation to Respond: Required in order to obtain or retain benefits.

Send comments on the need for the collection of information for the performance of the functions of the agency; the accuracy of the agency's burden estimates; ways to enhance the quality, utility and clarity of the information collection; and ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information, to the places listed under **ADDRESSES**. Please refer to control number 1029–0027 in all correspondence.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: December 4, 2015.

John A. Trelease,

Acting Chief, Division of Regulatory Support.

[FR Doc. 2015–30984 Filed 12–8–15; 8:45 am]

BILLING CODE 4310–05–P

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

[S1D1S SS08011000 SX064A000 167S180110; S2D2S SS08011000 SX064A000 16XS501520]

Notice of Proposed Information Collection; Request for Comments for 1029–0094

AGENCY: Office of Surface Mining Reclamation and Enforcement, Interior.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSMRE) is announcing that the information collection request for its General provisions has been forwarded to the Office of Management and Budget (OMB) for review and approval. This information collection request describes the nature of the information collection and its expected burden and cost. This information collection activity was previously approved by OMB and assigned control number 1029–0094.

DATES: OMB has up to 60 days to approve or disapprove the information

collection request but may respond after 30 days. Therefore, public comments should be submitted to OMB by January 8, 2016, in order to be assured of consideration.

ADDRESSES: Submit comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, Department of the Interior Desk Officer, via email at *OIRA_submission@omb.eop.gov*, or by facsimile to (202) 395–5806. Also, please send a copy of your comments to John Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave. NW., Room 203–SIB, Washington, DC 20240, or electronically to *JTrelease@osmre.gov.* Please reference 1029–0094 in your correspondence.

FOR FURTHER INFORMATION CONTACT: To receive a copy of the information collection request contact John Trelease at (202) 208–2783, or electronically at *jtrelease@OSMREre.gov.* You may also review this information collection request on the Internet by going to *http://www.reginfo.gov* (Information Collection Review, Currently Under Review, Agency is Department of the Interior, DOI–OSMRE).

SUPPLEMENTARY INFORMATION: OMB regulations at 5 CFR part 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [see 5 CFR 1320.8(d)]. OSMRE has submitted the request to OMB to renew its approval for the collection of information found at 30 CFR part 700. OSMRE is requesting a 3-year term of approval for this information collection activity.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this collection of information is 1029–0094, and may be found in OSMRE's regulations at 30 CFR 700.10.

As required under 5 CFR 1320.8(d), a **Federal Register** notice soliciting comments on this collection was published on September 8, 2015 (80 FR 53887). No comments were received. This notice provides the public with an additional 30 days in which to comment on the following information collection activity:

Title: 30 CFR part 700—General.

OMB Control Number: 1029–0094.

Summary: The information establishes procedures and requirements for terminating jurisdiction of surface coal mining and reclamation operations, petitions for rulemaking, and citizen suits filed under the Surface Mining Control and Reclamation Act of 1977.

Bureau Form Number: None.

Frequency of Collection: Once.

Description of Respondents: State and Tribal regulatory authorities, private citizens and citizen groups, and surface coal mining companies.

Total Annual Responses: 23.

Total Annual Burden Hours: 80 hours.

Obligation to Respond: Required in order to obtain or retain benefits.

Send comments on the need for the collection of information for the performance of the functions of the agency; the accuracy of the agency's burden estimates; ways to enhance the quality, utility and clarity of the information collection; and ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information, to the places listed in **ADDRESSES**. Please refer to control number 1029–0094 in all correspondence.

Before including your address, phone number, email address, or other personal identifying information in your comment, you should be aware that your entire comment—including your personal identifying information—may be made publicly available at any time. While you can ask us in your comment to withhold your personal identifying information from public review, we cannot guarantee that we will be able to do so.

Dated: December 4, 2015.

John A. Trelease,

Acting Chief, Division of Regulatory Support.

[FR Doc. 2015–30987 Filed 12–8–15; 8:45 am]

BILLING CODE 4310–05–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–934]

Certain Dental Implants; Notice of Request for Statements on the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the presiding administrative law judge has issued a Final Initial Determination and Recommended Determination on Remedy and Bonding in the above-captioned investigation. The Commission is soliciting comments on public interest issues raised by the recommended relief, specifically a limited exclusion order against certain dental implants imported by respondents Instradent USA, Inc. of Andover, Massachusetts and JJGC Indústria e Comércio de Materiais Dentários S/A of Paraná, Brazil. This notice is soliciting public interest comments from the public only. Parties are to file public interest submissions pursuant to 19 CFR 210.50(a)(4).

FOR FURTHER INFORMATION CONTACT: Megan M. Valentine, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 708–2301. The public version of the complaint can be accessed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov,* and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its Internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: Section 337 of the Tariff Act of 1930 provides that if the Commission finds a violation it shall exclude the articles concerned from the United States:

> unless, after considering the effect of such exclusion upon the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, it finds that such articles should not be excluded from entry.
> 19 U.S.C. 1337(d)(1).

The Commission is interested in further development of the record on the public interest in these investigations. Accordingly, members of the public are invited to file submissions of no more than five (5) pages, inclusive of attachments, concerning the public interest in light of the administrative law judge's Recommended Determination on Remedy and Bonding issued in this investigation on November 10, 2015. Comments should address whether issuance of a limited exclusion order in this investigation would affect the

public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the recommended order are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the recommended order;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the recommended exclusion order within a commercially reasonable time; and

(v) explain how the limited exclusion order would impact consumers in the United States.

Written submissions must be filed no later than by close of business on December 2, 2015.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the investigation number (''Inv. No. 337–TA–934'') in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, *http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf*). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. See 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. A redacted non-confidential version of the document must also be filed simultaneously with the any confidential filing. All non-confidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of sections 201.10 and 210.50 of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.50).

By order of the Commission.

Issued: November 12, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015–30963 Filed 12–8–15; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation Nos. 731–TA–753, 754, and 756 (Third Review)]

Cut-to-Length Carbon Steel Plate From China, Russia, and Ukraine

Determinations

On the basis of the record[1] developed in the subject five-year reviews, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930, that revocation of the antidumping duty order on cut-to-length carbon steel plate from China and termination of the suspended antidumping duty investigations on cut-to-length carbon steel plate from Russia and Ukraine would be likely to lead to continuation or recurrence of material injury to an industry in the United States within a reasonably foreseeable time.[2]

Background

The Commission, pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)), instituted these reviews on October 1, 2014 (79 FR 59294) and determined on January 5, 2015 that it would conduct full reviews (80 FR 2443, January 16, 2015). Notice of the scheduling of the Commission's reviews and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** on March 23, 2015 (80 FR 15251). The hearing was held in Washington, DC, on September 29, 2015, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission made these determinations pursuant to section 751(c) of the Tariff Act of 1930 (19 U.S.C. 1675(c)). It completed and filed its determinations in these reviews on December 3, 2015. The views of the Commission are contained in USITC Publication 4581 (December 2015), entitled *Cut-to-Length Carbon Steel Plate from China, Russia, and Ukraine: Investigation Nos. 731–753, 754, and 756 (Third Review).*

By order of the Commission.

Issued: December 3, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015–30954 Filed 12–8–15; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 701–TA–530 (Final)]

Supercalendered Paper From Canada; Determination

On the basis of the record [1] developed in the subject investigation, the United States International Trade Commission (''Commission'') determines, pursuant to the Tariff Act of 1930 (''the Act''), that an industry in the United States is materially injured by reason of imports of supercalendered paper from Canada, provided for in subheading 4802.61.30 of the Harmonized Tariff Schedule of the United States, that have been found by the Department of Commerce (''Commerce'') to be subsidized by the government of Canada.[2]

Background

The Commission, pursuant to section 705(b) of the Tariff Act of 1930 (19 U.S.C. 1671d(b)), instituted this investigation effective February 26, 2015, following receipt of a petition filed with the Commission and Commerce by the Coalition for Fair Paper Imports, which is an ad hoc association of U.S. producers that includes Madison Paper Industries, Inc., Madison, ME and Verso Corp., Memphis, TN. The final phase of the investigation was scheduled by the Commission following notification of a preliminary determination by Commerce that imports of supercalendered paper from Canada were being subsidized within the

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] Chairman Broadbent and Commissioner Kieff dissenting with respect to the suspended investigation on cut-to-length carbon steel plate from Ukraine.

[1] The record is defined in sec. 207.2(f) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(f)).

[2] Commissioner F. Scott Kieff did not participate in this investigation.

meaning of section 703(b) of the Act (19 U.S.C. 1671b(b)). Notice of the scheduling of the final phase of the Commission's investigation and of a public hearing to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of August 24, 2015 (80 FR 51309). The hearing was held in Washington, DC, on October 22, 2015, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission made this determination pursuant to section 705(b) of the Tariff Act of 1930 (19 U.S.C. 1671d(b)). It completed and filed its determination in this investigation on December 3, 2015. The views of the Commission are contained in USITC Publication 4583 (December 2015), entitled *Supercalendered Paper from Canada: Investigation No. 701–TA–530 (Final).*

By order of the Commission.

Issued: December 3, 2015.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2015–30953 Filed 12–8–15; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Notice of Lodging of Proposed Consent Decree Under the Clean Air Act

On December 3, 2015, the Department of Justice lodged a proposed consent decree with the United States District Court for the District of Idaho in the lawsuit entitled *United States of America, et al.* v. *J.R. Simplot Company,* Civil Action No. 1:15–cv–00562–CWD. The consent decree would resolve the claims of the United States, the State of Idaho, and the San Joaquin Valley Air Pollution Control District (SJVAPCD) against J.R. Simplot Company (Simplot) for injunctive relief and civil penalties for alleged violations of the New Source Review Prevention of Significant Deterioration (NSR/PSD) and Title V provisions of the Clean Air Act, at Simplot's five sulfuric acid manufacturing plants located in or near Lathrop, California, Pocatello, Idaho, and Rock Springs, Wyoming. The consent decree would require Simplot to comply with specified numerical emission limitations, including requirements applicable at all times at all five plants to comply with year-round emission limitations for sulfur dioxide (SO_2) and with good air pollution control practices. The consent decree also includes numerical emission limitations that apply to emissions of sulfuric acid mist and fine particulate matter ($PM_{2.5}$) at one of the Pocatello, Idaho plants at which the complaint alleged violations with respect to these pollutants. The consent decree would require Simplot to pay a civil penalty of $899,000, and to contribute $200,000 to a program operated by the SJVAPCD that incentivizes the replacement of old wood or pellet-burning devices with new, cleaner hearth options to reduce emissions of $PM_{2.5}$, volatile organic compounds, carbon monoxide, and hazardous air pollutants. The consent decree would resolve Simplot's liability for past violations of NSR/PSD alleged in the complaint, as well any related liability under Title V and New Source Performance Standards requirements, at Simplot's five sulfuric acid plants.

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 of America, et al.* v. *J.R. Simplot Company,* D.J. Ref. No. 90–7–1–08388/14. All comments must be submitted no later than thirty (30) days after the publication date of this notice. Comments may be submitted either by email or by mail:

To submit comments:	*Send them to:*
By e-mail	*pubcomment-ees.enrd@usdoj.gov.*
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 $19.75 (25 cents per page reproduction cost) payable to the United States Treasury.

Maureen Katz,

Assistant Section Chief, Environmental Enforcement Section, Environment and Natural Resources Division.

[FR Doc. 2015–30955 Filed 12–8–15; 8:45 am]

BILLING CODE 4410–15–P

DEPARTMENT OF JUSTICE

Office of Justice Programs

[OJP (NIJ) Docket No. 1703]

CBRN Protective Ensemble Standard Workshop

AGENCY: National Institute of Justice (NIJ), Justice.

ACTION: Notice of the CBRN Protective Ensemble Standard Workshop.

SUMMARY: The NIJ and the Technical Support Working Group are hosting a workshop in conjunction with the 2105 Personal Protective Equipment Workshop in Fort Lauderdale, FL. The focus of the workshop is the research conducted in support of the revision of NIJ Standard 0116.00 CBRN Protective Ensemble Standard for Law Enforcement, found at *https://www.ncjrs.gov/pdffiles1/nij/221916.pdf.* The session is intended to inform manufacturers, test laboratories, certification bodies, and other interested parties of these standards development efforts. The workshop is being held specifically to discuss recent progress made toward the revision and to receive input, comments, and recommendations.

Space is limited at the workshop, and as a result, only 50 participants will be allowed to register for each session. It is requested that each organization limit their representatives to no more than two per organization. Exceptions to this limit may occur, should space allow. Participants planning to attend are responsible for their own travel arrangements.

DATES: The workshop will be held on Friday, December 18, 2015 from 9 a.m. to 12 p.m.

Location: Fort Lauderdale Marriott Harbor Beach Resort & Spa, 3030 Holiday Drive, Fort Lauderdale, FL 33316.

FOR FURTHER INFORMATION CONTACT: For information about the NIJ CBRN Ensemble standard, please contact Brian Montgomery, by telephone at (202) 353–9786 [*Note:* this is not a toll-free telephone number], or by email at *brian.montgomery@usdoj.gov.* For general information about NIJ standards,

please visit *http://www.nij.gov/standards.*

Nancy Rodriguez,

Director, National Institute of Justice.

[FR Doc. 2015–30974 Filed 12–8–15; 8:45 am]

BILLING CODE 4410–18–P

LIBRARY OF CONGRESS

Copyright Office

[Docket No. 2015–5]

Copyright Royalty Judges' Ability To Set Rates and Terms That Distinguish Among Different Types or Categories of Licensors

AGENCY: U.S. Copyright Office, Library of Congress.

ACTION: Final order.

SUMMARY: The Copyright Royalty Judges (''CRJs'') referred a question of substantive law to the Register of Copyrights for resolution. The question asked whether section 114 of the Copyright Act or any other applicable provision of the Act prohibits the CRJs from setting rates and terms that distinguish among different types or categories of licensors. In a written opinion that was transmitted to the CRJs, the Register determined that the question was not properly presented in the proceeding and therefore the Register did not opine on its merits. That opinion is reproduced below.

DATES: *Effective Date:* November 24, 2015.

FOR FURTHER INFORMATION CONTACT: Stephen Ruwe, Assistant General Counsel, U.S. Copyright Office, P.O. Box 70400, Washington, DC 20024. Telephone: (202) 707–8350.

SUPPLEMENTARY INFORMATION: The Copyright Royalty Judges are tasked with determining and adjusting rates and terms of royalty payments for statutory licenses under the Copyright Act. *See* 17 U.S.C. 801. If, in the course of proceedings before the CRJs, novel material questions of substantive law concerning the interpretation of provisions of title 17 arise, the CRJs are required by statute to refer those questions to the Register of Copyrights for resolution. 17 U.S.C. 802(f)(1)(B).

On October 14, 2015, the CRJs, invoking 17 U.S.C. 802(f)(1)(B), referred to the Register the question of whether section 114 of the Copyright Act or any other applicable provision of the Act prohibits the CRJs from setting rates and terms that distinguish among different types or categories of licensors. The same day, the Register issued an order inviting the participants in the proceeding and other interested parties to file supplemental briefs on certain specified issues. On November 24, 2015, the Register issued a memorandum opinion in which she determined that the question was not presented within the meaning of 17 U.S.C. 802(f)(1)(B), and therefore the Register did not opine on the question's merits. To provide the public with notice of the Register's response, the Memorandum Opinion is reproduced in its entirety below.

Dated: December 2, 2015.

Maria A. Pallante,

Register of Copyrights.

Before the U.S. Copyright Office

Library of Congress

Washington, DC 20559

In the Matter of DETERMINATION OF ROYALTY RATES AND TERMS FOR EPHEMERAL RECORDING AND WEBCASTING DIGITAL PERFORMANCE OF SOUND RECORDINGS (Web IV), Docket No. 14–CRB–0001–WR (2016–2020) (Web IV)

MEMORANDUM OPINION ON NOVEL MATERIAL QUESTION OF LAW

In the above-captioned proceeding (''Web IV''), currently pending before the Copyright Royalty Judges (''CRJs'' or ''Judges''), the Judges will establish royalty rates and terms for webcasters' digital performance of sound recordings and making of ephemeral recordings under the statutory licenses embodied in sections 112(e) and 114(f)(2) of the Copyright Act (''Act''), such rates and terms to apply for the five-year period beginning January 1, 2016. The Act requires the CRJs to establish rates and terms that ''distinguish among the different types of eligible nonsubscription transmission services and new subscription services''—that is, among different types of webcasting services—but does not include the same instruction vis-a-vis the licensors of sound recordings under the relevant licenses.[1]

On September 11, 2015, relying upon section 802(f)(1)(B), the CRJs referred to the Register of Copyrights the following question:

Does Section 114 of the Act (or any other applicable provision of the Act) prohibit the Judges from setting rates and terms that distinguish among different types or categories of licensors, assuming a factual basis in the evidentiary record before the Judges demonstrates such a distinction in the marketplace?[2]

Section 802(f)(1)(B) requires the CRJs to request a decision of the Register ''[i]n any case in which a novel material question of substantive law concerning an interpretation of those provisions of [title 17] that are the subject of the proceeding is presented.''[3] The Register's decision is to be issued within thirty days after the Register receives all of the briefs or comments of the participants and her determination becomes part of the record of the proceeding.[4]

For the reasons explained below, the Register of Copyrights concludes that the question posed by the CRJs is not in fact ''presented'' in this proceeding, and was therefore not properly referred to the Register for decision.

I. Background

Rates and terms under the statutory licenses set forth in sections 112(e) and 114(f)(2) are to be to be set under the ''willing buyer/willing seller standard,'' meaning that the rates and terms should be those ''that most clearly represent the rates and terms that would have been negotiated in the marketplace between a willing buyer and a willing seller.''[5] In establishing those rates and terms, the CRJs ''may consider the rates and terms for comparable types of digital audio transmission services and comparable circumstances under voluntary license agreements.''[6] The Act also specifies that ''[s]uch rates and terms shall distinguish among the different types of [services] then in operation . . . such differences to be based on criteria including, but not limited to, the quantity and nature of the use of sound recordings and the degree to which use of the service may substitute for or may promote the purchase of phonorecords by consumers.''[7]

Neither section 114 nor any other provision of the Act includes any express language addressing whether or not webcasting rates and terms can distinguish among licensors of sound recordings. Since the inception of the statutory license for the digital performance of sound recordings in 1995, the CRJs—as well as their predecessor, the Copyright Arbitration Royalty Panels—have established uniform rates and terms for all licensors

[1] 17 U.S.C. 114(f)(2).

[2] Order Referring Novel Material Question of Law and Setting Briefing Schedule, Docket No. 14–CRB–0001–WR (2016–2020) (Sept. 11, 2015) (''Referral Order'').

[3] 17 U.S.C. 802(f)(1)(B)(i).

[4] *Id.*

[5] 17 U.S.C. 114(f)(2)(B); *see also id.* § 112(e)(4).

[6] 17 U.S.C. 114(f)(2)(B); *see also id.* § 112(e)(4).

[7] 17 U.S.C. 114(f)(2)(B).

of sound recordings under the section 114 and 112 licenses.[8]

On September 11, 2015, after the close of the record in this proceeding, the CRJs issued an order referring the above-cited novel material question of substantive law to the Register and requesting briefing on the question from the parties.[9] As noted, the CRJs invoked 17 U.S.C. 802(f)(1)(B) as the basis for their referral. That provision states that ''[i]n any case in which a novel material question of substantive law concerning an interpretation of those provisions of this title that are the subject of the proceeding is presented, the Copyright Royalty Judges shall request a decision of the Register of Copyrights, in writing, to resolve such novel question.'' [10] The CRJs must ''apply the legal determinations embodied in [a timely delivered] decision of the Register of Copyrights in resolving material questions of substantive law'' and must include the decision ''in the record that accompanies their final determination.'' [11]

The CRJs delivered the participants' initial and responsive briefs to the Copyright Office on October 14, 2015. That same day, the Register invited participants in the Web IV proceeding and other interested parties to file supplemental briefs on three specific issues relating to the novel material question of substantive law:

1. Is there any evidence in the legislative history of the 1909 Copyright Act, the 1976 Copyright Act, the Digital Performance Rights in Sound Recordings Act of 1995, the 1998 Digital Millennium Copyright Act, the Copyright Royalty and Distribution Reform Act of 2004, or any other legislation, of an intent by Congress to allow or disallow the establishment of rates and/or terms that distinguish among different types or categories of licensors?

2. How might the Register's decision affect other statutory licenses, *e.g.,* the statutory license in section 115 for the making and distribution of phonorecords of nondramatic musical works? How, if at all, should any such broader implications factor into the Register's analysis?

3. Are there administrative law or constitutional considerations (including rational basis or due process concerns) that would affect or should guide the Judges' ability to adopt rates and/or terms for the compensation of copyright owners, featured recording artists, and others for the use of sound recordings based on the identity of the licensor?

On October 26, 2015, the Office received supplemental briefing from participants and other interested parties in response to the above questions.

II. Summary of the Parties' Arguments

A. Position of SoundExchange

SoundExchange, Inc. (''SoundExchange'') is the entity currently designated for purposes of sections 114 and 112 to collect statutory royalties from webcasting (and certain other) services and distribute them to copyright owners and recording artists. In the Web IV ratesetting proceedings before the CRJs, SoundExchange served as the primary representative of copyright owners and artists, including major and independent record labels, featured recording artists, and the two artist unions designated under the statute to receive and distribute royalties to nonfeatured musicians and vocalists—the American Federation of Musicians of the United States and Canada (''AFM'') and the Screen Actors Guild-American Federation of Television and Radio Artists (''SAG–AFTRA'').[12] It is undisputed that during the ratesetting proceedings before the CRJs, SoundExchange—acting on behalf of its constituent interests—proposed rates and terms that did not distinguish among licensors of sound recordings.[13]

Although SoundExchange represented the vast majority of copyright owner participants during the Web IV ratesetting proceedings,[14] it has declined to take a position on the question referred by the CRJs.[15] Instead, SoundExchange noted that two groups of its constituents—UMG Recordings, Inc., Capitol Records, LLC, and Sony Music Entertainment (collectively, ''Major Labels''), on the one hand, and the American Association of Independent Music, AFM, and SAG–AFTRA (collectively, ''Independent Labels and Unions''), on the other—would be filing their own briefs.[16] These groups are represented by separate counsel for the present purpose and, as explained below, take diametrically opposed positions on the merits.

Although SoundExchange has declined to take a position on the merits of the referred question, it does, however, stress that ''[b]ecause segmentation by licensor would raise issues that no party has addressed'' in the proceeding, if the Register were to determine that segmentation were legally permissible, the parties would need to be given an opportunity to further address those issues.[17]

B. Position of Independent Labels and Unions, Music Managers, and Webcasters

The Independent Labels and Unions and Music Managers Forum, along with webcasting parties iHeartMedia, Inc., Pandora Media, Inc., SiriusXM Radio, Inc., and the National Association of Broadcasters and National Religious Broadcasters Noncommercial Music License Committee (''NAB/NRBNMLC'') (the webcasting parties collectively, ''Webcasters''), contend that the CRJs lack the authority to adopt different rates and terms for different categories of licensors.[18] These parties argue that the overall structure of section 114 demonstrates that Congress did not intend for parties to adopt differential rates for licensors.

For instance, these parties note that section 114 expressly allows the CRJs to set different rates and terms based on the type of webcasting service being licensed, but is silent as to whether the CRJs can differentiate among types of licensors. Relying on the canon of statutory construction known as *expressio unius est exclusio alterius*—that is, the express mention of one subject impliedly excludes other subjects—this group urges that this silence was purposeful, and shows Congress's intent to withhold from the CRJs the power to adopt different rates and terms for different licensors. They

[8] *See generally, e.g.,* Determination of Royalty Rates for Digital Performance Right in Sound Recordings and Ephemeral Recordings, 79 FR 23,102 (Apr. 25, 2014); Determination of Rates and Terms for Preexisting Subscription Services and Satellite Digital Audio Radio Services, 78 FR 23,054 (April 17, 2013); Digital Performance Right in Sound Recordings and Ephemeral Recordings, 76 FR 13,026 (Mar. 9, 2011); Digital Performance Right in Sound Recordings and Ephemeral Recordings, 72 FR 24,084 (May 1, 2007); Determination of Reasonable Rates and Terms for the Digital Performance of Sound Recordings by Preexisting Subscription Services, 68 FR 39,837 (July 3, 2003); Determination of Reasonable Rates and Terms for the Digital Performance of Sound Recordings and Ephemeral Recordings, 67 FR 45,240 (July 8, 2002); Determination of Reasonable Rates and Terms for the Digital Performance of Sound Recordings, 63 FR 25,394 (May 8, 1998).

[9] *See* Referral Order at 2.

[10] 17 U.S.C. 802(f)(1)(B)(i).

[11] *Id.*

[12] 17 U.S.C. 114(g)(2)(B), (C).

[13] SoundExchange Initial Br. at 2; *see also* SoundExchange Supp. Br. at 2 (''In the proceeding, SoundExchange identified, based on the best marketplace evidence, a single royalty rate for all commercial licensees utilizing the statutory license.'').

[14] George Johnson, an individual sound recording owner, represented himself during ratesetting proceedings. *See* George Johnson Initial Br. at 1; NAB/NRBNMLC Response Br. at 1 n.1.

[15] SoundExchange Initial Br. at 1; SoundExchange Response Br. at 1.

[16] SoundExchange Initial Br. at 1.

[17] *Id.* at 2.

[18] *See, e.g.,* Independent Labels and Unions Initial Br. at 24; iHeartMedia Initial Br. at 3; SiriusXM Initial Br. at 1; Pandora Initial Br. at 1; NAB/NRBNMLC Response Br.at 2; Music Managers Forum Supp. Br. at 1.

also point to the provision stating that ''[t]he schedule of reasonable rates and terms'' adopted by the CRJs ''shall . . . be binding on all copyright owners,'' [19] and argue that by referring to a single ''schedule'' that binds ''all'' copyright owners, Congress anticipated that the CRJs would maintain a single set of rates and terms for all licensors.[20]

These parties also urge that adopting rates and terms that differentiate among categories of licensors would undermine Congress's desire for an administrable statutory license. For example, they note that the ownership or distribution rights for any given sound recording can change hands repeatedly, and that it thus may be difficult to know the current owner of any particular recording at a given point in time.[21] According to these parties, it is unlikely that Congress would have established a scheme that made it difficult for a licensee to know what rates and terms apply to individual sound recordings.[22]

In addition to arguments about the merits of the referred question, the Independent Labels and Unions and Webcasters raise procedural concerns of due process under the Constitution and the Administrative Procedure Act.[23] Specifically, they urge that, even if the Register were to conclude that the CRJs could adopt rates that distinguish among categories of licensors, the CRJs could not actually adopt such rates in this ratesetting proceeding.[24] The Independent Labels and Unions and Webcasters argue that they had inadequate notice that the CRJs might adopt differential rates.[25] They point to the CRJs' uniform historical practice of adopting rates and terms for webcasting that do not distinguish among different categories of licensors,[26] and the fact that no party to the ratesetting proceeding proposed rates that distinguish among licensors.[27] As NAB/NRBNMLC puts it, ''no participant had the opportunity, or any reason, to introduce evidence or to respond to any such proposal, or to demonstrate the potential administrative difficulties or consequences of such rates and terms.'' [28]

Indeed, the Independent Labels and Unions urge that they agreed to be represented by SoundExchange in the ratesetting proceedings on the assumption that SoundExchange would seek, and the CRJs would adopt, a single set of rates for all licensors.[29] The Independent Labels and Unions suggest that, had the possibility of rates and terms that differentiate among licensors in fact been before the CRJs, SoundExchange could not have fairly represented all of its constituents—who disagree about the desirability of differential rates—and the Independent Labels and Unions would have participated in the proceedings in their own right.[30]

C. Position of the Major Labels and George Johnson

The Major Labels, supported by George Johnson, an individual sound recording owner, contend that the CRJs are permitted to adopt rates and terms that distinguish among types or categories of licensors.[31] Citing precedent from the U.S. Court of Appeals for the D.C. Circuit, the Major Labels argue that the CRJs have ''broad discretion to effectuate their mandate under Section 114 to establish rates that most clearly represent the rates negotiated by a willing buyer and a willing seller in the marketplace.'' [32] They stress that no provision of the Copyright Act limits the CRJs' ability to adopt rates that distinguish among licensors.

In addition, the Major Labels point to provisions of the statute that they claim indicate Congress's intent to allow the CRJs to establish such differential rates. For example, they argue that the willing buyer/willing seller standard ''necessarily contemplates the possibility of setting different rates for different kinds of licensors, because it directs the Judges to set rates and terms that reflect those that would be found in a hypothetical marketplace characterized by precisely such differentiation.'' [33] The Major Labels urge that the statutory provisions upon which the Independent Labels and Artists, the Music Managers Forum, and Webcasters rely do not cabin the CRJs' generally broad discretion to set rates and terms as they deem appropriate in light of the record evidence.[34] Furthermore, they dismiss the administrability concerns raised by those groups as irrelevant to the question asked, arguing that those arguments ''are outside the scope of the [referral order] and irrelevant to the pure question of law posed by the Judges.'' [35]

The Major Labels similarly dismiss the due process arguments raised by the Independent Labels and Unions and Webcasters as ''irrelevant to answering the question posed'' by the CRJs, which they again emphasize to be a ''pure question of law.'' [36] They further argue that, even if those issues were relevant, the CRJs are not foreclosed from adopting a rate structure that distinguishes among licensors by crediting evidence already in the record. They point in particular to the CRJs' notice initiating the ratesetting proceeding, in which the CRJs stated that they were '' 'open to receiving evidence, testimony, and argument regarding *any reasonable rate structure,' ''* requesting participants to ''address the importance 'of the presence of economic variation among buyers *and* sellers.' '' [37] The Major Labels suggest that these statements provided the parties with sufficient notice that the CRJs were willing to consider rates that differentiate among different licensors. Even so, the Major Labels do not challenge the assertion that no party to the ratesetting

[19] 17 U.S.C. 114(f)(2)(B); 17 U.S.C. 112(e)(4).

[20] iHeartMedia Response Br. at 2–3, iHeartMedia Supp. Br. at 9–10; *see also* Independent Labels and Unions Initial Br. at 5–8.

[21] *See, e.g.,* Independent Labels and Unions Initial Br. at 9 (''[T]he entity or person who owns or control rights of any particular recording can be quite fluid and historically quite hard to keep track of, as ownership and distribution rights change over time.''); Pandora Initial Br. at 5 (explaining that ''ownership of sound recordings is hardly static'' and providing examples of the different ways a given recording could cross back and forth between various categories of owners); Music Managers Forum Supp. Br. at 1 (''A recording could be made by an artist, licensed to an independent label, sold to a major label and then revert back to the artist.'').

[22] *See, e.g.,* Independent Labels and Unions Initial Br. at 9–11; iHeartMedia Initial Br. at 3; Pandora Initial Br. at 5–6 (''[M]ost if not all services would be unable to compute the license fees owed to SoundExchange under a differential-pricing regime, as they neither possess, nor have ready access to, all of the information necessary to determine which sound recordings are owned by which licensors, let alone at any given time, and into which licensor-category any given record label may fall.'').

[23] *See, e.g.,* Independent Labels and Unions Initial Br. at 14–22; NAB/NRBNMLC Response Br. at 1–2; SiriusXM Initial Br. at 3–4, 17–18; iHeartMedia Supp. Br. at 3–7.

[24] *See, e.g.,* Independent Labels and Unions Initial Br. at 22; iHeartMedia Response Br. at 10.

[25] *See, e.g.,* NAB/NRBNMLC Response Br. at 1; Independent Labels and Unions Initial Br. at 16; iHeartMedia Supp. Br. at 2, 4–6.

[26] *See, e.g.,* Independent Labels and Unions Initial Br. at 11–13; iHeartMedia Supp. Br. at 3.

[27] *See, e.g.,* Independent Labels and Unions Initial Br. at 13–14; Pandora Initial Br. at 4; iHeartMedia Response Br. at 9; SiriusXM Initial Br. at 6, 17; NAB/NRBNMLC Response Br. at 1.

[28] NAB/NRBNMLC Response Br. at 1; *see also* Independent Labels and Unions Initial Br. at 13–14.

[29] Independent Labels and Unions Initial Br. at 14.

[30] *Id.* at 14, 23.

[31] Major Labels Initial Br. at 2; George Johnson Response Br. at 4–5.

[32] Major Labels Initial Br. at 3.

[33] *Id.* at 6.

[34] *Id.* at 2–8, 12–14.

[35] *Id.* at 16.

[36] *Id.* at 15.

[37] Major Labels Supp. Br. at 13 (quoting 79 FR 412, 413 (Jan. 3, 2014)) (emphasis in orginal).

proceeding pressed for rates or terms that distinguish among licensors.

D. Position of Music Publishers Regarding Impact on Other Statutory Licenses

In response to the Register's invitation to non-participants to offer their views, the National Music Publishers Association, Inc. (''NMPA'') and a group comprising the Independent Music Publishers Forum, the Association of Independent Music Publishers, and a group of nine independent music publishers (this group collectively, ''IMPF/AIMP''), filed supplemental briefs. NMPA did not take a position on the merits of the referred question.[38] IMPF/AIMP, however, adopted the arguments of the Independent Labels and Artists, taking the position that ''Section 114 does not permit the Copyright Royalty Judges to award different rates based on the identity or categorization of the licensors.'' [39]

NMPA and IMPF/AIMP also addressed the Register's question regarding the implications of the decision here for other statutory licenses.[40] They asked the Register to expressly confine her decision to sections 112 and 114, and state that the decision does not have any impact on the statutory license in section 115 for the making and distribution of phonorecords of nondramatic musical works.[41] According to NMPA, ''Section 115 is a very different license than Section 114,'' as it concerns ''an entirely different type of royalty, and an entirely different group of stakeholders.'' [42]

III. Register's Determination

Having carefully considered the statutory framework and the parties' submissions, the Register of Copyrights concludes that there is no basis in the context of the current proceeding on which to render an opinion on the question posed by the CRJs, as the question does not meet the statutory criteria for referral.

In referring the question to the Register for a written opinion, the Judges relied on 17 U.S.C. 802(f)(1)(B). That provision, however, requires the CRJs to request a decision from the Register only in a ''case in which a novel material question of substantive law concerning an interpretation of those provisions of [title 17] that are the subject of the proceeding *is presented.''* [43] Similarly, section 802(f)(1)(A)(ii)—which the CRJs did not cite but also could arguably apply—gives the CRJs discretion to obtain a formal written opinion from the Register of Copyrights concerning ''any material questions of substantive law that relate to the construction of provisions of this title and *arise in the course of the proceeding.''* [44] Thus, by their plain terms, these two statutory mechanisms requiring a written opinion from the Register may only be invoked by the CRJs where a referred question is actually ''presented'' or ''arise[s]'' in a particular proceeding.

This reading of the statute is reinforced by its legislative history. Originally, when the CRJ system was enacted in 2004, the statute allowed the CRJs to refer material questions of substantive law to the Register under section 802(f)(1)(A)(ii) when they ''concern[ed] an interpretation or construction of those provisions of [title 17] that are the subject of the proceeding.'' [45] On its face, this language appeared broadly to permit the referral of questions concerning any provision that was generally the ''subject'' of the proceeding (*e.g.,* in the current proceeding, sections 112(e) and 114(f)), regardless of whether the specific question was actually implicated by the proceeding. But when Congress made technical corrections to the statute in 2006, it qualified section 802(f)(1)(A)(ii) to clarify that questions may be referred under this provision only when they actually ''arise in the course of the proceeding.'' [46] By adding the ''arise'' requirement, the amendment brought section 802(f)(1)(A)(ii) more closely into alignment with section 802(f)(1)(B)(i), which already contained the ''presented'' language. In limiting the referral mechanism in both cases, Congress signaled its intent that questions sent to the Register for a written opinion—whether novel and/or material—should be confined to matters actually at issue in a proceeding.

Whether a question of substantive law is actually ''presented'' or ''arises'' in a particular case will inevitably depend upon the circumstances of that proceeding. It will often be readily apparent that the question is presented, such as when the question concerns a statutory limitation on the CRJs' authority to consider certain types of evidence sought to be presented by participants,[47] whether a specific term proposed by a party for adoption in a settlement is consistent with the Act,[48] the extent of the CRJs' continuing jurisdiction over a prior determination under the Act,[49] or whether a statutory license extends to a particular activity for which a party seeks to have a rate established.[50] In each of these examples, the Register's answer to the question will presumably have an impact on the conduct or outcome of the proceeding.

Here, by contrast, the Register finds that the question whether the CRJs may adopt rates and terms for webcasting that distinguish among different types or categories of licensors is merely a theoretical one in the context of this proceeding. As noted, the CRJs have not previously adopted rates and terms for webcasting services that distinguish among licensors. Setting aside the question whether the CRJs have the authority to do so, it is clear from the submissions in response to the referred question that the various participants litigated this case on the assumption that the outcome would be an undifferentiated rate structure for licensors. To be sure, in initiating the proceeding, the CRJs broadly invited parties to provide evidence and argument ''regarding any reasonable rate structure'' or ''the presence of economic variations among buyers and sellers.'' [51]

[38] NMPA Supp. Br. at 2.

[39] IMPF/AIMP Supp. Br. at 4.

[40] *See* NMPA Supp. Br. at 3–7; IMPF/AIMP Supp. Br. at 4–5. Other parties also addressed this question to varying extents. *See, e.g.,* Independent Labels and Unions Supp. Br. at 2–3 (arguing that a decision here ''would impact all Copyright Office rate proceedings''); SiriusXM Supp. Br. at 5–7 (arguing that any ruling here ''should be strictly limited'' to the Web IV proceeding, discussing differences between the licenses); Major Labels Supp. Br. at 5–8 (arguing that the potential ramifications of any decision on other statutory licenses are beyond the scope of the referred question and irrelevant to its resolution, discussing differences between the licenses).

[41] NMPA Supp. Br. at 7; IMPF/AIMP Supp. Br. at 4–5.

[42] NMPA Supp. Br. at 3.

[43] 17 U.S.C. 802(f)(1)(B)(i) (emphasis added).

[44] *Id.* § 802(f)(1)(A)(ii) (emphasis added).

[45] Copyright Royalty and Distribution Reform Act of 2004, Pub. L. 108–419, § 3(a), 118 Stat. 2341, 2346 (2004).

[46] Copyright Royalty Judges Program Technical Corrections Act, Pub. L. 109–303, § 3, 120 Stat. 1478, 1478–79 (2006).

[47] Scope of the Copyright Royalty Judges' Continuing Jurisdiction, 80 FR 58,300 (Sept. 28, 2015).

[48] *See., e.g.,* Scope of the Copyright Royalty Judges Authority to Adopt Confidentiality Requirements upon Copyright Owners within a Voluntarily Negotiated License Agreement, 78 FR 47,421 (Aug. 5, 2013) (in section 115 proceeding, determining that CRJs lacked authority to adopt certain provisions imposing a duty of confidentiality upon copyright owners).

[49] *See, e.g.,* Scope of the Copyright Royalty Judges' Continuing Jurisdiction, 80 FR 25,333 (May 4, 2015) (determining that CRJs had the authority to issue a clarifying interpretation of regulations adopted in a prior ratesetting determination).

[50] Mechanical and Digital Phonorecord Delivery Rate Adjustment Proceeding, 71 FR 64,303 (Nov. 1, 2006).

[51] Determination of Royalty Rates for Digital Performance in Sound Recordings and Ephemeral Recordings (Web IV), 79 FR 412, 413 (Jan. 3, 2014). In that notice, the CRJs also referred generally to the concept of ''price discrimination'' in free market transactions, and invited participants to address

But it is undisputed that no participant in the proceeding in fact proposed rates or terms that differentiated among licensors and, accordingly, such a structure was not understood to be a subject of litigation.[52] Moreover, based on the parties' briefs in response to the referred question and the Copyright Office's review of the Web IV docket, there is no indication that the CRJs went beyond their general invitation at the outset of the proceeding to require that such differentiation be addressed.[53] As a result, no party addressed the question of ''segmentation by licensor,'' [54] and ''no participant had the opportunity, or any reason, to introduce evidence or to respond to any such proposal, or to demonstrate the potential administrative difficulties or consequences of such rates and terms.'' [55]

In this regard, the Register further observes that the CRJs are statutorily required to make determinations that are ''supported by the written record'' [56] and based ''on economic, competitive and programming information presented by the parties.'' [57] Significantly, the U.S. Court of Appeals for the D.C. Circuit has twice vacated CRJ determinations that relied on theories ''first presented in the Judges' determination and not advanced by any participant.''[58] Here—consistent with their rate proposals—the participants' respective proposed findings of fact and conclusions of law submitted at the conclusion of the proceeding uniformly fail to advocate for statutory rates and terms that distinguish among licensors.[59] Moreover, in briefing the question now before the Register, no party has identified any basis upon which the CRJs could reasonably rely to adopt a differentiated rate structure.[60] Thus, even assuming for the sake of argument that they possess the legal authority to establish rates that differentiate by licensor,[61] it seems that under the current circumstances, the CRJs could not meet their basic obligation ''to make [a] reasoned decision[] supported by the written record before them.'' [62]

In sum, given the posture of the case, the question referred by the CRJs appears to be only a theoretical one in that the Register is unable to discern how a written decision at this juncture could substantively impact the conduct or outcome of this proceeding.[63] Indeed, the question itself is presented in hypothetical terms: it asks the Register to ''assum[e] a factual basis in the evidentiary record'' for a distinction among licensors. As significant as the question of a differentiated rate structure for licensors might be under different circumstances, the Register does not believe that the statute contemplates the issuance of a written opinion when the inquiry is wholly theoretical in nature.

The language of the Act makes clear that the referral procedure under section 802(f)(1)(B) is limited to novel material questions of substantive law that are actually ''presented.'' As the Register has concluded that the question set forth in the CRJs' September 11, 2015 order is not actually presented in this proceeding, she leaves the answer for another day.

November 24, 2015

Maria A. Pallante

Register of Copyrights and Director, United States Copyright Office

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''the potential applicability or inapplicability of price discrimination within the commercial webcaster segment of the market as well.'' *Id.* at 413–14. But the CRJs' discussion focused on price discrimination by *sellers—i.e.,* where sellers charge different prices for identical goods with the price differences based on the status of the buyers. *Id.* at 413. That, of course, is the type of price discrimination expressly contemplated by the statute, which requires the CRJs to adopt ''rates and terms [that] distinguish among the different types of [services] then in operation.'' 17 U.S.C. 114(f)(2).

[52] *See* NAB/NRBNMLC Response Br. at 1; SiriusXM Initial Br. at 6; Independent Labels and Unions Initial Br. at 11–12; *see also* Direct Testimony of Kurt Hanson Submitted on behalf of AccuRadio, LLC, 16–18 (Oct. 6, 2014); Written Direct Statement of College Broadcasters, Inc. (Oct. 7, 2014) (attaching proposed regulations); Letter from David Oxenford on behalf of Educational Media Foundation to Copyright Royalty Board (Oct. 7, 2014) (joining in the rate proposal submitted by NRBNMLC); Written Direct Statement of Geo Music Group, 4–5 (Oct. 10, 2014); Written Testimony of Michael Papish on behalf of Harvard Radio Broadcasting Co., Inc. (WHRB) (Oct. 7, 2014); Written Testimony of Frederick J. Kass on behalf of Intercollegiate Broadcasting System (Oct. 7, 2014); Proposed Rates and Terms of iHeartMedia, Inc. (Oct. 7, 2014); Written Direct Statement of the National Association of Broadcasters, Vol. 1B (Oct. 7, 2014); Written Direct Case of the Corporation for Public Broadcasting, on behalf of National Public Radio, Inc., including National Public Radio, Inc.'s Member Stations, American Public Media, Public Radio International, and Public Radio Exchange Broadcasting, 6–8 (Oct. 7, 2014); Written Direct Statement of the National Religious Broadcasters Noncommercial Music License Committee, Including Educational Media Foundation (Oct. 7, 2014); Proposed Rates and Terms of Pandora Media, Inc.; Written Direct Statement of Sirius XM Radio Inc., 1–2 (Oct. 7, 2014); Proposed Rates and Terms of SoundExchange, Inc. (Oct. 7, 2014).

[53] *See* Notice of Participants, Commencement of Voluntary Negotiation Period, and Case Scheduling Order, Docket No. 14–CRB–0001–WR (2016–2020), 1 (Feb. 19, 2014) (asking parties to ''address expressly issues relating to categories of licensees,'' but omitting any mention of issues relating to categories of licensors).

[54] SoundExchange Initial Br. at 2. In this regard, it is notable that SoundExchange finds itself unable to put forth a unified view on the question of differentiated rates. Presumably SoundExchange could not have acted as the representative of virtually all of the rightsholders in the proceeding if the question of a differentiated rate structure was actually in contention. *See* Independent Labels and Unions Initial Br. at 14.

[55] *See* NAB/NRBNMLC Response Br. at 1.

[56] 17 U.S.C. 803(c)(3).

[57] *Id.* § 114(f)(2)(B).

[58] *Settling Devotional Claimants* v. *Copyright Royalty Bd.,* 797 F.3d 1106, 1121 (D.C. Cir. 2015) (quoting *Intercollegiate Broad. Sys.* v. *Copyright Royalty Bd.,* 574 F.3d 748, 767 (D.C. Cir. 2009) (internal quotation marks omitted)).

[59] *See* Proposed Findings and Conclusions of Intercollegiate Broadcasting Systems, 13 (July 19, 2015); Proposed Findings of Fact of iHeartMedia, Inc., 207 (June 24, 2015); National Association of Broadcasters' Proposed Findings of Fact and Conclusions of Law (July 19, 2015) (attaching NAB's Proposed Rates and Terms); The National Religious Broadcasters Noncommercial Music License Committee's Corrected Proposed Findings of Fact and Conclusions of Law (June 24, 2015) (attaching NRBNMLC's Proposed Noncommercial Webcaster Rates and Terms); Pandora Media, Inc.'s Proposed Findings of Fact and Conclusions of Law, 1–2 (June 19, 2015); Sirius XM Radio Inc.'s Proposed Findings of Fact, 1 (June 19, 2015); Proposed Findings of Fact of SoundExchange, Inc., 94–96 (June 19, 2015); Proposed Findings and Conclusions on behalf of Harvard Radio Broadcasting Co., Inc. (WHRB) (June 19, 2015).

[60] Although the Major Labels suggest that the CRJs could ''credit evidence supporting a different rate structure than they have adopted in the past,'' they do not point to any actual argument or evidence in the record that would support such an approach. *See* Majors Labels Supp. Br. at 14. In any event, as noted, such an approach would appear to run afoul of controlling precedent. *See Settling Devotional Claimants,* 797 F.3d at 1121 (reversing CRJ determination where theory was ''first presented in the Judges' determination and not advanced by any participant'').

[61] In considering these procedural issues, the Register does not mean to suggest any conclusion concerning the CRJs' legal authority to adopt rates and terms that distinguish among licensors.

[62] *Settling Devotional Claimants,* 797 F.3d at 1121.

[63] Referral Order at 2.

OFFICE OF MANAGEMENT AND BUDGET

Information Collection; Request for Public Comments

AGENCY: Executive Office of the President, Office of Management and Budget.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the Office of Management and Budget (OMB) invites the general public and Federal agencies to comment on a revision of an approved information collection, Form SF–SAC, that is used to report audit results, audit findings, and questioned costs as required by the Single Audit Act Amendments of 1996 (31 U.S.C. 7501 *et seq.)* and 2 CFR part 200, ''Uniform Administrative Requirements, Cost Principles, and Audit

Requirements for Federal Awards.'' A draft of the proposed Form SF–SAC can be reviewed at the OMB Grants Management Internet home page at *http://www.whitehouse.gov/OMB/grants/grants_docs.html.* The Form SF–SAC instructions contain a detailed listing of the proposed changes to the Form SF–SAC.

DATES: Submit comments on or before February 8, 2016. Late comments will be considered to the extent practicable.

ADDRESSES: Due to potential delays in OMB's receipt and processing of mail sent through the U.S. Postal Service, we encourage respondents to submit comments electronically to ensure timely receipt. We cannot guarantee that mailed comments will be received before the comment closing date.

Electronic mail comments may be submitted to: Gilbert Tran at *hai_m._tran@omb.eop.gov.* Please include ''2016 Form SF–SAC Comments'' in the subject line and the full body of your comments in the text of the electronic message, not as an attachment. Please include your name, title, organization, postal address, telephone number and email address in the text of the message. Comments may also be submitted via facsimile to 202–395–3952 (with ''2016 Form SF–SAC Comments'' as title page).

Comments may be mailed to Gilbert Tran, Office of Federal Financial Management, Office of Management and Budget, Room 6025, New Executive Office Building, Washington, DC 20503.

In general, responses will be summarized and included in the request for OMB approval. All comments will also be a matter of public record.

FOR FURTHER INFORMATION CONTACT: Gilbert Tran, Office of Federal Financial Management, Office of Management and Budget, (202) 395–3052. The proposed revisions to the Information Collection Form, Form SF–SAC can be obtained by contacting the Office of Federal Financial Management as indicated above or by download from the OMB Grants Management home page on at *https://www.whitehouse.gov/omb/grants_forms*

SUPPLEMENTARY INFORMATION:

I. Abstract

This is a revision of a currently approved form with changes of Form SF–SAC, OMB Control Number 0348–0057.

Non-Federal entities (states, local governments, Indian tribes, institutions of higher education, and nonprofit organizations) that expend a total amount of Federal awards equal to or in excess of $750,000 in any fiscal year are required by the Single Audit Act Amendments of 1996 (31 U.S.C. 7501, *et. seq.*) (Act) and 2 CFR part 200, ''Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards,'' (Uniform Guidance) to have audits of their Federal awards and file the resulting reporting packages and data collection forms (Single Audit reports) with the Federal Audit Clearinghouse (FAC). The data collection form (Form SF–SAC) is Appendix X to 2 CFR part 200. The Office of Management and Budget (OMB) has designated the U.S. Bureau of the Census as the FAC, which serves as the government-wide repository of record for Single Audit reports. The Uniform Guidance imposes new reporting requirements effective for non-Federal entity fiscal years beginning on or after December 26, 2014. The first year under the new requirements is the fiscal year ending on or after December 26, 2015.

The Single Audit process is the primary method Federal agencies and pass-through entities use to provide oversight for Federal awards and reduce risk of non-compliance and improper payments. This includes following up on audit findings and questioned costs. The proposed changes make revisions to the Form SF–SAC that reflect Uniform Guidance requirements; revise some existing data elements; and add data elements that would make the reports easier for Federal agencies, pass-through entities, and the public to use. The changes would also delete data elements that are no longer needed.

In particular, the Uniform Guidance requires the FAC to make Single Audit reports publically available on a Web site. This represents a change as the FAC previously only made publically available the Form SF–SAC data. The Uniform Guidance also requires non-Federal entities to sign a statement that the reporting package does not include protected personally identifiable information and that the FAC is authorized to make the reporting package and the data collection form publicly available on a Web site. An exception is provided in 2 CFR 200.512(b)(2) for Indian tribes and tribal organizations to opt not to authorize the public display of their reporting packages on the FAC Web site. The revised form reflects the Uniform Guidance's requirements.

For fiscal year starting on or after December 26, 2014, the FAC also plans to allow Non-Federal entities who did not meet the threshold requiring submission of a Single Audit report to voluntarily notify the FAC that they did not meet the reporting threshold. This information helps the Federal agencies in the review of applicants that fall below the reporting requirements. The FAC plans to put this information on their Web site.

In addition, we are planning a pilot project to combine the reporting of this form and the Schedule of Expenditures of Federal Awards into a singular form to streamline the Non-Federal entities reporting process. This proposal will be included under a separate notice.

II. Method of Collection

The information will be collected electronically through FAC's Web based Internet Data Entry System available at *https://harvester.census.gov/facweb.*

III. Data

OMB Control Number: 0348–0057.

Title: Data Collection Form.

Form Number(s): SF–SAC.

Type of Review: Revision of a currently approved collection.

Respondents: States, local governments, non-profit organizations (Non-Federal entities) and their auditors.

Estimated Number of Respondents: 80,000 (40,000 from auditees and 40,000 from auditors).

Estimated Time per Response: 65 hours for each of the 400 large respondents and 20 hours for each of the 79,600 small respondents.

Estimated Total Annual Burden Hours: 1,618,000.

Estimated Number of Responses per Respondent: 1.

Frequency of Response: Annually.

Legal Authority: Title 31 U.S.C. Section 7501 *et. seq.* and 2 CFR Part 200.

Needs and Uses: Reports from auditors to auditees and reports from auditees to the Federal government are used by non-Federal entities, pass-through entities and Federal agencies to ensure that Federal awards are expended in accordance with applicable laws and regulations. The FAC (designated by the U.S. Bureau of the Census) uses the information on the Form SF–SAC to ensure proper distribution of audit reports to Federal agencies and identify non-Federal entities who have not filed the required reports. The FAC also uses the information on the Form SF–SAC to create a government-wide database, which contains information on audit results. This database is publicly accessible on the Internet at *http://harvester.census.gov/fac/.* It is used by Federal agencies, pass-through entities, non-Federal entities, auditors, the Government Accountability Office, OMB and the general public for management of and information about Federal awards and the results of audits.

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.

In general, 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.

Mark Reger,

Deputy Controller.

[FR Doc. 2015–30986 Filed 12–8–15; 8:45 am]

BILLING CODE P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Submission for Office of Management and Budget Review; Comment Request; for Reinstatement With Change of a Previously Approved Collection; Organization and Operation of Federal Credit Unions—Loan Participation

AGENCY: National Credit Union Administration (NCUA).

ACTION: Request for comment.

SUMMARY: National Credit Union Administration 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 (PRA). This is related to NCUA's regulation 701.22 that outlines requirements for loan participation programs. The rule requires various information collections, which NCUA uses to ensure credit unions have implemented a safe and sound loan participation program.

DATES: Comments will be accepted until January 8, 2016.

ADDRESSES: Interested persons are invited to submit written comments on the information collection to:

NCUA Contact: Tracy Crews, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. 703–837–2861, Email: *OCIOPRA@ncua.gov*

OMB Reviewer: Office of Management and Budget, ATTN: Desk Officer for the National Credit Union Administration, Office of Information and Regulatory Affairs, Washington, DC 20503

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to:

NCUA Contact: Tracy Crews, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. 703–837–2861, Email: *OCIOPRA@ncua.gov*

SUPPLEMENTARY INFORMATION:

I. Abstract and Request for Comments

NCUA is requesting comments on 3133–0141; Organization and Operation of Federal Credit Unions—Loan Participation, 12 CFR part 701.22. NCUA's regulation, 12 CFR (§ 701.22), outlines loan participation requirements. Loan participations pose inherent risk to the NCUSIF due to the interconnectedness between participants. Section 741.225 extends the requirements of Section 701.22 of NCUA's regulations to Federally Insured State Chartered Credit Unions (FISCUs), noting there are strong indications of potential risk to the NCUSIF from FISCUs' loan participation activity. Section 701.22 includes three collection requirements (1) maintenance of a written policy, (2) requirements on the purchasing credit union to have a written loan participation agreement, (3) options to apply for waivers from concentration limits.

In the **Federal Register** of August 28, 2015, (80 FR 52344), NCUA published a 60-day notice requesting public comment on the proposed collection of information. NCUA received no comments.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

NCUA requests that you send your comments on this collection to the location listed in the addresses section. Your comments should address: (a) The necessity of the information collection for the proper performance of NCUA, including whether the information will have practical utility; (b) the accuracy of our estimate of the burden (hours and cost) of the collection of information, including the validity of the methodology and assumptions used; (c) ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) ways we could minimize the burden of the collection of the information on the respondents such as through the use of automated collection techniques or other forms of information technology. It is NCUA's policy to make all comments available to the public for review.

II. Data

Title: Organization and Operation of Federal Credit Unions—Loan Participation, 12 CFR part 701.22.

OMB Number: 3133–0141.

Form Number: None.

Type of Review: Reinstatement with change.

Description: Section 701.22 of NCUA's regulations, 12 CFR 701.22, outlines the requirements for the administration of a loan participation program. Section 741 of NCUA's regulations, 12 CFR 741.225, extends 12 CFR 701.22 to Federally Insured State Chartered Credit Unions. Section 701.22 includes various collections which NCUA uses to ensure credit unions have implemented a safe and sound program.

Respondents: Federally Insured Credit Unions.

Estimated No. of Respondents/Recordkeepers: 1,515 for loan participation policy revision and loan agreement retention, 10 for waiver submission and 1 for appeal request.

Estimated Burden Hours per Response: 3 hours per policy revision, 4 hours per waiver submission and 4 hours per appeal.

Frequency of Response: One time and optionally with each waiver submission.

Estimated Total Annual Burden Hours: 4,589 hours total.

Estimated Total Annual Cost: $146,343.21.

By the National Credit Union Administration Board on November 18, 2015.

Gerard Poliquin,

Secretary of the Board.

[FR Doc. 2015–30934 Filed 12–8–15; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection Activities: Submission to OMB for Reinstatement With Change, Bank Conversions and Mergers, 12 CFR Part 708a; Comment Request

AGENCY: National Credit Union Administration (NCUA).

ACTION: Request for comments.

SUMMARY: NCUA intends to submit the following information collection to the Office of Management and Budget

(OMB) for review and clearance under the Paperwork Reduction Act of 1995 (Pub. L. 104–13, 44 U.S.C. Chapter 35). The purpose of this notice is to allow for 30 days of public comment. The information collection relates to NCUA's regulation on conversions of federally insured credit unions (FICUs) to mutual savings banks (MSBs) and mergers of FICUs into banks. The regulation requires an insured credit union that proposes to convert to an MSB or merge into a bank to provide notice and disclosure of the proposal to members and NCUA and to conduct a membership vote.

DATES: Comments will be accepted until January 8, 2016.

ADDRESSES: Interested persons are invited to submit written comments to the NCUA Contact and OMB Reviewer listed below:

NCUA Contact: Tracy Crews, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. 703–837–2861, Email: *OCIOPRA@ncua.gov.*

OMB Reviewer: Office of Management and Budget, ATTN: Desk Officer for the National Credit Union Administration, Office of Information and Regulatory Affairs, Washington, DC 20503, Email: *oirasubmission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to:

NCUA Contact: Tracy Crews, National Credit Union Administration, 1775 Duke Street, Alexandria, Virginia 22314–3428, Fax No. 703–837–2861, Email: *OCIOPRA@ncua.gov.*

SUPPLEMENTARY INFORMATION:

I. Abstract and Request for Comments

NCUA is requesting reinstatement, with change, of the previously approved collection of information for NCUA's regulation on Bank Conversions and Mergers, 12 CFR part 708a (Part 708a), which provides the requirements for conversions of FICUs to MSBs and mergers of FICUs into banks. Part 708a requires an insured credit union that proposes to convert to an MSB or to merge into a bank to provide notice and disclosure of the proposal to members and NCUA and to conduct a membership vote. These requirements are authorized under section 205(b)(2) of the Federal Credit Union Act, 12 U.S.C. 1785(b)(2). They are also necessary to ensure safety and soundness in the credit union industry, and to protect the interests of credit union members in the charter conversion and merger contexts. Submission of this information is designed to ensure NCUA has sufficient information to administer the member vote in an MSB conversion and to approve or disapprove a proposed merger into a bank. The information collection allows NCUA to ensure compliance with statutory and regulatory requirements for conversions and mergers. It also ensures that members of credit unions have sufficient and accurate information to exercise an informed vote concerning a proposed conversion or merger.

Subpart A of Part 708a (Subpart A) covers the conversion of insured credit unions to MSBs. Subpart A requires insured credit unions that intend to convert to MSBs to provide notice and disclosure of their intent to convert to their members and NCUA. It also requires insured credit unions to provide additional information to NCUA at various points in the conversion process.

Subpart C of Part 708a (Subpart C) covers the merger of insured credit unions into banks. Subpart C requires insured credit unions that intend to merge into banks (both mutual and stock banks) to determine the merger value of the credit union and provide notice and disclosure of their intent to merge to their members and NCUA. It also requires insured credit unions to provide additional information to NCUA at various points in the merger process.

The categories of burden and burden hours for credit unions complying with Part 708a may include the following:

Conversions to MSBs:

In the last five years, five credit unions have engaged in MSB conversion transactions. NCUA estimates it takes an average of approximately 300 hours to comply with the notice and disclosure requirements of Subpart A. Of the 300 hours, NCUA estimates that respondents will spend approximately 50 hours on recordkeeping, 42 hours on reporting, and 208 hours on third-party disclosure. Based on NCUA's experience, NCUA estimates that in the future one insured credit union will engage in an MSB conversion transaction in any given year, so that the total annual collection burden is estimated to be approximately 300 hours. The credit union is required to:

a. Publish advance notice of intent to convert (section 708a.103(a))—3 hours;

b. Solicit and review member comments on the advance notice (sections 708a.103(a) and (b))—4 hours;

c. Have the directors approve the conversion proposal (section 708a.103(c))—50 hours;

d. Notify NCUA of intent to convert (section 708a.105)—40 hours;

e. Prepare a directors' certification of support for the conversion proposal and submit to NCUA (section 708a.105(a)(2))—1 hour;

f. Prepare and mail notices to members and conduct a membership vote on the proposed conversion (sections 708a.104, 708a.106)—200 hours;

g. Transmit, upon request, a member's communication to the other members (section 708a.104(f))—1 hour; and

h. Prepare a member vote certification and submit to NCUA (section 708a.107)—1 hour.

Mergers into Banks:

In the last five years, no credit unions have engaged in bank merger transactions. If a credit union were to engage in a bank merger transaction in the future, NCUA estimates it would take approximately 410 hours to comply with the merger valuation, notice, and disclosure requirements of Subpart C. Of the 410 hours, NCUA estimates that respondents will spend approximately 100 hours on recordkeeping, 102 hours on reporting, and 208 hours on third-party disclosure. NCUA estimates that in the future one insured credit union will engage in a bank merger transaction in any given year, so that the total annual collection burden is estimated to be approximately 410 hours. The credit union is required to:

a. Obtain a merger valuation (section 708a.303(a))—50 hours;

b. Publish advance notice of intent to merge (section 708a.303(b))—3 hours;

c. Solicit and review member comments on the advance notice (section 708a.303(c))—4 hours;

d. Conduct due diligence and have the directors approve the merger proposal (sections 708a.303(d), 708a.304(d))—50 hours;

e. Prepare the Merger Plan and Notice of Intent to Merge and Request for NCUA Authorization and submit to NCUA (sections 708a.304(a) and (b))—100 hours;

f. Prepare a directors' certification of support for the merger proposal and submit to NCUA (section 708a.304(c))—1 hour;

g. Prepare and mail notices to members and conduct a membership vote on the proposed merger (sections 708a.305, 708a.306)—200 hours;

h. Transmit, upon request, a member's communication to the other members (section 708a.305(g))—1 hour; and

i. Prepare a member vote certification and submit to NCUA (section 708a.307)—1 hour.

In the **Federal Register** of August 28, 2015 (80 FR 52342), NCUA published a 60-day notice requesting public comment on the proposed collection of

information. NCUA received no comments.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

NCUA requests that you send your comments on this collection for part 708a to the location listed in the **ADDRESSES** section. Your comments should address: (a) The necessity of the information collection for the proper performance of NCUA, including whether the information will have practical utility; (b) the accuracy of our estimate of the burden of the information collection, including the validity of the methodology and assumptions used; (c) ways we could enhance the quality, utility, and clarity of the information to be collected; and (d) ways we could minimize the burden of the information collection on respondents, such as through the use of automated collection techniques or other forms of information technology. It is NCUA's policy to make all comments available to the public for review.

II. Data

Title: Bank Conversions and Mergers, 12 CFR part 708a.

OMB Number: 3133–0182.

Form Number: None.

Type of Review: Reinstatement, with change.

Description: Part 708a requires an insured credit union that proposes to convert to an MSB or to merge into a bank to provide notice and disclosure of the proposal to members and NCUA and to conduct a membership vote. Submission of this information is designed to ensure NCUA has sufficient information to administer the member vote in an MSB conversion and to approve or disapprove a proposed merger into a bank. The information collection allows NCUA to ensure compliance with statutory and regulatory requirements for conversions and mergers. It also ensures that members of credit unions have sufficient and accurate information to exercise an informed vote concerning a proposed conversion or merger.

Respondents: Federally insured credit unions.

Estimated Number of Respondents: 2.

Estimated Number of Responses: 2.

Frequency of Response: One-time; on occasion.

Estimated Time per Response: Ranges from 300 to 410 hours.

Estimated Total Annual Hour Burden: 710 hours.

Estimated Total Annual Cost: $28,400.00.

By the National Credit Union Administration Board on November 18, 2015.

Gerard Poliquin,

Secretary of the Board.

[FR Doc. 2015–30933 Filed 12–8–15; 8:45 am]

BILLING CODE 7535–01–P

NATIONAL CREDIT UNION ADMINISTRATION

Agency Information Collection; Submission for OMB Review; Comment Request; Joint Standards for Assessing the Diversity Policies and Practices of Entities Regulated by the Agencies

AGENCY: National Credit Union Administration (NCUA).

ACTION: Notice, request for comment, and notice of information collection to be submitted to the Office of Management and Budget (OMB) for review and approval under the Paperwork Reduction Act of 1995 (PRA).

SUMMARY: The NCUA has submitted to OMB a request for approval under the PRA of the collection of information discussed below. An agency may not conduct or sponsor, and a respondent is not required to respond to, an information collection unless it displays a currently valid OMB control number.

DATES: Comments must be submitted on or before January 8, 2016.

ADDRESSES: Interested persons are invited to submit written comments on the information collection to Tracy Crews, National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428; by fax to 703–837–2861; or by email to *OCIOPRA@ncua.gov.*

Additionally, commenters may send a copy of their comments to the OMB desk officer for the Agencies by mail to the Office of Information and Regulatory Affairs, U.S. Office of Management and Budget, New Executive Office Building Room 10235, 725 17th Street NW., Washington, DC 20503: by fax to (202) 395–6974; or by email to *oira_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: For further information about the information collection discussed in this notice, please contact Tracy Crews, National Credit Union Administration, 1775 Duke Street, Alexandria, VA 22314–3428; by fax to 703–837–2861; or by email to *OCIOPRA@ncua.gov.* In addition, background documentation for this information collection may be viewed at *www.reginfo.gov.*

SUPPLEMENTARY INFORMATION: Section 342 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (Dodd-Frank Act) required each Agency, including NCUA, to establish an Office of Minority and Women Inclusion (OMWI) to be responsible for all matters of the Agency relating to diversity in management, employment, and business activities. The Dodd-Frank Act also instructed the OMWI Directors to develop standards for assessing the diversity policies and practices of entities regulated by their Agencies. The Agencies worked together to develop joint standards and, on June 10, 2015, they published a **Federal Register** notice (80 FR 33016) entitled ''Final Interagency Policy Statement Establishing Joint Standards for Assessing the Diversity Policies and Practices of Entities Regulated by the Agencies'' (Policy Statement). The NCUA joined the Agencies in issuing the Policy Statement. The NCUA is issuing a separate **Federal Register** notice for PRA clearance using this notice. The Policy Statement contains a collection of information within the meaning of the PRA (44 U.S.C. 3501 *et seq.*).

A. Overview of the Collection of Information

1. Description of the Collection of Information and Proposed Use

The title for this proposed collection of information is:

- Joint Standards for Assessing Diversity Policies and Practices

The Policy Statement includes Joint Standards that cover ''Practices to Promote Transparency of Organizational Diversity and Inclusion.'' These standards contemplate that a regulated entity is transparent about its diversity and inclusion activities by making certain information available to the public annually on its Web site or in other appropriate communications, in a manner reflective of the entity's size and other characteristics. The information noted in these standards is the entity's diversity and inclusion strategic plan; its policy on its commitment to diversity and inclusion; progress toward achieving diversity and inclusion in its workforce and procurement activities (which may include the entity's current workforce and supplier demographic profiles); and employment and procurement opportunities available at the entity that promote diversity.

In addition, the Policy Statement includes standards that address ''Entities' Self-Assessment.'' These standards envision that the regulated entity conducts a voluntary self-

assessment of its diversity policies and practices at least annually, provides information pertaining to this self-assessment to its primary federal financial regulator, and publishes information pertaining to its efforts with respect to the Joint Standards. The information provided to the Agencies will be used to monitor progress and trends among regulated entities with regard to diversity and inclusion in employment and contracting activities, as well as to identify and publicize leading diversity policies and practices. NCUA designed a proposed, draft ''Voluntary, Sample Credit Union Self-Assessment Checklist,'' which federally insured credit unions would be able to use to as tool to perform their assessment and to submit this information to NCUA.

2. Description of Likely Respondents and Estimate of Annual Burden

The collections of information contemplated by the Joint Standards will impose no new recordkeeping burdens as regulated entities will only publish or provide information pertaining to diversity policies and practices that they maintain during the normal course of business. The NCUA estimates that, on average, it will take a federally insured credit union approximately 12 burden hours annually to assess diversity and inclusion practices and publish information pertaining to its diversity policies and practices on its Web site or in other appropriate communications and to retrieve and submit information pertaining to its self-assessment to NCUA.

NCUA estimates the total burden for federally insured credit unions as follows:

Information Collection: Joint Standards for Assessing Diversity Policies and Practices.

Estimated Number of Respondents: 367.

Frequency of Collection: Annual.

Average Response Time per Respondent: 12 hours.

Estimated Total Annual Burden Hours: 4,404.

Obligation to respond: Voluntary.

B. Solicitation of Public Comments

The Policy Statement included a 60-day notice requesting public comments on the collection of information. 80 FR 33016, 33021 (June 10, 2015). In addition, NCUA designed a draft proposed ''Voluntary, Sample Credit Union Self-Assessment Checklist,'' which federally insured credit unions would be able to use to perform their assessment and to submit information to NCUA. NCUA released the draft checklist with the Joint Standards, and the NCUA Letter to Credit Unions, No. 15–CU–05.

During the comment period, the Agencies collectively received four comment letters: Two from industry trade associations, one from an advocacy organization, and one from an individual. Separately, the NCUA received a comment letter from an industry trade association. The Agencies considered this comment and have included it in the discussion of comments below. The comments addressed the collection of information under the ''Entities Self-Assessment'' Joint Standards. (As noted above, these Joint Standards envision that a regulated entity provides self-assessment information to the OMWI Director of the entity's primary federal financial regulator.) The commenters also commented on aspects of the Policy Statement unrelated to the collection of information; these views are not relevant to this notice or the paperwork burden analysis and, accordingly, they are not addressed below.

After reviewing and considering the comments related to the collection of information, the Agencies have decided not to make any changes to the collection of information described in the 60-day notice.

1. Practical Utility of Information Collection

Two commenters addressed whether the collection of information pertaining to self-assessments will have practical utility. One commenter asserted that it is premature to gauge how useful information will be without knowing precisely what information the Agencies will request. The other commenter maintained that the information collection request in the Policy Statement will yield large variations in the information submitted and predicted that the information received will have little practical utility. This commenter argued that the Agencies should standardize the information they request so they are able to assess accurately the state of diversity and inclusion across the industry. The commenter's view is that standardization of the data request would enhance the quality, utility, and clarity of the collected information.

Although the Agencies have not specified the content or format for the information collection described in the Policy Statement, they anticipate that the information submitted to them will be similar in content, if not in form. They contemplate that regulated entities will organize their information collection around the categories in the Joint Standards. The Agencies also expect that the information they receive will help achieve the purpose of the collection, which is to allow the Agencies to identify trends in the financial services industry regarding diversity and inclusion in employment and contracting and to identify leading diversity policies and practices.

2. Specific Collection Instrument

As mentioned above, NCUA developed a draft, proposed voluntary checklist as an option for a collection tool for federally insured credit unions.

Three commenters requested that the Agencies be more specific about the information collection. One commenter asked the Agencies to send questions that ''comport with how its member firms operate'' and that the information collection request allow entities to submit qualitative information to add context to quantitative submissions. Another commenter asked the Agencies to provide a ''robust'' example or template of the information the entities should submit. This commenter also recommended that the Agencies provide a non-exhaustive list of materials that respondents can use to compare against what they are planning to submit. The third commenter recommended that the Agencies develop a standardized collection instrument. This commenter noted that it had recommended standardized survey questions when it commented on the proposed Policy Statement. The commenter urged the Agencies to adopt a thorough framework for collecting specific and consistent data.

The Agencies appreciate the collection instrument recommendations and the offers to assist in developing an instrument. At this time, however, the Agencies have not developed a joint information collection instrument. The Agencies believe that the Policy Statement encourages regulated entities to provide information regarding their self-assessments in a manner reflective of the Joint Standards and that any such information received will be useful.

3. Assurance of Confidentiality

The Joint Standards addressing Self-Assessments provide that the entities submitting information may designate such information as confidential commercial information, where appropriate. Three commenters expressed concerns about whether the information submitted would remain confidential. One commenter indicated that its members are concerned that information submitted to their primary federal financial regulator might be

provided, without context, to other regulators or to the U.S. Congress, leading to confusion or to the disclosure of competitive information. This commenter asked the Agencies to provide a clearer confidentiality policy and clarify that submissions will remain confidential unless the submitting entity expressly waives confidentiality. Similarly, another commenter stated that its members are concerned that third parties may have access to the information submitted and could use this information to the submitter's disadvantage. This commenter requested additional clarification regarding how the Agencies will use and protect submitted information, as well as a written statement providing assurance that the Agencies will not share the information with third parties.

The remaining commenter expressed concern that designating information as confidential will not guarantee protection from disclosure. The commenter observed that, if the public requests information under the Freedom of Information Act (FOIA), the regulated entity will be notified of the request and provided an opportunity to argue against disclosure. In the event that the regulated entity's argument does not prevail, the voluntarily submitted information could be released to the public.

Two of these commenters recommended that regulated entities be allowed to submit information anonymously. One commenter said its members might support the use of a third-party vendor that could capture and potentially anonymize submissions as a way to minimize information collection burden. The other commenter asserted that giving respondents the option to submit information anonymously would enhance the quality, utility, and clarity of the information, minimize burden, and address confidentiality concerns. This commenter also recommended that the Agencies allow submitters to classify themselves into general categories, such as by approximate asset size, number of employees, and geographic location.

The Agencies understand that regulated entities want assurances that the Agencies will treat the submitted information as confidential and will not disclose the information unless the submitter expressly waives confidentiality. To the extent that a submission includes confidential information, the Agencies will keep such information confidential to the extent allowed by law. The Agencies advise regulated entities submitting private information to follow their primary federal financial regulator's FOIA regulations with respect to designating information as confidential or seeking confidential treatment.

Finally, with respect to anonymity, the Agencies are concerned that anonymous submissions would be less useful than submissions in which the submitting entity is identified. As indicated in the Policy Statement, the OMWI Directors plan to reach out to regulated entities to discuss diversity and inclusion practices and methods of assessment, and these contacts will be more informative for both the Agencies and the entities if the Agencies know which submission came from which entity. However, the Agencies will reassess this matter over time.

4. Accuracy of Burden Estimate

The Agencies estimated that, annually, it would take an entity 12 burden hours, on average, to publish information pertaining to its diversity policies and practices on its Web site and to retrieve and submit self-assessment information to its primary federal financial regulator. One commenter stated that the Agencies grossly underestimated the time it would take to collect, categorize, and submit this information. The commenter asserted that retrieving diversity data is a time-consuming and labor-intensive task, particularly for entities with hundreds or thousands of employees located throughout U.S. and the world. In addition, the commenter maintained that an entity's submission would have to undergo a time-consuming review by legal counsel and others to assure accuracy and clarity before the entity could submit the information.

The Agencies note that the commenter did not provide an alternative estimate or formula for calculating this burden and that 12 hours is an estimated average. In the absence of more specific information, the Agencies do not have a basis for changing their burden estimate at this time. If, however, future feedback indicates that the current estimate needs further refinement, the Agencies will consider adjusting their estimates accordingly.

5. Estimate of Start-Up Costs

One commenter asserted that it would take substantial IT, legal, and operational resources to put diversity data into a format appropriate for submission to a regulator. The commenter said that it could not provide an exact estimate of capital or start-up costs for submitting this information until an actual information request was available. In response, the Agencies note that there are no start-up costs associated with the collection of information contained in the Joint Standards. Furthermore, any costs incurred by a regulated entity, aside from the 12 burden hours discussed above to publish information pertaining to its diversity policies and practices on its Web site and to retrieve and submit self-assessment information to its primary federal financial regulator, will be incurred in the normal course of its business activities.

Written comments continue to be invited on:

(a) The necessity of the collection of information for the proper performance of the Agencies' functions, including whether the information will have practical utility;

(b) The accuracy of the Agencies' estimate of the information collection burden, including the validity of the methods and the assumptions used;

(c) Ways to enhance the quality, utility, and clarity of the information proposed to be collected;

(d) Ways to minimize the information collection burden on respondents, including through the use of automated collection techniques or other forms of information technology; and

(e) Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

The Agencies encourage interested parties to submit comments in response to these questions. Comments submitted in response to this notice will be shared among the Agencies. All comments will become a matter of public record.

By National Credit Union Administration.

Dated: November 18, 2015.

Gerard Poliquin,

Secretary of the Board.

[FR Doc. 2015–30932 Filed 12–8–15; 8:45 am]

BILLING CODE P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Humanities

Meetings of Humanities Panel

AGENCY: National Endowment for the Humanities.

ACTION: Notice of Meetings.

SUMMARY: The National Endowment for the Humanities will hold three meetings of the Humanities Panel, a federal advisory committee, during January, 2016. The purpose of the meetings is for panel review, discussion, evaluation, and recommendation of applications for financial assistance under the National

Foundation on the Arts and Humanities Act of 1965.

DATES: See **SUPPLEMENTARY INFORMATION** section for meeting dates.

ADDRESSES: The meetings will be held at 10 First Street SE., Room LJ220, Washington, DC 20540.

FOR FURTHER INFORMATION CONTACT: Lisette Voyatzis, Committee Management Officer, 400 7th Street SW., Room, 4060, Washington, DC 20506; (202) 606–8322; *evoyatzis@neh.gov.* Hearing-impaired individuals who prefer to contact us by phone may use NEH's TDD terminal at (202) 606–8282.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App.), notice is hereby given of the following meetings:

1. *Date:* January 21, 2016.
Time: 9:00 a.m. to 5:00 p.m.
This meeting will discuss applications for Kluge Fellowships, submitted to the Division of Research Programs.

2. *Date:* January 26, 2016.
Time: 9:00 a.m. to 5:00 p.m.
This meeting will discuss applications for Kluge Fellowships, submitted to the Division of Research Programs.

3. *Date:* January 28, 2016.
Time: 9:00 a.m. to 5:00 p.m.
This meeting will discuss applications for Kluge Fellowships, submitted to the Division of Research Programs.

Because these meetings will include review of personal and/or proprietary financial and commercial information given in confidence to the agency by grant applicants, the meetings will be closed to the public pursuant to sections 552b(c)(4) and 552b(c)(6) of Title 5, U.S.C., as amended. I have made this determination pursuant to the authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee Meetings dated July 19, 1993.

Dated: December 2, 2015.

Elizabeth Voyatzis,

Committee Management Officer.

[FR Doc. 2015–30983 Filed 12–8–15; 8:45 am]

BILLING CODE 7536–01–P

NATIONAL SCIENCE FOUNDATION

Agency Information Collection Activities: Comment Request

AGENCY: National Science Foundation.

ACTION: Submission for OMB review; comment request.

SUMMARY: The National Science Foundation (NSF) has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1995, Public Law 104–13. This is the second notice for public comment; the first was published in the **Federal Register** at 80 FR 50662 and no comments were received. NSF is forwarding the proposed renewal submission to the Office of Management and Budget (OMB) for clearance simultaneously with the publication of this second notice. The full submission may be found at: *http://www.reginfo.gov/public/do/PRAMain.*

Comments: 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; or (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 should be addressed to: Office of Information and Regulatory Affairs of OMB, Attention: Desk Officer for National Science Foundation, 725 17th Street, NW., Room 10235, Washington, DC 20503, and to Suzanne H. Plimpton, Reports Clearance Officer, National Science Foundation, 4201 Wilson Boulevard, Suite 295, Arlington, Virginia 22230 or send email to *splimpto@nsf.gov.* Comments regarding these information collections are best assured of having their full effect if received within 30 days of this notification. Copies of the submission(s) may be obtained by calling 703–292–7556.

FOR FURTHER INFORMATION CONTACT: Suzanne H. Plimpton at (703) 292–7556 or send email to *splimpto@nsf.gov.* Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339, which is accessible 24 hours a day, 7 days a week, 365 days a year (including federal holidays).

NSF 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.

SUPPLEMENTARY INFORMATION:

Title of Collection: Grantee Reporting Requirements for the Research Experiences for Undergraduates (REU) Program.

OMB Number: 3145–0224.

Type of Request: Intent to seek approval extend, with revisions, an information collection.

Abstract:

Overview of this information collection: The Research Experiences for Undergraduates (REU) Reporting Module is a component of the NSF Project Reports System that is designed to gather information about students participating in REU Sites and Supplements projects. All NSF Principal Investigators are required to submit annual and final project reports through Research.gov. If NSF cannot collect information about undergraduate participants in undergraduate research experiences, NSF will have no other means to consistently document the number and diversity of participants, types of participant involvement in the research, and types of institutions represented by the participants.

NSF is committed to providing program stakeholders with formation regarding the expenditure of taxpayer funds on these types of activities, which provide authentic research experiences and related training for postsecondary students in STEM fields.

Consult with Other Agencies & the Public: NSF has not consulted with other agencies but has gathered information from its grantee community through attendance at PI conferences. A request for public comments will be solicited through announcement of data collection in the **Federal Register**.

Background: All NSF Principal Investigators are required to use the project reporting functionality in Research.gov to report on progress, accomplishments, participants, and activities annually and at the conclusion of their project. Information from annual and final reports provides yearly updates on project inputs, activities, and outcomes for agency reporting purposes. If project participants include undergraduate students supported by the Research Experiences for Undergraduates (REU) Sites Program or by an REU Supplement, then the Principal Investigator and his or her students are required to complete the REU Reporting Module.

Respondents: Individuals (Principal Investigators and REU undergraduate student participants).

Number of Principal Investigator Respondents: 2,300.

Burden on the Public: 383 total hours.

Dated: December 4, 2015.

Suzanne H. Plimpton,

Reports Clearance Officer, National Science Foundation.

[FR Doc. 2015–31041 Filed 12–8–15; 8:45 am]

BILLING CODE 7555–01–P

NATIONAL SCIENCE FOUNDATION

National Science Board; Sunshine Act Meetings; Notice

The National Science Board's *ad hoc* Task Force on NEON Performance and Plans, pursuant to NSF regulations (45 CFR part 614), the National Science Foundation Act, as amended (42 U.S.C. 1862n–5), and the Government in the Sunshine Act (5 U.S.C. 552b), hereby gives notice in regard to the scheduling of a meeting for the transaction of National Science Board business, as follows:

DATE AND TIME: Friday, December 11, 2015 at 3:00 to 3:30 p.m. EST.

SUBJECT MATTER: Task Force Chair's opening remarks; approval of minutes; Director's update; and Chair's closing remarks.

STATUS: Closed.

This meeting will be held by teleconference originating at the National Science Board Office, National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230.

Please refer to the National Science Board Web site (*www.nsf.gov/nsb*) for information or schedule updates, or contact: Elise Lipkowitz (*elipcowi@nsf.gov*), National Science Foundation, 4201 Wilson Blvd., Arlington, VA 22230.

Kyscha Slater-Williams,

Program Specialist.

[FR Doc. 2015–31080 Filed 12–7–15; 11:15 am]

BILLING CODE 7555–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2015–0146]

Information Collection: Export and Import of Nuclear Equipment and Material

AGENCY: Nuclear Regulatory Commission.

ACTION: Notice of submission to the Office of Management and Budget; request for comment.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) has recently submitted a request for renewal of an existing collection of information to the Office of Management and Budget (OMB) for review. The information collection is entitled, ''Export and Import of Nuclear Equipment and Material.''

DATES: Submit comments by January 8, 2016.

ADDRESSES: Submit comments directly to the OMB reviewer at: Vlad Dorjets, Desk Officer, Office of Information and Regulatory Affairs (3150–0036), NEOB–10202, Office of Management and Budget, Washington, DC 20503; Telephone: 202–395–7315; Email: *oira_submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Tremaine Donnell, NRC Clearance Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; Telephone: 301–415–6258; Email: *INFOCOLLECTS.Resource@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Obtaining Information and Submitting Comments

A. Obtaining Information

Please refer to Docket ID 2015–0146 when contacting the NRC about the availability of information for this action. You may obtain publicly-available information related to this action by any of the following methods:

- Federal Rulemaking Web site: Go to *http://www.regulations.gov* and search for Docket ID 2015–0146. A copy of the collection of information and related instructions may be obtained without charge by accessing Docket ID 2015–0146 on this Web site.
- 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 via email to *pdr.resource@nrc.gov.* A copy of the collection of information and related instructions may be obtained without charge by accessing ADAMS Accession No. ML15275A150. The supporting statement is available in ADAMS under Accession No. ML15275A153.
- 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.
- NRC's Clearance Officer: A copy of the collection of information and related instructions may be obtained without charge by contacting the NRC's Clearance Officer, Tremaine Donnell, Office of the Chief Information Officer, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; Telephone: 301–415–6258; Email: *INFOCOLLECTS.Resource@NRC.GOV.*

B. Submitting Comments

The NRC cautions you not to include identifying or contact information in comment submissions that you do not want to be publicly disclosed in your comment submission. All comment submissions are posted at *http://www.regulations.gov* and entered into ADAMS. Comment submissions are not routinely edited to remove identifying or contact information.

If you are requesting or aggregating comments from other persons for submission to the OMB, then you should inform those persons not to include identifying or contact information that they do not want to be publicly disclosed in their comment submission. Your request should state that comment submissions are not routinely edited to remove such information before making the comment submissions available to the public or entering the comment into ADAMS.

II. Background

Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the NRC recently submitted a request for renewal of an existing collection of information to OMB for review entitled, ''Export and Import of Nuclear Equipment and Material.'' The NRC hereby informs potential respondents that an agency may not conduct or sponsor, and that a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

The NRC published a **Federal Register** notice with a 60-day comment period on this information collection on July 1, 2015 (80 FR 37669).

1. *The title of the information collection:* 10 CFR part 110, ''Export and Import of Nuclear Equipment and Material.''

2. *OMB approval number:* 3150–0036.

3. *Type of submission:* Extension.

4. *The form number if applicable:* NRC Form 830, NRC Form 830A, NRC Form 831, and NRC Form 831A.

5. *How often the collection is required or requested:* On occasion.

6. *Who will be required or asked to respond:* Any person in the U.S. who wishes to export or import (a) nuclear

material and equipment subject to the requirements of a specific license; (b) amend a license; (c) renew a license; (d) obtain consent to export Category 1 quantities of materials listed in Appendix P to 10 CFR part 110; or (5) request an exemption from a licensing requirement under Part 110.

7. *The estimated number of annual responses:* 2,945.

8. *The estimated number of annual respondents:* 136.

9. *An estimate of the total number of hours needed annually to comply with the information collection requirement or request:* 929.

10. *Abstract:* Persons in the U.S. who export or import nuclear material or equipment under a general or specific authorization must comply with certain reporting and recordkeeping requirements under 10 CFR part 110.

Dated at Rockville, Maryland, this 3rd day of December, 2015.

For the Nuclear Regulatory Commission.

Tremaine Donnell,

NRC Clearance Officer, Office of the Chief Information Officer.

[FR Doc. 2015–30949 Filed 12–8–15; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

Request for a License To Export Nuclear Reactor Major Components and Equipment

Pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) 110.70(b) ''Public Notice of Receipt of an Application,'' please take notice that the U.S. Nuclear Regulatory Commission (NRC) has received the following request for an export license. Copies of the request are available electronically through the Agencywide Documents Access and Management System and can be accessed through the Public Electronic Reading Room link *http://www.nrc.gov/reading-rm.html* at the NRC Homepage.

A request for a hearing or petition for leave to intervene may be filed within 30 days after publication of this notice in the **Federal Register** (FR). Any request for hearing or petition for leave to intervene shall be served by the requestor or petitioner upon the applicant, the office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555; the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555; and the Executive Secretary, U.S. Department of State, Washington, DC 20520.

A request for a hearing or petition for leave to intervene may be filed with the NRC electronically in accordance with NRC's E-Filing rule promulgated in August 2007, 72 FR 49139; August 28, 2007. Information about filing electronically is available on the NRC's public Web site at *http://www.nrc.gov/site-help/e-submittals.html.* To ensure timely electronic filing, at least 5 days prior to the filing deadline, the petitioner/requestor should contact the Office of the Secretary by email at *HEARINGDOCKET@NRC.GOV*, or by calling (301) 415–1677, to request a digital ID certificate and allow for the creation of an electronic docket.

In addition to a request for hearing or petition for leave to intervene, written comments, in accordance with 10 CFR 110.81, should be submitted within thirty days after publication of this notice in the **Federal Register** to Office of the Secretary, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Rulemaking and Adjudications.

The information concerning this application for an export license follows.

NRC EXPORT LICENSE APPLICATION

[Description of Material]

Name of applicant, date of application, date received, application No., docket No.	Material type	Total quantity	End use	Destination
Westinghouse Electric Company LLC, October 21, 2015, October 28, 2015, XR178, 11006216.	Complete reactor systems, rod cluster control assemblies, primary coolant pumps, and associated equipment, with the power level of 1876 MWt.	For continued operation of the previously exported pressurized-water reactor.	For electricity generation at the KRSKO Nuclear Power Plant.	Republic of Slovenia.

For the Nuclear Regulatory Commission.

Dated this 1st day of December 2015, at Rockville, Maryland.

David L. Skeen,

Deputy Director, Office of International Programs.

[FR Doc. 2015–30978 Filed 12–8–15; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF SCIENCE AND TECHNOLOGY POLICY

Request for Input on the United States Group on Earth Observations Draft Common Framework for Earth-Observation Data

ACTION: Notice of Request for Information (RFI).

SUMMARY: The U.S. Group on Earth Observations (USGEO), a Subcommittee of the National Science and Technology Council (NSTC) Committee on Environment, Natural Resources, and Sustainability (CENRS), requests comment on the draft *Common Framework for Earth-observation data* (referred to in this document as *''the Common Framework''*). The draft Common Framework will be posted at *https://www.whitehouse.gov/administration/eop/ostp/library/shareyourinput.* Comments of approximately five pages or less in length (up to 20,000 characters) are requested and must be received by 8 p.m. (Eastern Standard Time), January 15, 2016 to be considered. The public input provided in response to this Notice will inform USGEO as it works to develop the Common Framework.

DATES: Responses must be received by 8 p.m. (Eastern Standard Time), January 15, 2016 to be considered.

ADDRESSES: You may submit comments by any of the following methods:

- On-line form: To aid in information collection and analysis, the Office of Science and Technology Policy (OSTP) encourages responses to be provided by filling out the on-line form located at *https://www.whitehouse.gov/administration/eop/ostp/library/shareyourinput.*
- Fax: (202) 456–6071. On the cover page, please state ''Draft Common Framework for Earth Observation Data, attn: Timothy Stryker''.

• Mail: Office of Science and Technology Policy, 1650 Pennsylvania Avenue NW., Washington, DC, 20504, attn: Timothy Stryker. Information submitted by postal mail should be postmarked by January 15, 2016.

Response to this RFI is voluntary. Respondents need not reply to all questions listed; however, they should clearly identify the questions to which they are responding by listing the corresponding number for each question. Each individual or institution is requested to submit only one response. OSTP may post responses to this RFI without change, online, at *www.usgeo.gov.* OSTP therefore requests that no business proprietary information, copyrighted information, or personally identifiable information be submitted in response to this RFI. Please note that the U.S. Government will not pay for response preparation, or for the use of any information contained in the response.

FOR FURTHER INFORMATION CONTACT: Timothy Stryker, Director, U.S. Group on Earth Observations Program, 202–419–3471, *tstryker@ostp.eop.gov,* OSTP.

SUPPLEMENTARY INFORMATION: On behalf of USGEO, OSTP is seeking public comment on a draft Common Framework for data scientists, users of Earth-observation data, and others, both inside and outside the government.

The Common Framework originated as the ''Big Earth Data Initiative (BEDI) Common Framework'' to provide guidance to agencies on what standards and protocols to use when managing data under the OMB/OSTP Big Earth Data Initiative. In the course of BEDI implementation, USGEO data-management practitioners identified a set of effective practices for managing Earth-observation data that had value beyond BEDI and would be a useful resource for many data managers in the Federal government. The Common Framework encourages standard protocols for finding, accessing, and using Earth-observation data. USGEO agencies expect the Common Framework will make it easier to obtain and assemble data from diverse sources for improved analysis, understanding, decision-making, community resilience, and commercial uses. To ensure that a recommended set of shared standards across agencies results in greater discovery, access, and use of data, OSTP is seeking public comment on the Common Framework, which may be accessed at *https://www.whitehouse.gov/administration/eop/ostp/library/shareyourinput.*

OSTP seeks comment from the public on the following questions:

1. How would adoption of this set of recommended standards by Federal agencies affect your discovery, access, and use of government Earth-observation data and data catalogs, if at all?

2. Do you agree that Common Framework-recommended standards are current, appropriate, and valuable practices for civil Earth observation agencies within the Federal Government? Why or why not?

3. Do you wish to share specific examples of how the use of Common Framework-recommended standards have aided or hindered the use of government Earth-observation data or the development of products such as data portals, visualizations, or decision-support tools?

Ted Wackler,

Deputy Chief of Staff and Assistant Director; OSTP.

[FR Doc. 2015–30929 Filed 12–8–15; 8:45 am]

BILLING CODE 3270–F6–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76552; File No. SR–BATS–2015–108]

Self-Regulatory Organizations; BATS Exchange, Inc.; Notice of Filing of a Proposed Rule Change To Adopt Rule 11.27 Regarding the Quoting and Trading Requirements of the Tick Size Pilot Program

December 3, 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 November 30, 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 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 is proposing to adopt Exchange Rule 11.27 to implement the Regulation NMS Plan to Implement a Tick Size Pilot Program (''Plan'').[3]

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

On August 25, 2014, NYSE Group, Inc., on behalf of the Exchange, BATS Y-Exchange, Inc., Chicago Stock Exchange, Inc., EDGA Exchange, Inc., EDGX Exchange, Inc., Financial Industry Regulatory Authority, Inc. (''FINRA''), NASDAQ OMX BX, Inc., NASDAQ OMX PHLX LLC, the Nasdaq Stock Market LLC, New York Stock Exchange LLC (''NYSE''), NYSE MKT LLC, and NYSE Arca, Inc. (collectively ''Participants''), filed with the Commission, pursuant to Section 11A of the Act[4] and Rule 608 of Regulation NMS thereunder, the Plan to implement a tick size pilot program (''Pilot'').[5] The Participants filed the Plan to comply with an order issued by the Commission on June 24, 2014.[6] The Plan[7] was published for comment in the **Federal Register** on November 7, 2014, and approved by the Commission, as modified, on May 6, 2015.[8]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange notes that proposed rule change is substantially similar to that proposed by FINRA under their proposed Rule 6191. *See* SR–FINRA–2015–047 (filed November 13, 2015).

[4] 15 U.S.C. 78k–1.

[5] *See* Letter from Brendon J. Weiss, Vice President, Intercontinental Exchange, Inc., to Secretary, Commission, dated August 25, 2014.

[6] *See* Securities Exchange Act Release No. 72460 (June 24, 2014), 79 FR 36840 (June 30, 2014).

[7] Unless otherwise specified, capitalized terms used in this rule filing are defined as set forth in the Plan. The Exchange also proposes supplementary material as part of this proposed rule change to, among other things, provide that the terms used in proposed Rule 11.27 shall have the same meaning as provided in the Plan, unless otherwise specified.

[8] *See* Securities Exchange Act Release No. 74892 (May 6, 2015), 80 FR 27514 (May 13, 2015) (''Approval Order'').

The Plan is designed to allow the Commission, market participants, and the public to study and assess the impact of increment conventions on the liquidity and trading of the common stocks of small-capitalization companies. Each Participant is required to comply with, and to enforce compliance by its member organizations, as applicable, with the provisions of the Plan. As is described more fully below, the proposed rules would require Members [9] to comply with the applicable quoting and trading increments for Pilot Securities.[10]

The Pilot will include stocks of companies with $3 billion or less in market capitalization, an average daily trading volume of one million shares or less, and a volume weighted average price of at least $2.00 for every trading day. The Pilot will consist of a control group of approximately 1400 Pilot Securities and three test groups with 400 Pilot Securities in each selected by a stratified sampling.[11] During the pilot, Pilot securities in the control group will be quoted and traded at the currently permissible increments. Pilot Securities in the first test group (''Test Group One'') will be quoted in $0.05 minimum increments but will continue to trade at any price increment that is currently permitted.[12] Pilot Securities in the second test group (''Test Group Two'') will be quoted in $0.05 minimum increments and will trade at $0.05 minimum increments subject to a midpoint exception, a retail investor order exception, and a negotiated trade exception.[13] Pilot Securities in the third test group (''Test Group Three'') will be subject to the same restrictions as Test Group Two and also will be subject to the ''Trade-at'' requirement to prevent price matching by a market participant that is not displaying at a price of a Trading Center's [14] ''Best Protected Bid'' or ''Best Protected Offer,'' unless an enumerated exception applies.[15] In addition to the exceptions provided under Test Group Two, an exception for Block Size orders and exceptions that mirror those under Rule 611 of Regulation NMS [16] will apply to the Trade-at requirement.

Compliance With the Quoting and Trading Increments of the Plan

The Plan requires the Exchange to establish, maintain, and enforce written policies and procedures that are reasonably designed to comply with applicable quoting and trading requirements specified in the Plan.[17] Accordingly, the Exchange is proposing new Rule 11.27 (Compliance with Regulation NMS Plan to Implement a Tick Size Pilot Program) to require Members to comply with the quoting and trading provisions of the Plan.

Proposed Rule 11.27(a) (Compliance with Quoting and Trading Restrictions) sets forth the requirements for the Exchange and Members in meeting their obligations under the Plan. Rule 11.27(a)(1) will require Members to establish, maintain and enforce written policies and procedures that are reasonably designed to comply with the applicable quoting and trading requirements of the Plan. Rule 11.27(a)(2) provides that the Exchange Systems [18] will not display, quote or trade in violation of the applicable quoting and trading requirements for a Pilot Security specified in the Plan and this Rule, unless such quotation or transaction is specifically exempted under the Plan.

Proposed Rule 11.27(a)(3) clarifies the treatment of Pilot Securities that drop below $1.00 during the Pilot Period. In particular, Rule 11.27(a)(3) provides that, if the price of a Pilot Security drops below $1.00 during regular trading hours on any trading day, such Pilot Security will continue to be a Pilot Security subject to the Plan. However, if the Closing Price of a Pilot Security on any given trading day is below $1.00, such Pilot Security will be moved out of its Pilot Test Group into the Control Group, and may then be quoted and traded at any price increment that is currently permitted for the remainder of the Pilot Period. Rule 11.27(a)(3) also provides that, notwithstanding anything contained within these rules to the contrary, Pilot Securities (whether in the Control Group or any Pilot Test Group) will continue to be subject to the data collection requirements of the Plan at all times during the Pilot Period and for the six-month period following the end of the Pilot Period.

In approving the Plan, the Commission noted that the Participants had proposed additional selection criteria to minimize the likelihood that securities that trade with a share price of $1.00 or less would be included in the Pilot, and stated that, once established, the universe of Pilot Securities should stay as consistent as possible so that the analysis and data can be accurate throughout the Pilot Period.[19] The Exchange notes that a Pilot Security that drops below $1.00 during regular trading hours will remain in its applicable Test Group; a Pilot Security will only be moved to the Control Group if its Closing Price on any given trading day is below $1.00. The Exchange believes that this provision is appropriate because it will help ensure that Pilot Securities in Test Groups One, Two and Three continue to reflect the Pilot's selection criteria, helping ensure the accuracy of the resulting data. The Exchange also believes that this provision is appropriate because it responds to comments that the Plan address the treatment of securities that trade below $1.00 during the Pilot Period.[20]

Proposed Rule 11.27(a)(4) sets forth the applicable limitations for securities in Test Group One. Consistent with the language of the Plan, Rule 11.27(a)(4) provides that no Member may display, rank, or accept from any person any displayable or non-displayable bids or offers, orders, or indications of interest in any Pilot Security in Test Group One in increments other than $0.05. However, orders priced to execute at the midpoint of the national best bid and national best offer (''NBBO'') or best protected bid and best protected offer (''PBBO'') [21] and orders entered in a

[9] The term ''Member'' is defined as ''any registered broker or dealer, or any person associated with a registered broker or dealer, that has been admitted to membership in the Exchange. A Member will have the status of a ''member'' of the Exchange as that term is defined in Section 3(a)(3) of the Act.'' *See* Exchange Rule 1.5(n).

[10] The Exchange proposes to add Information and Policy .03 to Rule 11.27 to provide that the Rule shall be in effect during a pilot period to coincide with the pilot period for the Plan (including any extensions to the pilot period for the Plan).

[11] *See* Section V of the Plan for identification of Pilot Securities, including criteria for selection and grouping.

[12] *See* Section VI(B) of the Plan.

[13] *See* Section VI(C) of the Plan.

[14] The Plan incorporates the definition of ''Trading Center'' from Rule 600(b)(78) of Regulation NMS. Regulation NMS defines a Trading Center as ''a national securities exchange or national securities association that operates an SRO trading facility, an alternative trading system, an exchange market maker, an OTC market maker, or any other broker or dealer that executes orders internally by trading as principal or crossing orders as agent.''

[15] *See* Section VI(D) of the Plan.

[16] 17 CFR 242.611.

[17] The Exchange is also required by the Plan to develop appropriate policies and procedures that provide for data collection and reporting to the Commission of data described in Appendixes B and C of the Plan. The Exchange intends to separately propose rules that would require compliance by its Members with the collection of data provisions of the Plan described in Section VII of the Plan, and has reserved Paragraph (b) for such rules.

[18] The term ''System'' is defined as ''the electronic communications and trading facility designated by the Board through which securities orders of Users are consolidated for ranking, execution and, when applicable, routing away.'' *See* Exchange Rule 1.5(aa).

[19] *See* Approval Order, *supra* note 7, 80 FR at 27535.

[20] *Id.*

[21] Regulation NMS defines a protected bid or protected offer as a quotation in an NMS stock that (1) is displayed by an automated trading center; (2) is disseminated pursuant to an effective national

Participant-operated retail liquidity program may be ranked and accepted in increments of less than $0.05. Pilot Securities in Test Group One may continue to trade at any price increment that is currently permitted by applicable Participant, SEC and Exchange rules.

Proposed Rule 11.27(a)(5) sets forth the applicable quoting and trading requirements for securities in Test Group Two. This provision states that no Member may display, rank, or accept from any person any displayable or non-displayable bids or offers, orders, or indications of interest in any Pilot Security in Test Group Two in increments other than $0.05. However, orders priced to execute at the midpoint of the NBBO or PBBO and orders entered in a Participant-operated retail liquidity program may be ranked and accepted in increments of less than $0.05.

Proposed Rule 11.27(a)(5) also sets forth the applicable trading restrictions for Test Group Two securities. Absent any of the exceptions listed in the Rule, no Member may execute orders in any Pilot Security in Test Group Two in price increments other than $0.05. The $0.05 trading increment will apply to all trades, including Brokered Cross Trades.

Consistent with the language of the Plan, the Rule provides that Pilot Securities in Test Group Two may trade in increments of less than $0.05 under the following circumstances: (1) Trading may occur at the midpoint between the NBBO or the PBBO; (2) Retail Investor Orders may be provided with price improvement that is at least $0.005 better than the PBBO; and (3) Negotiated Trades may trade in increments of less than $0.05.

Proposed Rule 11.27(a)(6) sets forth the applicable quoting and trading restrictions for Pilot Securities in Test Group Three. The rule provides that no Member may display, rank, or accept from any person any displayable or non-displayable bids or offers, orders, or indications of interest in any Pilot Security in Test Group Three in increments other than $0.05. However, orders priced to execute at the midpoint of the NBBO or PBBO and orders entered in a Participant-operated retail liquidity program may be ranked and accepted in increments of less than $0.05. The rule also states that, absent any of the applicable exceptions, no Member that operates a Trading Center may execute orders in any Pilot Security in Test Group Three in price increments other than $0.05. The $0.05 trading increment will apply to all trades, including Brokered Cross Trades.[22]

Proposed Rule 11.27(a)(6)(C) sets forth the exceptions pursuant to which Pilot Securities in Test Group Three may trade in increments of less than $0.05. First, trading may occur at the midpoint between the NBBO or PBBO. Second, Retail Investor Orders may be provided with price improvement that is at least $0.005 better than the PBBO. Third, Negotiated Trades may trade in increments of less than $0.05.

Proposed Rule 11.27(a)(6)(D) sets forth the ''Trade-at Prohibition,'' which is the prohibition against executions by a Member that operates a Trading Center of a sell order for a Pilot Security in Test Group Three at the price of a Protected Bid or the execution of a buy order for a Pilot Security in Test Group Three at the price of a Protected Offer during regular trading hours, absent any of the exceptions set forth in Rule 11.27(a)(6)(D). Consistent with the Plan, the rule reiterates that a member that operates a Trading Center that is displaying a quotation, via either a processor or an SRO quotation feed, that is a Protected Bid or Protected Offer is permitted to execute orders at that level, but only up to the amount of its displayed size. A Member that operates a Trading Center that was not displaying a quotation that is the same price as a Protected Quotation, via either a processor or an SRO quotation feed, is prohibited from price-matching protected quotations unless an exception applies.

Consistent with the Plan, proposed Rule 11.27(a)(6)(D) also sets forth the exceptions to the Trade-at prohibition, pursuant to which a Member that operates a Trading Center may execute a sell order for a Pilot Security in Test Group Three at the price of a Protected Bid or execute a buy order for a Pilot Security in Test Group Three at the price of a Protected Offer. The first exception to the Trade-at Prohibition is the ''display exception,'' which allows a trade to occur at the price of the Protected Quotation, up to the Trading Center's full displayed size, if the order ''is executed by a trading center that is displaying a quotation.'' [23]

In Rule 11.27(a)(6)(D), the Exchange proposes that a Member that utilizes the independent aggregation unit concept may satisfy the display exception only if the same independent aggregation unit that displays interest via either a processor or an SRO Quotation Feed also executes an order in reliance upon this exception. The rule provides that ''independent aggregation unit'' has the same meaning as provided under Rule 200(f) of SEC Regulation SHO.[24] This provision also recognizes that not all members may utilize the independent aggregation unit concept as part of their regulatory structure, and still permits such members to utilize the display exception if all the other requirements of that exception are met.

As initially proposed by the Participants, the Plan contained an additional condition to the display exception, which would have required that, where the quotation is displayed through a national securities exchange, the execution at the size of the order must occur against the displayed size on that national securities exchange; and where the quotation is displayed through the Alternative Display Facility or another facility approved by the Commission that does not provide execution functionality, the execution at the size of the order must occur against the displayed size in accordance with the rules of the Alternative Display Facility of such approved facility (''venue limitation'').[25] Some commenters stated that this provision was anti-competitive, as it would have forced off-exchange Trading Centers to route orders to the venue on which the order was displayed.[26]

In approving the Plan, the Commission modified the Trade-At Prohibition to remove the venue limitation.[27] The Commission noted that the venue limitation was not

market system plan; and (3) is an automated quotation that is the best bid or best offer of a national securities exchange, the best bid or best offer of The Nasdaq Stock Market, Inc., or the best bid or best offer of a national securities association other than the best bid or best offer of The Nasdaq Stock Market, Inc. *See* 17 CFR 242.600(57). In the Approval Order, the Commission noted that the protected quotation standard encompasses the aggregate of the most aggressively priced displayed liquidity on all Trading Centers, whereas the NBBO standard is limited to the single best order in the market. *See* Approval Order, *supra* note 7, 80 FR at 27539.

[22] A brokered cross trade is a trade that a broker-dealer that is a member of a Participant executes directly by matching simultaneous buy and sell orders for a Pilot Security. *See* Section I(G) of the Plan.

[23] *See* Section VI(D)(1) of the Plan.

[24] 17 CFR 242.200. Treatment as an independent aggregation unit is available if traders in an aggregation unit pursue only the particular trading objective(s) or strategy(ies) of that aggregation unit and do not coordinate that strategy with any other aggregation unit. Therefore, one independent aggregation unit within a Trading Center cannot execute trades pursuant to the display exception in reliance on quotations displayed by a different independent aggregation unit. As an example, an agency desk of a Trading Center cannot rely on the quotation of a proprietary desk in a separate independent aggregation unit at that same Trading Center.

[25] *See* Securities Exchange Act Release No. 73511 (November 3, 2014), 79 FR 66423, 66437 (November 7, 2014).

[26] *See* Approval Order, *supra* note 7, 80 FR at 27540.

[27] *Id.*

prescribed in its Order mandating the filing of the Plan.[28] The Commission also noted that the venue limitation would have unnecessarily restricted the ability of off-exchange market participants to execute orders in Test Group Three Securities, and that removing the venue limitation should mitigate concerns about the cost and complexity of the Pilot by reducing the need for off-exchange Trading Centers to route to the exchange.[29] The Commission also stated that the venue limitation did not create any additional incentives to display liquidity in furtherance of the purposes of the Trade-At Prohibition, because the requirement that a Trading Center could only trade at a protected quotation up to its displayed size should be sufficient to incentivize displayed liquidity.[30]

Consistent with Plan and the SEC's determination to remove the venue limitation, the Exchange is making clear that the display exception applies to trades done by a Trading Center otherwise than on an exchange where the Trading Center has previously displayed a quotation in either an agency or a principal capacity. As part of the display exception, the Exchange also proposes that a Trading Center that is displaying a quotation as agent or riskless principal may only execute as agent or riskless principal, while a Trading Center displaying a quotation as principal (excluding riskless principal) may execute either as principal or agent or riskless principal. The Exchange believes this is consistent with the Plan and the objective of the Trade-at Prohibition, which is to promote the display of liquidity and generally to prevent any Trading Center that is not quoting from price-matching Protected Quotations.[31] Providing that a Trading Center may not execute on a proprietary basis in reliance on a quotation representing customer interest (whether agency or riskless principal) ensures that the Trading Center cannot avoid compliance with the Trade-at Prohibition by trading on a proprietary basis in reliance on a quotation that does not represent such Trading Center's own interest. Where a Trading Center is displaying a quotation at the same price as a Protected Quotation in a proprietary capacity, transactions in any capacity at the price and up to the size of such Trading Center's displayed quotation would be permissible. Transactions executed pursuant to the display exception may occur on the venue on which such quotation is displayed or over the counter.

The proposal also excepts Block Size orders [32] and permits Trading Centers to trade at the price of a Protected Quotation, provided that the order is of Block Size at the time of origin and is not an aggregation of non-block orders, broken into orders smaller than Block Size prior to submitting the order to a Trading Center for execution; or executed on multiple Trading Centers.[33] The Plan only provides that Block Size orders shall be exempted from the Trade-At Prohibition. In requiring that the order be of Block Size at the time of origin and not an aggregation of non-block orders, or broken into orders smaller than Block Size prior to submitting the order to a Trading Center for execution; or executed on multiple Trading Centers, the Exchange believes that it is providing clarity as to the circumstances under which a Block Size order will be excepted from the Trade-At Prohibition.

Consistent with the Plan, the proposal also excepts an order that is a Retail Investor Order that is executed with at least $0.005 price improvement.

The exceptions set forth in proposed Rule 11.27(a)(6)(D)(ii) d. through l. are based on the exceptions found in Rule 611 of Regulation NMS.[34] The subparagraph d. exception applies when the order is executed when the Trading Center displaying the Protected Quotation that was traded at was experiencing a failure, material delay, or malfunction of its systems or equipment. The subparagraph e. exception applies to an order that is executed as part of a transaction that was not a ''regular way'' contract. The subparagraph f. exception applies to an order that is executed as part of a single-priced opening, reopening, or closing transaction by the Trading Center. The subparagraph g. exception applies to an order that is executed when a Protected Bid was priced higher than a Protected Offer in a Pilot Security. The subparagraph h. exception applies when the order is identified as a Trade-at Intermarket Sweep Order. The subparagraph i. exception applies when the order is executed by a Trading Center that simultaneously routed Trade-at Intermarket Sweep Orders to execute against the full displayed size of the Protected Quotation that was traded at. The subparagraph j. exception applies when the order is executed as part of a Negotiated Trade. The subparagraph k. exception applies when the order is executed when the Trading Center displaying the Protected Quotation that was traded at had displayed, within one second prior to execution of the transaction that constituted the Trade-at, a Best Protected Bid or Best Protected Offer, as applicable, for the Pilot Security with a price that was inferior to the price of the Trade-at transaction.

The exception proposed in subparagraph l. applies to a ''stopped order.'' Both the Plan and Rule 11.27(a)(6) define a ''stopped order'' as an order that is executed by a Trading Center which, at the time of order receipt, the Trading Center had guaranteed an execution at no worse than a specified price, where (1) the stopped order was for the account of a customer; (2) the customer agreed to the specified price on an order-by-order basis; and (3) the price of the Trade-at transaction was, for a stopped buy order, equal to the National Best Bid in the Pilot Security at the time of execution or, for a stopped sell order, equal to the National Best Offer in the Pilot Security at the time of execution.

Consistent with the Plan, the final exception to the Trade-At Prohibition and its accompanying supplementary material applies to an order that is for a fractional share of a Pilot Security. The supplementary material provides that such fractional share orders may not be the result of breaking an order for one or more whole shares of a Pilot Security into orders for fractional shares or that otherwise were effected to evade the requirements of the Trade-at Prohibition or any other provisions of the Plan. In approving the Plan, the Commission noted that this exception was appropriate, as there could be

[28] *Id.*

[29] *Id.*

[30] *Id.*

[31] The Exchange notes that proposed Rule 11.27(a)(6)(D)(ii) a. is identical to that proposed by FINRA under their proposed Rule 6191(a)(6)(D)(ii) a. *See* SR–FINRA–2015–047 (filed November 13, 2015). The Exchange also notes that the New York Stock Exchange, Inc. (''NYSE'') has recently proposed a rule that states the display exception would only apply to trades done by a Trading Center otherwise than on an exchange where the Trading Center has previously displayed a quotation in a principal capacity only. *See* Securities Exchange Act Release No. 76229 (October 22, 2015), 80 FR 66065 (October 28, 2015) (SR–NYSE–2015–46) (proposing NYSE Rule 67(e)(4)(C)(i)). The Exchange does not believe proposed NYSE Rule 67(e)(4)(C)(i) is consistent with the SEC's modification of the Trade-At Prohibition to remove the venue limitation.

[32] ''Block Size'' is defined in the Plan as an order (1) of at least 5,000 shares or (2) for a quantity of stock having a market value of at least $100,000.

[33] Once a Block Size order or portion of such Block Size order is routed from one Trading Center to another Trading Center in compliance with Rule 611 of Regulation NMS, the Block Size order would lose the proposed Trade-at exemption, unless the Block Size remaining after the first route and execution meets the Block Size definition under the Plan.

[34] *See* 17 CFR 242.611.

potential difficulty in the routing and executing of fractional shares.[35]

If the Commission approves the proposed rule change, the proposed rule change will be effective upon Commission approval and shall become operative upon the commencement of the Pilot Period.

2. Statutory Basis

The Exchange believes that its proposal is consistent with Section 6(b) of the Act [36] in general, and furthers the objectives of Section 6(b)(5) of the Act [37] in particular, in that it is designed to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in 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 this proposal is consistent with the Act because it implements, interprets, and clarifies the provisions of the Plan, and is designed to assist the Exchange and Members in meeting regulatory obligations pursuant to the Plan. In approving the Plan, the SEC noted that the Pilot was an appropriate, data-driven test that was designed to evaluate the impact of a wider tick size on trading, liquidity, and the market quality of securities of smaller capitalization companies, and was therefore in furtherance of the purposes of the Act. To the extent that this proposal implements, interprets, and clarifies the Plan and applies specific requirements to Members, the Exchange believes that this proposal is in furtherance of the objectives of the Plan, as identified by the SEC, and is therefore consistent with the Act.

(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. The Exchange notes that the proposed rule change implements the provisions of the Plan, and is designed to assist the Exchange in meeting its regulatory obligations pursuant to the Plan. The Exchange also notes that the quoting and trading requirements of the Plan will apply equally to all Members that trade Pilot Securities.

[35] *See* Approval Order, *supra* note 7, 80 FR at 27541.

[36] 15 U.S.C. 78f(b).

[37] 15 U.S.C. 78f(b)(5).

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the 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 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–BATS–2015–108 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 No. SR–BATS–2015–108. 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; 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–BATS–2015–108 and should be submitted on or before December 30, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[38]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–30943 Filed 12–8–15; 8:45 am]

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[38] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76549; File No. SR–NYSEArca–2015–115]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending NYSE Arca Equities Rules 7.44 and 7.44P To Distinguish Between Retail Orders Routed on Behalf of Other Broker-Dealers and Retail Orders That are Routed on Behalf of Introduced Retail Accounts That are Carried on a Fully Disclosed Basis

December 3, 2015.

Pursuant to Section 19(b)(1) [1] of the Securities Exchange Act of 1934 (''Act'') [2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on November 19, 2015, NYSE Arca, Inc. (''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend NYSE Arca Equities Rules 7.44 and 7.44P (''Retail Liquidity Program'') to distinguish between retail orders routed on behalf of other broker-dealers and retail orders that are routed on behalf of introduced retail accounts that are carried on a fully disclosed basis. The proposed rule change is available on the Exchange's Web site at *www.nyse.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 those 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 the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend NYSE Arca Equities Rules 7.44 and 7.44P,[4] which govern the Exchange's Retail Liquidity Program (the ''Program''), to distinguish between orders routed on behalf of other broker-dealers and orders routed on behalf of introduced retail accounts that are carried on a fully disclosed basis, as further described below.

The Exchange established the Program in an attempt to attract retail order flow to the Exchange, primarily by offering pricing incentives. Under the Program, Retail Member Organizations[5] (''RMOs'') are permitted to submit Retail Orders,[6] and receive rebates for added liquidity that are higher than the exchanges [sic] standard rebates for added liquidity.[7]

Rule 7.44(b)(1) currently states that ''[t]o qualify as an RMO, an ETP Holder must conduct a retail business or handle retail orders on behalf of another broker-dealer.'' Rather than stating that one way to qualify as an RMO is to ''handle'' retail orders on behalf of another broker-dealer, the Exchange proposes to state that an ETP Holder may qualify as an RMO if it ''routes'' retail orders on behalf of another broker-dealer. The Exchange believes that providing routing services on behalf of other broker-dealers with retail order flow better represents the function that ETP Holders would be performing on behalf of other broker-dealers. Thus, the Exchange believes that the description would be more transparent if it referred to routing services provided to another broker-dealer with retail customers. The Exchange also proposes to distinguish such routing services on behalf of another broker-dealer from services provided by broker-dealers that carry retail customer accounts on a fully disclosed basis, as described below.

As background with respect to the proposed change, the Exchange first would like to describe the terms ''introducing broker'', ''carrying firm'' or ''carrying broker-dealer'', and ''fully disclosed,'' as such terms are commonly used in the securities industry. An ''introducing'' broker-dealer is ''one that has a contractual arrangement with another firm, known as the carrying or clearing firm, under which the carrying firm agrees to perform certain services for the introducing firm. Usually, the introducing firm submits its customer accounts and customer orders to the carrying firm, which executes the orders and carries the account. The carrying firm's duties include the proper disposition of the customer funds and securities after the trade date, the custody of customer securities and funds, and the recordkeeping associated with carrying customer accounts.'' [8]

Further, a ''fully disclosed'' introducing arrangement is ''distinguished from an omnibus clearing arrangement where the clearing firm maintains one account for all the customer transactions of the introducing firm. In an omnibus relationship, the clearing firm does not know the identity of the customers of the introducing firm. In a fully disclosed clearing arrangement, the clearing firm knows the names, addresses, securities positions and other relevant data as to each customer.'' [9]

With respect to a broker-dealer that is routing on behalf of another broker-dealer, the Exchange does not believe that the routing broker-dealer has sufficient information to assess whether orders are truly retail in nature, and thus, requires an RMO routing on behalf of other broker-dealers to maintain additional supervisory procedures and obtain annual attestations, as described below, in order to submit Retail Orders to the Exchange. In contrast, however, if an ETP Holder is carrying a customer account on a fully disclosed basis, then such carrying broker-dealer is required to perform certain diligence regarding such account that the Exchange believes is sufficient to assess whether a customer is a retail customer in order to submit orders on behalf of such a customer to the Exchange as a Retail Order. The carrying broker of an account typically handles orders from its retail customers that are ''introduced'' by an introducing broker. However, as noted above, in contrast to a typical routing relationship on behalf of another broker-dealer, a carrying broker obtains a significant level of information regarding each customer introduced by the introducing broker. Accordingly, the Exchange proposes to state in Rule 7.44(b)(1) that for purposes of Rule 7.44, ''conducting a retail business includes carrying retail customer accounts on a fully disclosed basis.''

Rule 7.44(b)(6) currently states, in part, that ''[i]f an RMO represents Retail Orders from another broker-dealer customer, the RMO's supervisory procedures must be reasonably designed to assure that the orders it receives from such broker-dealer customer that it designates as Retail Orders meet the definition of a Retail Order.'' This includes obtaining attestations from the other broker-dealers for whom the RMO routes. In addition to the proposed changes to Rule 7.44(b)(1) described above, the Exchange proposes to modify the language of Rule 7.44(b)(6) to again distinguish between an RMO that conducts a retail business because it carries accounts on a fully disclosed basis from an RMO that routes orders on behalf of another broker-dealer. As proposed, the additional annual written representation requirements of Rule 7.44(b)(6) would apply to an RMO that does not itself conduct a retail business

[4] The relevant portions of Rules 7.44 and 7.44P proposed to be amended have identical rule text and will be referred to collectively as ''Rule 7.44.''

[5] As defined in Rule 7.44(a)(2), a Retail Member Organization is an ETP Holder that has been approved by the Exchange under Rule 7.44 to submit Retail Orders.

[6] As defined in Rule 7.44(a)(3), a Retail Order is 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 an RMO, 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.

[7] *See* the Exchange's Price List, available at *https://www.nyse.com/publicdocs/nyse/markets/nyse-arca/NYSE_Arca_Marketplace_Fees.pdf.*

[8] *See* Securities Exchange Act Release No. 31511 (Nov. 24, 1992), 57 FR 56973 (December 2, 1992).

[9] *Id.*

but routes Retail Orders on behalf of other broker-dealers. In turn, such additional annual written representation requirements of Rule 7.44(b)(6) would not apply to an RMO that carries retail customer accounts on a fully disclosed basis. In connection with this change, the Exchange is proposing various edits to the existing rule text so that the reference is consistently to ''other broker-dealers'' rather than ''broker-dealer customers.''

The Exchange believes that allowing an RMO that carries retail customer accounts on a fully disclosed basis to submit Retail Orders to the Exchange without obtaining attestations from broker-dealers that might introduce such accounts will encourage participation in the Program. As noted above, the Exchange believes that the carrying broker has sufficient information to itself confirm that orders are Retail Orders without such attestations. The Exchange still believes it is necessary to require the attestation by broker-dealers that route Retail Orders on behalf of other broker-dealers, because, in contrast, such broker-dealers typically do not have a relationship with the retail customer and would not be in position to confirm that such customers are in fact retail customers.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[10] in general, and furthers the objectives of Section 6(b)(5) of the Act,[11] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices because it highlights the parties for whom additional procedures are required because they do not maintain relationships with the end customer (*i.e.,* routing brokers) and still requires the RMO to follow such procedures to ensure that such orders qualify as Retail Orders. As proposed, however, an RMO would not be required to follow such procedures, including obtaining annual attestations, to the extent such RMO actually knows the end customer and carries the account of such customer and thus can itself confirm that the orders qualify as Retail Orders.

The Exchange believes that the proposed rule change will remove impediments to and perfect the mechanism of a free and open market and a national market system because it will allow RMOs that carry retail customer accounts to participate in the Program without imposing additional attestation requirements that the Exchange did not initially intend to impose upon them. By removing impediments to participation in the Program, the proposed change would permit expanded access of retail customers to the Program.

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 that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the amendment, by increasing the level of participation in the Program, will increase the level of competition around retail executions. The Exchange believes that the transparency and competitiveness of operating a program such as the Program on an exchange market would result in better prices for retail investors and benefits retail investors by expanding the capabilities of Exchanges to encompass practices currently allowed on non-exchange venues.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[12] and Rule 19b–4(f)(6) thereunder.[13] 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, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[14] and Rule 19b–4(f)(6) thereunder.[15]

A proposed rule change filed under Rule 19b–4(f)(6)[16] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[17] the Commission may 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 proposed rule change may become operative immediately.[18] In requesting the waiver, the Exchange stated its belief that having harmonized requirements for RMOs across multiple exchanges with a retail program would promote competition by enabling ETP Holders to operate as RMOs on multiple exchanges in the same manner. The Commission notes that, to become an RMO, an ETP Holder would still be required under Exchange Rules 7.44(b)(2)(C) and 7.44P(b)(2)(C) to submit an attestation to the Exchange that substantially all orders submitted as Retail Orders would qualify as such under Exchange Rules 7.44 and 7.44P. Rather, the proposal would change when an RMO must obtain the annual written representation from other broker-dealers that send Retail Orders to the RMO. The Commission finds that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[19]

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

[10] 15 U.S.C. 78f(b).

[11] 15 U.S.C. 78f(b)(5).

[12] 15 U.S.C. 78s(b)(3)(A)(iii).

[13] 17 CFR 240.19b–4(f)(6).

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's 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 of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[16] 17 CFR 240.19b–4(f)(6).

[17] 17 CFR 240.19b–4(f)(6)(iii).

[18] The Commission notes that another national securities exchange has a similar rule for its Retail Member Organizations and that the proposal does not raise any novel regulatory issues. *See* Securities Exchange Act Release No. 76207 (October 21, 2015), 80 FR 65824 (October 27, 2015) (SR–BYX–2015–45).

[19] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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 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–NYSEArca–2015–115 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–NYSEArca–2015–115. 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–NYSEArca–2015–115 and should be submitted on or before December 30, 2015December 30, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–30940 Filed 12–8–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: [To Be Published].

STATUS: Closed Meeting.

PLACE: 100 F Street NE., Washington, DC.

DATE AND TIME OF PREVIOUSLY ANNOUNCED MEETING: December 10, 2015 at 2:00 p.m.

CHANGE IN THE MEETING: Additional Item.

The following matter will also be considered during the 2:00 p.m. Closed Meeting scheduled for Thursday, December 10, 2015: Litigation matter.

The General Counsel of the Commission, or her designee, has certified that, in her opinion, one or more of the exemptions as set forth in 5 U.S.C. 552b(c)(3), (5), (7), (9)(B) and 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.

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: December 4, 2015.

Brent J. Fields,

Secretary.

[FR Doc. 2015–31106 Filed 12–7–15; 11:15 am]

BILLING CODE 8011–01–P

[20] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76554; File No. SR–NYSEMKT–2015–96]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Rule 107C—Equities To Distinguish Between Retail Orders Routed on Behalf of Other Broker-Dealers and Retail Orders That Are Routed on Behalf of Introduced Retail Accounts That Are Carried on a Fully Disclosed Basis

December 3, 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 November 19, 2015, NYSE MKT LLC (the ''Exchange'' or ''NYSE MKT'') 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 amend Rule 107C—Equities (Retail Liquidity Program) to distinguish between retail orders routed on behalf of other broker-dealers and retail orders that are routed on behalf of introduced retail accounts that are carried on a fully disclosed basis. The proposed rule change is available on the Exchange's Web site at *www.nyse.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 those 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 107C—Equities (''Rule 107C''), which governs the Exchange's Retail Liquidity Program (the ''Program''), to distinguish between orders routed on behalf of other broker-dealers and orders routed on behalf of introduced retail accounts that are carried on a fully disclosed basis, as further described below.

The Exchange established the Program in an attempt to attract retail order flow to the Exchange, primarily by offering pricing incentives. Under the Program, Retail Member Organizations [3] (''RMOs'') are permitted to submit Retail Orders,[4] and receive rebates for added liquidity that are higher than the exchanges [sic] standard rebates for added liquidity.[5]

Rule 107C(b)(1) currently states that ''[t]o qualify as a Retail Member Organization, a member organization must conduct a retail business or handle retail orders on behalf of another broker-dealer.'' Rather than stating that one way to qualify as an RMO is to ''handle'' retail orders on behalf of another broker-dealer, the Exchange proposes to state that a member organization may qualify as an RMO if it ''routes'' retail orders on behalf of another broker-dealer. The Exchange believes that providing routing services on behalf of other broker-dealers with retail order flow better represents the function that member organizations would be performing on behalf of other broker-dealers. Thus, the Exchange believes that the description would be more transparent if it referred to routing services provided to another broker-dealer with retail customers. The Exchange also proposes to distinguish such routing services on behalf of another broker-dealer from services provided by broker-dealers that carry retail customer accounts on a fully disclosed basis, as described below.

As background with respect to the proposed change, the Exchange first would like to describe the terms ''introducing broker'', ''carrying firm'' or ''carrying broker-dealer'', and ''fully disclosed,'' as such terms are commonly used in the securities industry. An ''introducing'' broker-dealer is ''one that has a contractual arrangement with another firm, known as the carrying or clearing firm, under which the carrying firm agrees to perform certain services for the introducing firm. Usually, the introducing firm submits its customer accounts and customer orders to the carrying firm, which executes the orders and carries the account. The carrying firm's duties include the proper disposition of the customer funds and securities after the trade date, the custody of customer securities and funds, and the recordkeeping associated with carrying customer accounts.'' [6]

Further, a ''fully disclosed'' introducing arrangement is ''distinguished from an omnibus clearing arrangement where the clearing firm maintains one account for all the customer transactions of the introducing firm. In an omnibus relationship, the clearing firm does not know the identity of the customers of the introducing firm. In a fully disclosed clearing arrangement, the clearing firm knows the names, addresses, securities positions and other relevant data as to each customer.'' [7]

With respect to a broker-dealer that is routing on behalf of another broker-dealer, the Exchange does not believe that the routing broker-dealer has sufficient information to assess whether orders are truly retail in nature, and thus, requires an RMO routing on behalf of other broker-dealers to maintain additional supervisory procedures and obtain annual attestations, as described below, in order to submit Retail Orders to the Exchange. In contrast, however, if a member organization is carrying a customer account on a fully disclosed basis, then such carrying broker-dealer is required to perform certain diligence regarding such account that the Exchange believes is sufficient to assess whether a customer is a retail customer in order to submit orders on behalf of such a customer to the Exchange as a Retail Order. The carrying broker of an account typically handles orders from its retail customers that are ''introduced'' by an introducing broker. However, as noted above, in contrast to a typical routing relationship on behalf of another broker-dealer, a carrying broker obtains a significant level of information regarding each customer introduced by the introducing broker. Accordingly, the Exchange proposes to state in Rule 107C(b)(1) that for purposes of Rule 107C, ''conducting a retail business includes carrying retail customer accounts on a fully disclosed basis.''

Rule 107C(b)(6) currently states, in part, that ''[i]f a Retail Member Organization represents Retail Orders from another broker-dealer customer, the Retail Member Organization's supervisory procedures must be reasonably designed to assure that the orders it receives from such broker-dealer customer that it designates as Retail Orders meet the definition of a Retail Order.'' This includes obtaining attestations from the other broker-dealers for whom the RMO routes. In addition to the proposed changes to Rule 107C(b)(1) described above, the Exchange proposes to modify the language of Rule 107C(b)(6) to again distinguish between an RMO that conducts a retail business because it carries accounts on a fully disclosed basis from an RMO that routes orders on behalf of another broker-dealer. As proposed, the additional annual written representation requirements of Rule 107C(b)(6) would apply to an RMO that does not itself conduct a retail business but routes Retail Orders on behalf of other broker-dealers. In turn, such additional annual written representation requirements of Rule 107C(b)(6) would not apply to an RMO that carries retail customer accounts on a fully disclosed basis. In connection with this change, the Exchange is proposing various edits to the existing rule text so that the reference is consistently to ''other broker-dealers'' rather than ''broker-dealer customers.''

The Exchange believes that allowing an RMO that carries retail customer accounts on a fully disclosed basis to submit Retail Orders to the Exchange without obtaining attestations from broker-dealers that might introduce such accounts will encourage participation in the Program. As noted above, the Exchange believes that the carrying broker has sufficient information to itself confirm that orders are Retail Orders without such attestations. The Exchange still believes it is necessary to require the attestation by broker-dealers that route Retail Orders on behalf of other broker-dealers, because, in contrast, such broker-dealers typically do not have a relationship with the retail customer and would not be in position to confirm that such customers are in fact retail customers.

[3] As defined in Rule 107C(a)(2), a Retail Member Organization is a member organization (or division thereof) that has been approved by the Exchange under Rule 107C to submit Retail Orders.

[4] As defined in Rule 107C(a)(3), a Retail Order is 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.

[5] *See* the Exchange's Price List, available at *https://www.nyse.com/publicdocs/nyse/markets/nyse-mkt/NYSE_MKT_Equities_Price_List.pdf.*

[6] *See* Securities Exchange Act Release No. 31511 (Nov. 24, 1992), 57 FR 56973 (December 2, 1992).

[7] *Id.*

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[8] in general, and furthers the objectives of Section 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 facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices because it highlights the parties for whom additional procedures are required because they do not maintain relationships with the end customer (*i.e.,* routing brokers) and still requires the RMO to follow such procedures to ensure that such orders qualify as Retail Orders. As proposed, however, an RMO would not be required to follow such procedures, including obtaining annual attestations, to the extent such RMO actually knows the end customer and carries the account of such customer and thus can itself confirm that the orders qualify as Retail Orders.

The Exchange believes that the proposed rule change will remove impediments to and perfect the mechanism of a free and open market and a national market system because it will allow RMOs that carry retail customer accounts to participate in the Program without imposing additional attestation requirements that the Exchange did not initially intend to impose upon them. By removing impediments to participation in the Program, the proposed change would permit expanded access of retail customers to the Program.

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 that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the amendment, by increasing the level of participation in the Program, will increase the level of competition around retail executions. The Exchange believes that the transparency and competitiveness of operating a program such as the Program on an exchange market would result in better prices for retail investors and benefits retail investors by expanding the capabilities of Exchanges to encompass practices currently allowed on non-exchange venues.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[10] and Rule 19b–4(f)(6) thereunder.[11] 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, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[12] and Rule 19b–4(f)(6) thereunder.[13]

A proposed rule change filed under Rule 19b–4(f)(6)[14] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[15] the Commission may 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 proposed rule change may become operative immediately.[16] In requesting the waiver, the Exchange stated its belief that having harmonized requirements for RMOs across multiple exchanges with a retail program would promote competition by enabling member organizations to operate as RMOs on multiple exchanges in the same manner. The Commission notes that, to become an RMO, a member organization would still be required under Exchange Rule 107C(b)(2)(C)—Equities to submit an attestation to the Exchange that substantially all orders submitted as Retail Orders would qualify as such under Exchange Rule 107C—Equities. Rather, the proposal would change when an RMO must obtain the annual written representation from other broker-dealers that send Retail Orders to the RMO. The Commission finds that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[17]

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 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–NYSEMKT–2015–96 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–NYSEMKT–2015–96. This

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

[10] 15 U.S.C. 78s(b)(3)(A)(iii).

[11] 17 CFR 240.19b–4(f)(6).

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's 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 of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 240.19b–4(f)(6)(iii).

[16] The Commission notes that another national securities exchange has a similar rule for its Retail Member Organizations and that the proposal does not raise any novel regulatory issues. *See* Securities Exchange Act Release No. 76207 (October 21, 2015), 80 FR 65824 (October 27, 2015) (SR–BYX–2015–45).

[17] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

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 offices 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–NYSEMKT–2015–96, and should be submitted on or before December 30, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–30945 Filed 12–8–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request Copies Available From: Securities and Exchange Commission, Office of Investor Education and Advocacy, Washington, DC 20549–0213.

Extension: Rules 6a–1 and 6a–2, Form 1. SEC File No. 270–0017, OMB Control No. 3235–0017.

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (''PRA''), the Securities and Exchange Commission (''Commission'') is soliciting comments on the existing collection of information provided for in Rule 6a–1 (17 CFR 240.6–1), Rule 6–2 (17 CFR 240.6–2), and Form 1 (17 CFR 249.1) under the Securities Exchange Act of 1934 (15 U.S.C. 78a *et seq.*) (''Exchange Act'' or Act''). The Commission plans to submit this existing collection of information to the Office of Management and Budget (''OMB'') for extension and approval.

The Exchange Act sets forth a regulatory scheme for national securities exchanges. Rule 6–1 under the Act generally requires an applicant for initial registration as a national securities exchange to file an application with the Commission on Form 1. An exchange that seeks an exemption from registration based on limited trading volume also must apply for such exemption on Form 1. Rule 6–2 under the Act requires registered and exempt exchanges: (1) To amend the Form 1 if there are any material changes to the information provided in the initial Form 1; and (2) to submit periodic updates of certain information provided in the initial Form 1, whether such information has changed or not. The information required pursuant to Rules 6–1 and 6–2 is necessary to enable the Commission to maintain accurate files regarding the exchange and to exercise its statutory oversight functions. Without the information submitted pursuant to Rule 6–1 on Form 1, the Commission would not be able to determine whether the respondent has met the criteria for registration (or an exemption from registration) set forth in Section 6 of the Exchange Act. The amendments and periodic updates of information submitted pursuant to Rule 6–2 are necessary to assist the Commission in determining whether a national securities exchange or exempt exchange is continuing to operate in compliance with the Exchange Act.

Initial filings on Form 1 by new exchanges are made on a one-time basis. The Commission estimates that it will receive approximately one initial Form 1 filing per year and that each respondent would incur an average burden of 880 hours to file an initial Form 1 at an average internal labor cost per response of approximately $302,694. Therefore, the Commission estimates that the annual burden for all respondents to file the initial Form 1 would be 880 hours (one response/respondent x one respondents x 880 hours/response) and an internal cost of compliance of $302,694 (one response/respondent x one respondents x $302,694/response).

There currently are 18 entities registered as national securities exchanges. The Commission estimates that each registered or exempt exchange files nine amendments or periodic updates to Form 1 per year, incurring an average burden of 25 hours to comply with Rule 6–2. The SEC estimates that the average internal labor cost for a national securities exchange per response would be approximately $9,445. The Commission estimates that the annual burden for all respondents to file amendments and periodic updates to the Form 1 pursuant to Rule 6–2 is 4,050 hours (18 respondents x 25 hours/response x nine responses/respondent per year) and an internal cost of compliance of $1,530,090 (18 respondents x $9,445/response x nine responses/respondent per year).

Written comments are invited on: (a) 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; (b) the accuracy of the Commission's estimate of the burden of the proposed collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

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.

Please direct your written comments to: Pamela Dyson, Director/Chief Information Officer, Securities and Exchange Commission, c/o Remi Pavlik-Simon, 100 F Street NE., Washington, DC 20549, or send an email to: *PRA_Mailbox@sec.gov.*

Dated: December 2, 2015.

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–30866 Filed 12–8–15; 8:45 am]

BILLING CODE 8011–01–P

[18] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76551; File No. SR–NYSE–2015–46]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Designation of a Longer Period for Commission Action on a Proposed Rule Change To Establish Rules To Comply With the Requirements of the Plan To Implement a Tick Size Pilot Plan Submitted to the Commission Pursuant to Rule 608 of Regulation NMS Under the Act

December 3, 2015.

On October 9, 2015, the New York Stock Exchange LLC (''NYSE'' or ''Exchange'') filed with the Securities and Exchange Commission (''Commission''), pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (''Act'') [1] and Rule 19b–4 thereunder,[2] a proposed rule change to establish rules to comply with the requirements of the plan to implement a Tick Size Pilot Plan submitted to the Commission pursuant to Rule 608 of Regulation NMS under the Act. The proposed rule change was published for comment in the **Federal Register** on October 28, 2015.[3] The Commission received one comment letter on the proposal.[4]

Section 19(b)(2) of the Act [5] provides that, within 45 days of the publication of the notice of the filing of a proposed rule change, or within such longer period up to 90 days as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or as to which the self-regulatory organization consents, the Commission shall either approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether the proposed rule change should be disapproved. The 45th day for this filing is December 12, 2015.

The Commission is extending this 45-day time period. The Commission finds that it is appropriate to designate a longer period within which to take action on the proposed rule change so that it has sufficient time to consider the proposal.

Accordingly, pursuant to Section 19(b)(2) of the Act,[6] the Commission designates January 26, 2016, as the date by which the Commission should either approve or disapprove or institute proceedings to determine whether to disapprove the proposed rule change (File No. SR–NYSE–2015–46).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[7]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–30942 Filed 12–8–15; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76548; File No. SR–OCC–2015–804]

Self-Regulatory Organizations; The Options Clearing Corporation; Notice of No Objection to Advance Notice Filing to Modify The Options Clearing Corporation's Margin Methodology by Incorporating Variations in Implied Volatility

December 3, 2015.

On October 5, 2015, The Options Clearing Corporation (''OCC'') filed with the Securities and Exchange Commission (''Commission'') the advance notice SR–OCC–2015–804 pursuant to section 806(e)(1) of the Payment, Clearing, and Settlement Supervision Act of 2010 (''Payment, Clearing and Settlement Supervision Act'') [1] and Rule 19b–4(n)(1)(i) under the Securities Exchange Act of 1934 ('' Exchange Act'').[2] The advance notice was published for comment in the **Federal Register** on November 17, 2015.[3] The Commission did not receive any comments on the advance notice publication. This publication serves as a notice that the Commission does not object to the changes set forth in the advance notice.

I. Description of the Advance Notice

According to OCC, it is modifying its margin methodology by more broadly incorporating variations in implied volatility within OCC's System for Theoretical Analysis and Numerical Simulations (''STANS'').[4] As explained below, OCC believes that expanding the use of variations in implied volatility within STANS for substantially all [5] option contracts available to be cleared by OCC that have a residual tenor [6] of less than three years (''Shorter Tenor Options'') will enhance OCC's ability to ensure that option prices and the margin coverage related to such positions more appropriately reflect possible future market value fluctuations and better protect OCC in the event it must liquidate the portfolio of a suspended clearing member.

Implied Volatility in STANS Generally

According to OCC, STANS is OCC's proprietary risk management system that calculates clearing members' margin requirements. According to OCC, the STANS methodology uses Monte Carlo simulations to forecast price movement and correlations in determining a clearing member's margin requirement. According to OCC, under STANS, the daily margin calculation for each clearing member account is constructed to ensure OCC maintains sufficient financial resources to liquidate a defaulting member's positions, without loss, within the liquidation horizon of two business days.

As described by OCC, the STANS margin requirement for an account is composed of two primary components: A base component and a stress test component. According to OCC, the base component is obtained from a risk

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 76229 (October 22, 2015), 80 FR 66065.

[4] *See* Letter from Mary Lou Von Kaenel, Managing Director, Financial Information Forum, to Brent J. Fields, Secretary, Commission, dated November 5, 2015. (''FIF Letter'').

[5] 15 U.S.C. 78s(b)(2).

[6] *Id.*

[7] 17 CFR 200.30–3(a)(31).

[1] 12 U.S.C. 5465(e)(1). The Financial Stability Oversight Council designated OCC a systemically important financial market utility on July 18, 2012. *See* Financial Stability Oversight Council 2012 Annual Report, Appendix A, *http://www.treasury.gov/initiatives/fsoc/Documents/2012%20Annual%20Report.pdf.* Therefore, OCC is required to comply with the Payment, Clearing, and Settlement Supervision Act and file advance notices with the Commission. *See* 12 U.S.C. 5465(e).

[2] 17 CFR 240.19b–4(n)(1)(i).

[3] Securities Exchange Act Release No. 76421 (November 10, 2015), 80 FR 71900 (November 17, 2015) (SR–OCC–2015–804). OCC also filed a proposed rule change with the Commission pursuant to section 19(b)(1) of the Exchange Act and Rule 19b–4 thereunder, seeking approval of changes to its rules necessary to implement the proposal. 15 U.S.C. 78s(b)(1) and 17 CFR 240.19b–4, respectively. *See* Exchange Act Release 76128 (October 13, 2015), 80 FR 63264 (October 19, 2015) (SR–OCC–2015–016). The Commission did not receive any comments on the proposed rule change.

[4] This proposal did not propose any changes concerning futures. According to OCC, OCC uses a different system to calculate initial margin requirements for segregated futures accounts: Standard Portfolio Analysis of Risk Margin Calculation System.

[5] According to OCC, it proposes to exclude: (i) Binary options, (ii) options on energy futures, and (iii) options on U.S. Treasury securities. OCC excluded them because: (i) They are new products that were introduced as OCC was completing this proposal and (ii) OCC did not believe that there was substantive risk if they were excluded at this time because they only represent a *de minimis* open interest. According to OCC, it plans to modify its margin methodology to accommodate these new products.

[6] According to OCC, the ''tenor'' of an option is the amount of time remaining to its expiration.

measure of the expected margin shortfall for an account that results under Monte Carlo price movement simulations. For the exposures that are observed regarding the account, the base component is established as the estimated average of potential losses higher than the 99% VaR[7] threshold. In addition, OCC augments the base component using the stress test component. According to OCC, the stress test component is obtained by considering increases in the expected margin shortfall for an account that would occur due to: (i) Market movements that are especially large and/or in which certain risk factors would exhibit perfect or zero correlations rather than correlations otherwise estimated using historical data or (ii) extreme and adverse idiosyncratic movements for individual risk factors to which the account is particularly exposed.

According to OCC, including variations in implied volatility within STANS is intended to ensure that the anticipated cost of liquidating each Shorter Tenor Option position in an account recognizes the possibility that implied volatility could change during the two business day liquidation time horizon in STANS and lead to corresponding changes in the market prices of the options. According to OCC, generally speaking, the implied volatility of an option is a measure of the expected future volatility of the value of the option's annualized standard deviation of the price of the underlying security, index, or future at exercise, which is reflected in the current option premium in the market. Using the Black-Scholes options pricing model, the implied volatility is the standard deviation of the underlying asset price necessary to arrive at the market price of an option of a given strike, time to maturity, underlying asset price and given the current risk-free rate. In effect, the implied volatility is responsible for that portion of the premium that cannot be explained by the then-current intrinsic value[8] of the option, discounted to reflect its time value. According to OCC, it currently incorporates variations in implied volatility as risk factors for certain options with residual tenors of at least three years (''Longer Tenor Options'').

Implied Volatility for Shorter Tenor Options

OCC is proposing certain modifications to STANS to more broadly incorporate variations in implied volatility for Shorter Tenor Options. Consistent with its approach for Longer Tenor Options, OCC will model a volatility surface[9] for Shorter Tenor Options by incorporating into the econometric models underlying STANS certain risk factors regarding a time series of proportional changes in implied volatilities for a range of tenors and absolute deltas. Shorter Tenor Option volatility points will be defined by three different tenors and three different absolute deltas, which produce nine ''pivot points.'' In calculating the implied volatility values for each pivot point, OCC will use the same type of series-level pricing data set to create the nine pivot points that it uses to create the pivot points used for Longer Tenor Options, so that the nine pivot points will be the result of a consolidation of the entire series-level dataset into a smaller and more manageable set of pivot points before modeling the volatility surface.

According to OCC, it considered incorporating more than nine pivot points but concluded that would not be appropriate for Shorter Tenor Options because: (i) Back-testing results, from January 2008 to May 2013, revealed that using more pivot points did not produce more meaningful information (*i.e.* more pivot points produced a comparable number of under-margined instances) and (ii) given the large volume of Shorter Tenor Options, using more pivot points could increase computation time and, therefore, would impair OCC from making timely calculations.

Under OCC's model for Shorter Tenor Options, the volatility surfaces will be defined using tenors of one month, three months, and one year with absolute deltas, in each case, of 0.25, 0.5, and 0.75,[10] thus resulting in the nine implied volatility pivot points. OCC believes that it is appropriate to focus on pivot points representing at- and near-the-money options because prices for those options are more sensitive to variations in implied volatility over the liquidation time horizon of two business days. According to OCC, four factors explain 99% variance of implied volatility movements: (i) A parallel shift of the entire surface; (ii) a slope or skewness with respect to delta; (iii) a slope with respect to time to maturity; and (iv) a convexity with respect to the time to maturity. According to OCC, the nine correlated pivot points, arranged by delta and tenor, give OCC the flexibility to capture these factors.

According to OCC, it first will use its econometric models to jointly simulate changes to implied volatility at the nine pivot points and changes to underlying prices.[11] For each Shorter Tenor Option in the account of a clearing member, changes in its implied volatility then will be simulated according to the corresponding pivot point and the price of the option will be computed to determine the amount of profit or loss in the account under the particular STANS price simulation. Additionally, as OCC does today, it will continue to use simulated closing prices for the assets underlying options in the account of a clearing member that are scheduled to expire within the liquidation time horizon of two business days to compute the options' intrinsic value and use those values to help calculate the profit or loss in the account.[12]

Effects of the Proposed Change and Implementation

OCC believes that the proposed change will enhance OCC's ability to ensure that STANS appropriately takes into account normal market conditions that OCC may encounter in the event that, pursuant to OCC Rule 1102, it suspends a defaulted clearing member and liquidates its accounts.[13] Accordingly, OCC believes that the change will promote OCC's ability to

[7] The term ''value at risk'' or ''VaR'' refers to a statistical technique that, generally speaking, is used in risk management to measure the potential risk of loss for a given set of assets over a particular time horizon.

[8] According to OCC, generally speaking, the intrinsic value is the difference between the price of the underlying and the exercise price of the option.

[9] According to OCC, the term ''volatility surface'' refers to a three-dimensional graphed surface that represents the implied volatility for possible tenors of the option and the implied volatility of the option over those tenors for the possible levels of ''moneyness'' of the option. According to OCC, the term ''moneyness'' refers to the relationship between the current market price of the underlying interest and the exercise price.

[10] According to OCC, given that premiums of deep-in-the-money options (those with absolute deltas closer to 1.0) and deep-out-of-the-money options (those with absolute deltas closer to 0) are insensitive to changes in implied volatility, in each case notwithstanding increases or decreases in implied volatility over the two business day liquidation time horizon, those higher and lower absolute deltas have not been selected as pivot points.

[11] According to OCC, STANS relies on 10,000 price simulation scenarios that are based generally on a historical data period of 500 business days, which is updated monthly to keep model results from becoming stale.

[12] For such Shorter Tenor Options that are scheduled to expire on the open of the market rather than the close, OCC will use the relevant opening price for the underlying assets.

[13] According to OCC, under authority in OCC Rules 1104 and 1106, OCC has authority to promptly liquidate margin assets and options positions of a suspended clearing member in the most orderly manner practicable, which might include, but would not be limited to, a private auction.

ensure that margin assets are sufficient to liquidate the accounts of a defaulted clearing member without incurring a loss.

OCC estimates that this change generally will increase margin requirements overall, but will decrease margin requirements for certain accounts with certain positions. Specifically, OCC expects this change to increase aggregate margins by about 9% ($1.5 billion). OCC also estimates the change will most significantly affect customer accounts and least significantly affect firm accounts, with the effect on market maker accounts falling in between.

According to OCC, it expects customer accounts to experience the largest margin increases because positions considered under STANS for customer accounts typically consist of more short than long options positions, and therefore reflect a greater magnitude of directional risk than other account types. According to OCC, positions considered under STANS for customer accounts typically consist of more short than long options positions to facilitate clearing members' compliance with Commission requirements for the protection of certain customer property under Exchange Act Rule 15c3–3(b).[14] Therefore, OCC segregates the long option positions in the customer accounts of each clearing member and does not assign the long option positions any value when determining the margin for the customer account, resulting in higher margin.[15]

OCC expects margin requirements to decrease for accounts with underlying exposure and implied volatility exposure in the same direction, such as concentrated call positions, due to the negative correlation typically observed between these two factors. According to OCC, over the back-testing period, about 28% of the observations for accounts on the days studied had lower margins under the proposed methodology and the average reduction was about 2.7%. Parallel results will be made available to the membership in the weeks ahead of implementation.

To help clearing members prepare for the proposed change, OCC has provided clearing members with an information memorandum explaining the proposal, including the planned timeline for its implementation, and discussed with certain other clearinghouses the likely effects of the change on OCC's cross-margin agreements with them. OCC also published an information memorandum to notify clearing members of the submission of this filing to the Commission. Subject to all necessary regulatory approvals regarding the proposed change, OCC intends to begin making parallel margin calculations with and without the changes in the margin methodology. The commencement of the calculations will be announced by an information memorandum, and OCC will provide the calculations to clearing members each business day. OCC also will provide at least thirty days prior notice to clearing members before implementing the change. OCC believes that clearing members will have sufficient time and data to plan for the potential increases in their respective margin requirements.

II. Discussion and Commission Findings

Although the Payment, Clearing and Settlement Supervision Act does not specify a standard of review for an advance notice, its stated purpose is instructive.[16] The stated purpose is to mitigate systemic risk in the financial system and promote financial stability by, among other things, promoting uniform risk management standards for systemically important financial market utilities and strengthening the liquidity of systemically important financial market utilities.[17] Section 805(a)(2) of the Payment, Clearing and Settlement Supervision Act[18] authorizes the Commission to prescribe risk management standards for the payment, clearing, and settlement activities of designated clearing entities and financial institutions engaged in designated activities for which it is the Supervisory Agency or the appropriate financial regulator. Section 805(b) of the Payment, Clearing and Settlement Supervision Act[19] states that the objectives and principles for the risk management standards prescribed under section 805(a) shall be to:

- Promote robust risk management;
- promote safety and soundness;
- reduce systemic risks; and
- support the stability of the broader financial system.

The Commission has adopted risk management standards under section 805(a)(2) of the Payment, Clearing and Settlement Supervision Act[20] and the Exchange Act (''Clearing Agency Standards'').[21] The Clearing Agency Standards require registered clearing agencies to establish, implement, maintain, and enforce written policies and procedures that are reasonably designed to meet certain minimum requirements for their operations and risk management practices on an ongoing basis.[22] Therefore, it is appropriate for the Commission to review advance notices against these Clearing Agency Standards and the objectives and principles of these risk management standards as described in section 805(b) of the Payment, Clearing and Settlement Supervision Act.[23]

The Commission believes that the proposal in the advance notice is consistent with the Clearing Agency Standards, in particular, Rule 17Ad–22(b)(2) under the Exchange Act.[24] Rule 17Ad–22(b)(2) under the Exchange Act[25] requires OCC to establish, implement, maintain and enforce written policies and procedures reasonably designed to use margin requirements to limit its credit exposures to participants under normal market conditions and use risk-based models and parameters to set margin requirements, among other things. Through this proposal, OCC is modifying its margin methodology, which is designed to use margin requirements to limit its credit exposures to clearing members holding Shorter Tenor Options under normal market conditions. Specifically, OCC is modifying its risk-based model, STANS, to set margin requirements in a way that includes changes in implied volatility for Shorter Tenor Options. With this change in place, STANS is now designed to recognize a range of possible changes in implied volatility during the two business day liquidation time horizon that could lead to corresponding changes in the market prices of Shorter Tenor Options. Therefore, OCC's change is consistent with Rule 17Ad–22(b)(2) under the Exchange Act.[26]

The Commission believes that OCC's proposal is consistent with the objectives and principles described in

[14] 17 CFR 240.15c3–3(b).

[15] *See* OCC Rule 601(d)(1). According to OCC, pursuant to OCC Rule 611, however, a clearing member, subject to certain conditions, may instruct OCC to release segregated long option positions from segregation. Long positions may be released, for example, if they are part of a spread position. Once released from segregation, OCC receives a lien on each unsegregated long securities option carried in a customers' account and therefore OCC permits the unsegregated long to offset corresponding short option positions in the account.

[16] *See* 12 U.S.C. 5461(b).

[17] *Id.*

[18] 12 U.S.C. 5464(a)(2).

[19] 12 U.S.C. 5464(b).

[20] 12 U.S.C. 5464(a)(2).

[21] *See* 17 CFR 240.17Ad–22. Securities Exchange Act Release No. 68080 (October 22, 2012), 77 FR 66220 (November 2, 2012) (S7–08–11).

[22] *Id.*

[23] 12 U.S.C. 5464(b).

[24] 17 CFR 240.17Ad–22(b)(2).

[25] *Id.*

[26] *Id.*

section 805(b) of the Payment, Clearing and Settlement Supervision Act,[27] including that it is consistent with promoting robust risk management and promoting safety and soundness. The Commission believes that the proposal is consistent with promoting risk management because, with this change, STANS is now designed to recognize the possibility that implied volatility could change during the two business day liquidation time horizon and lead to corresponding changes in the market prices of the options. This change to STANS is consistent with promoting robust risk management because it is designed so that OCC now will be less likely to face operational disruption in the event of a participant default.

This change also is consistent with promoting safety and soundness of OCC. As a result of this proposal, STANS is now designed to recognize a range of possible changes in implied volatility during the two business day liquidation time horizon that could lead to corresponding changes in the market prices of Shorter Tenor Options. This change is designed to enable OCC to more accurately calculate the amount of margin a member must post, and, therefore, make it less likely, in the event of a member default, that OCC will need to access mutualized clearing fund deposits to cover losses associated with such member's default, which is consistent with promoting safety and soundness.

For these reasons, the Commission does not object to the advance notice.

III. Conclusion

It is therefore noticed, pursuant to section 806(e)(1)(I) of the Payment, Clearing and Settlement Supervision Act,[28] that the Commission *does not object* to the proposed change, and *authorizes* OCC to implement the change in this advance notice (SR–OCC–2015–804) as of the date of this notice or the date of an order by the Commission approving a proposed rule change that reflects rule changes that are consistent with this advance notice (SR–OCC–2015–016), whichever is later.

By the Commission.

Robert W. Errett,

Deputy Secretary.

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BILLING CODE 8011–01–P

[27] 12 U.S.C. 5464(b).

[28] 12 U.S.C. 5465(e)(1)(I).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76550; File No. SR–NASDAQ–2015–146]

Self-Regulatory Organizations; The NASDAQ Stock Market LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Adopt Record Keeping Change and Substitution Listing Event Fees for Securities Listed Under the Rule 5700 Series

December 3, 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 November 23, 2015, The NASDAQ Stock Market LLC (''Nasdaq'' or ''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 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

Nasdaq is proposing to adopt record keeping change and substitution listing event fees for securities listed under the Rule 5700 Series.[3] The text of the proposed rule change is available at *nasdaq.cchwallstreet.com,* at Nasdaq's principal office, 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, Nasdaq 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 those 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange originally filed SR–NASDAQ–2015–118 on October 23, 2015, which was replaced by SR–NASDAQ–2015–139 on November 4, 2015. SR–NASDAQ–2015–139 was replaced by SR–NASDAQ–2015–141 on November 11, 2015. The instant proposal replaces SR–NASDAQ–2015–141 in its entirety.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Nasdaq rules require issuers to notify Nasdaq about certain record keeping changes and substitution listing events. Specifically, Rule 5250(e)(3) defines a ''Record Keeping Change'' as any change to a company's name, the par value or title of its security, its symbol, or a similar change and requires a listed company to provide notification to Nasdaq no later than 10 days after the change. Rule 5005(a)(40) defines a ''Substitution Listing Event'' as certain changes in the equity or legal structure of a company[4] and Rule 5250(e)(4) requires a listed company to provide notification to Nasdaq about these events no later than 15 calendar days prior to the implementation of the event. While most listed companies pay fees in connection with these notifications,[5] issuers of securities listed under the Rule 5700 Series, including Linked Securities and Exchange Traded Products such as Portfolio Depository Receipts, Index Fund Shares, and Managed Fund Shares, are required to notify Nasdaq about Record Keeping Changes and Substitution Listing Events, but are not currently subject to the fees for such notifications. Nasdaq proposes to adopt a $2,500 fee for any such issuer providing a Record Keeping Change and a $5,000 fee for any such issuer effecting a Substitution Listing Event. These fees will apply for each security affected by the event. The fees will be used to address the costs associated with maintaining and revising Nasdaq's records, collecting and verifying the underlying information, and distributing the information to market participants when issuers with securities listed under the

[4] A ''Substitution Listing Event'' means: A reverse stock split, re-incorporation or a change in the company's place of organization, the formation of a holding company that replaces a listed company, reclassification or exchange of a company's listed shares for another security, the listing of a new class of securities in substitution for a previously-listed class of securities, a business combination described in IM–5101–2 (unless the transaction was publicly announced in a press release or Form 8–K prior to October 15, 2013), or any technical change whereby the Shareholders of the original company receive a share-for-share interest in the new company without any change in their equity position or rights.

[5] The fee is $7,500 for a company making a Record Keeping Change and $15,000 for a company executing a Substitution Listing Event. *See* Rules 5910(e) and (f) (Nasdaq Global and Global Select Markets) and Rules 5920(d) and (e) (Nasdaq Capital Market). Companies on the all-inclusive annual fee are not subject to these separate fees. *See* IM–5910–1(c) and IM–5920–1(c).

Rule 5700 Series engage in these actions. In addition, in the case of a Substitution Listing Event, the fee will also offset the cost of Nasdaq's review of the substituted entity for compliance with the listing requirements.

2. Statutory Basis

Nasdaq believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[6] in general, and with Sections 6(b)(4) and (5) of the Act,[7] in particular, in that it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities, and does not unfairly discriminate between customers, issuers, brokers or dealers.

The proposed Record Keeping Change and Substitution Listing Event fees are reasonable and equitably allocated in that they are designed to compensate Nasdaq for the work required in connection with effecting changes that the issuer has initiated. Record Keeping Changes require Nasdaq to update its systems and distribute information about the changes to the marketplace. Substitution Listing Events involve similar updates and information dissemination and also require Nasdaq to review the issuer's listing compliance. Other listed companies currently pay fees for these changes and it is reasonable and equitable to similarly allocate costs through these modest fees to issuers of securities listed under the Rule 5700 Series when they take actions resulting in Record Keeping Changes or Substitution Listing Events.

In addition, while the proposed fees could be lower than those charged other companies for similar actions, Nasdaq believes it is not unfairly discriminatory to charge a slightly lower fee for these issuers. First, the listing fees for securities listed under the Rule 5700 Series are generally lower than the listing fees for other types of issuers, reflecting the passive nature of these issuers and the extreme focus on their expenses as a means for various products to compete.[8] In that regard, the proposed $5,000 Substitution Listing Event fee is the same amount as the minimum Entry Fee paid under Rules 5930 and 5940 for these products, and will similarly offset the costs of reviewing the substitute entity for compliance with the listing requirements. On the other hand, the $7,500 Record Keeping Fee and $15,000 Substitution Listing Fee charged other companies would exceed the minimum entry fee that companies listed under the Rule 5700 Series are charged, and charging such a higher amount for these changes would be incongruent with the lower entry fees they are charged. Further, other companies that could pay the Record Keeping Fee and Substitution Listing Fee had the option to avoid the fee by electing to be on Nasdaq's all-inclusive annual fee, which eliminates the fees for these events. Securities listed under the Rule 5700 Series do not have the option to elect an all-inclusive fee alternative, and it is therefore reasonable and equitable to charge them a lower amount. Nasdaq also notes that other market centers also charge lower fees when these types of issuers make changes.[9] Nasdaq believes that the lower existing fees, lack of an all-inclusive fee alternative, and competitive considerations are reasonable, fair and equitable reasons to propose charging issuers of securities listed under the Rule 5700 Series different fees than other Nasdaq-listed companies.[10]

Finally, Nasdaq believes that the proposed fees are consistent with the investor protection objectives of Section 6(b)(5) of the Act[11] in that they are designed to promote just and equitable principles of trade, to remove impediments to a free and open market and national market system, and in general to protect investors and the public interest. Specifically, the proposed change will help ensure adequate resources are available for Nasdaq to process Record Keeping Changes and Substitution Listing Events and distribute information to the marketplace about these changes and events.

B. Self-Regulatory Organization's Statement on Burden on Competition

Nasdaq 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. The market for listing services is extremely competitive and listed companies may freely choose alternative venues based on the aggregate fees assessed, and the value provided by the listing. This rule proposal does not burden competition with other listing venues, which are similarly free to set their fees, but rather reflects the competition between listing venues and will further enhance such competition. For these reasons, Nasdaq does not believe that the proposed rule change will result in any burden on competition for listings.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing change has become effective pursuant to Section 19(b)(3)(A)(ii) of the Act[12]. 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:

[6] 15 U.S.C. 78f.

[7] 15 U.S.C. 78f(b)(4) and (5).

[8] For example, entry fees for securities listed on the Nasdaq Global Market under the Rule 5700 Series range from $5,000 to $45,000 pursuant to Rules 5930 and 5940, whereas entry fees for other companies listed on the Nasdaq Global Market range from $125,000 to $225,000 pursuant to Rule 5910(a).

[9] NYSE Arca charges $2,500 for equivalent events. *See* NYSE Arca Equities: Listing Fees. BATS does not charge a fee for equivalent events. *See* Chapter XIV of the Rules of the BATS Exchange and Rule 14.13 of the BATS Exchange Listing Rules.

[10] Nasdaq also notes that Rules 5910(f) and 5920(e) provide that the Substitution Listing Event Fee is not applicable to securities that are listed on a national securities exchange other than Nasdaq and not designated by Nasdaq as Nasdaq national market system securities. Nasdaq IM–5220 describes the only current circumstance where Nasdaq does not designate a security as a Nasdaq national market system security. Specifically, IM–5220 provides that Nasdaq will not designate securities that are listed on the New York Stock Exchange (NYSE) when the issuing company also lists those securities on The Nasdaq Global Market, and that such securities therefore will not become subject to the Nasdaq UTP Plan, the national market system plan governing securities designated by Nasdaq. Because NYSE does not list exchange traded products (such products are listed on the affiliated NYSE Arca Exchange), this fee exemption is not necessary in Rules 5930 and 5940 because the securities listed under the Rule 5700 Series would not be dually listed on the NYSE. If Nasdaq later determines to dually list products listed under the Rule 5700 Series, including those listed on NYSE Arca or BATS Exchange, Nasdaq would file a rule change and address whether the Substitution Listing Event Fee should be applicable to those securities.

[11] 15 U.S.C. 78f(b)(5).

[12] 15 U.S.C. 78s(b)(3)(A)(ii).

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–NASDAQ–2015–146 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–NASDAQ–2015–146. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NASDAQ–2015–146 and should be submitted on or before December 30, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[13]

Robert W. Errett,

Deputy Secretary.

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[13] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76553; File No. SR–NYSE–2015–59]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Amending Rule 107C To Distinguish Between Retail Orders Routed on Behalf of Other Broker-Dealers and Retail Orders That Are Routed on Behalf of Introduced Retail Accounts That Are Carried on a Fully Disclosed Basis

December 3, 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 November 19, 2015, New York Stock Exchange LLC (''NYSE'' or the ''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 amend Rule 107C (''Retail Liquidity Program'') to distinguish between retail orders routed on behalf of other broker-dealers and retail orders that are routed on behalf of introduced retail accounts that are carried on a fully disclosed basis. The proposed rule change is available on the Exchange's Web site at *www.nyse.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 those 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.

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Rule 107C, which governs the Exchange's Retail Liquidity Program (the ''Program''), to distinguish between orders routed on behalf of other broker-dealers and orders routed on behalf of introduced retail accounts that are carried on a fully disclosed basis, as further described below.

The Exchange established the Program in an attempt to attract retail order flow to the Exchange, primarily by offering pricing incentives. Under the Program, Retail Member Organizations [3] (''RMOs'') are permitted to submit Retail Orders,[4] and receive rebates for added liquidity that are higher than the exchanges [sic] standard rebates for added liquidity.[5]

Rule 107C(b)(1) currently states that ''[t]o qualify as a Retail Member Organization, a member organization must conduct a retail business or handle retail orders on behalf of another broker-dealer.'' Rather than stating that one way to qualify as an RMO is to ''handle'' retail orders on behalf of another broker-dealer, the Exchange proposes to state that a member organization may qualify as an RMO if it ''routes'' retail orders on behalf of another broker-dealer. The Exchange believes that providing routing services on behalf of other broker-dealers with retail order flow better represents the function that member organizations would be performing on behalf of other broker-dealers. Thus, the Exchange believes that the description would be more transparent if it referred to routing services provided to another broker-dealer with retail customers. The Exchange also proposes to distinguish such routing services on behalf of another broker-dealer from services provided by broker-dealers that carry retail customer accounts on a fully disclosed basis, as described below.

[3] As defined in Rule 107C(a)(2), a Retail Member Organization is a member organization (or division thereof) that has been approved by the Exchange under Rule 107C to submit Retail Orders.

[4] As defined in Rule 107C(a)(3), a Retail Order is 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.

[5] *See* the Exchange's Price List, available at *https://www.nyse.com/publicdocs/nyse/markets/nyse/NYSE_Price_List.pdf.*

As background with respect to the proposed change, the Exchange first would like to describe the terms ''introducing broker'', ''carrying firm'' or ''carrying broker-dealer'', and ''fully disclosed,'' as such terms are commonly used in the securities industry. An ''introducing'' broker-dealer is ''one that has a contractual arrangement with another firm, known as the carrying or clearing firm, under which the carrying firm agrees to perform certain services for the introducing firm. Usually, the introducing firm submits its customer accounts and customer orders to the carrying firm, which executes the orders and carries the account. The carrying firm's duties include the proper disposition of the customer funds and securities after the trade date, the custody of customer securities and funds, and the recordkeeping associated with carrying customer accounts.'' [6]

Further, a ''fully disclosed'' introducing arrangement is ''distinguished from an omnibus clearing arrangement where the clearing firm maintains one account for all the customer transactions of the introducing firm. In an omnibus relationship, the clearing firm does not know the identity of the customers of the introducing firm. In a fully disclosed clearing arrangement, the clearing firm knows the names, addresses, securities positions and other relevant data as to each customer.'' [7]

With respect to a broker-dealer that is routing on behalf of another broker-dealer, the Exchange does not believe that the routing broker-dealer has sufficient information to assess whether orders are truly retail in nature, and thus, requires an RMO routing on behalf of other broker-dealers to maintain additional supervisory procedures and obtain annual attestations, as described below, in order to submit Retail Orders to the Exchange. In contrast, however, if a member organization is carrying a customer account on a fully disclosed basis, then such carrying broker-dealer is required to perform certain diligence regarding such account that the Exchange believes is sufficient to assess whether a customer is a retail customer in order to submit orders on behalf of such a customer to the Exchange as a Retail Order. The carrying broker of an account typically handles orders from its retail customers that are ''introduced'' by an introducing broker. However, as noted above, in contrast to a typical routing relationship on behalf of another broker-dealer, a carrying broker obtains a significant level of information regarding each customer introduced by the introducing broker. Accordingly, the Exchange proposes to state in Rule 107C(b)(1) that for purposes of Rule 107C, ''conducting a retail business includes carrying retail customer accounts on a fully disclosed basis.''

Rule 107C(b)(6) currently states, in part, that ''[i]f a Retail Member Organization represents Retail Orders from another broker-dealer customer, the Retail Member Organization's supervisory procedures must be reasonably designed to assure that the orders it receives from such broker-dealer customer that it designates as Retail Orders meet the definition of a Retail Order.'' This includes obtaining attestations from the other broker-dealers for whom the RMO routes. In addition to the proposed changes to Rule 107C(b)(1) described above, the Exchange proposes to modify the language of Rule 107C(b)(6) to again distinguish between an RMO that conducts a retail business because it carries accounts on a fully disclosed basis from an RMO that routes orders on behalf of another broker-dealer. As proposed, the additional annual written representations requirements of Rule 107C(b)(6) would apply to an RMO that does not itself conduct a retail business but routes Retail Orders on behalf of other broker-dealers. In turn, such additional written representation requirements of Rule 107C(b)(6) would not apply to an RMO that carries retail customer accounts on a fully disclosed basis. In connection with this change, the Exchange is proposing various edits to the existing rule text so that the reference is consistently to ''other broker-dealers'' rather than ''broker-dealer customers.''

The Exchange believes that allowing an RMO that carries retail customer accounts on a fully disclosed basis to submit Retail Orders to the Exchange without obtaining attestations from broker-dealers that might introduce such accounts will encourage participation in the Program. As noted above, the Exchange believes that the carrying broker has sufficient information to itself confirm that orders are Retail Orders without such attestations. The Exchange still believes it is necessary to require the attestation by broker-dealers that route Retail Orders on behalf of other broker-dealers, because, in contrast, such broker-dealers typically do not have a relationship with the retail customer and would not be in position to confirm that such customers are in fact retail customers.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with Section 6(b) of the Act,[8] in general, and furthers the objectives of Section 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 facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system.

The Exchange believes that the proposed rule change is designed to prevent fraudulent and manipulative acts and practices because it highlights the parties for whom additional procedures are required because they do not maintain relationships with the end customer (*i.e.,* routing brokers) and still requires the RMO to follow such procedures to ensure that such orders qualify as Retail Orders. As proposed, however, an RMO would not be required to follow such procedures, including obtaining annual attestations, to the extent such RMO actually knows the end customer and carries the account of such customer and thus can itself confirm that the orders qualify as Retail Orders.

The Exchange believes that the proposed rule change will remove impediments to and perfect the mechanism of a free and open market and a national market system because it will allow RMOs that carry retail customer accounts to participate in the Program without imposing additional attestation requirements that the Exchange did not initially intend to impose upon them. By removing impediments to participation in the Program, the proposed change would permit expanded access of retail customers to the Program.

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 that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes that the amendment, by increasing the level of participation in the Program, will increase the level of competition around retail executions. The Exchange believes that the transparency and competitiveness of operating a program such as the Program on an exchange market would

[6] *See* Securities Exchange Act Release No. 31511 (Nov. 24, 1992), 57 FR 56973 (December 2, 1992).

[7] *Id.*

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(5).

result in better prices for retail investors and benefits retail investors by expanding the capabilities of Exchanges to encompass practices currently allowed on non-exchange venues.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has filed the proposed rule change pursuant to Section 19(b)(3)(A)(iii) of the Act[10] and Rule 19b–4(f)(6) thereunder.[11] 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, if consistent with the protection of investors and the public interest, the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[12] and Rule 19b–4(f)(6) thereunder.[13]

A proposed rule change filed under Rule 19b–4(f)(6)[14] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[15] the Commission may 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 proposed rule change may become operative immediately.[16] In requesting the waiver, the Exchange stated its belief that having harmonized requirements for RMOs across multiple exchanges with a retail program would promote competition by enabling member organizations to operate as RMOs on multiple exchanges in the same manner. The Commission notes that, to become an RMO, a member organization would still be required under Exchange Rule 107C(b)(2)(C) to submit an attestation to the Exchange that substantially all orders submitted as Retail Orders would qualify as such under Exchange Rule 107C. Rather, the proposal would change when an RMO must obtain the annual written representation from other broker-dealers that send Retail Orders to the RMO. The Commission finds that waiving the 30-day operative delay is consistent with the protection of investors and the public interest. Accordingly, the Commission hereby waives the 30-day operative delay and designates the proposal operative upon filing.[17]

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 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–NYSE–2015–59 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–NYSE–2015–59. 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 offices 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–NYSE–2015–59, and should be submitted on or before December 30, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[18]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–30944 Filed 12–8–15; 8:45 am]

BILLING CODE 8011–01–P

[10] 15 U.S.C. 78s(b)(3)(A)(iii).

[11] 17 CFR 240.19b–4(f)(6).

[12] 15 U.S.C. 78s(b)(3)(A).

[13] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6)(iii) requires the Exchange to give the Commission written notice of the Exchange's 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 of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[14] 17 CFR 240.19b–4(f)(6).

[15] 17 CFR 240.19b–4(f)(6)(iii).

[16] The Commission notes that another national securities exchange has a similar rule for its Retail Member Organizations and that the proposal does not raise any novel regulatory issues. *See* Securities Exchange Act Release No. 76207 (October 21, 2015), 80 FR 65824 (October 27, 2015) (SR–BYX–2015–45).

[17] For purposes only of waiving the 30-day operative delay, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[18] 17 CFR 200.30–3(a)(12), (59).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–76547; File No. SR–BOX–2015–37]

Self-Regulatory Organizations; BOX Options Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To amend IM–5050–10 to BOX Rule 5050 (Mini Option Contracts)

December 3, 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 November 20, 2015, BOX Options Exchange LLC (the ''Exchange'') filed with the Securities and Exchange Commission

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

(''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 from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to replace the name ''Google Inc.'' with ''Alphabet Inc.'' Google Inc. (''Google'') recently announced plans to reorganize and create a new public holding company, which will be called Alphabet Inc. (''Alphabet''). 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 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 IM–5050–10 to BOX Rule 5050 (Mini Option Contracts) to replace the name ''Google Inc.'' with ''Alphabet Inc.'' Google Inc. (''Google'') recently announced plans to reorganize and create a new public holding company, which will be called Alphabet Inc. (''Alphabet''). As a result of the holding company reorganization, each share of Class A Common Stock (''GOOGL''), which the Exchange has the ability to list as a Mini Option, will automatically convert into an equivalent corresponding share of Alphabet Inc. stock.[3]

The Exchange is proposing to make this change to IM–5050–10 to enable the Exchange to continue trading Mini Options on Google, now Alphabet Class A shares. The Exchange is proposing to make this change because, on October 5, 2015 Google reorganized and as a result underwent a name change.

The purpose of this change is to ensure that IM–5050–10 properly reflects the intention and practice of the Exchange to have the ability to trade Mini Options on only an exhaustive list of underlying securities outlined in IM–5050–10. This change is meant to continue the inclusion of Class A shares of Google in the current list of underlying securities that Mini Options can be traded on, while continuing to make clear that class C shares of Google are not part of that list as that class of options has not been approved for Mini Options trading. As a result, the proposed change will help avoid confusion.

2. Statutory Basis

The Exchange believes that the proposal is consistent with the requirements of Section 6(b) of the Securities Exchange Act of 1934 (the ''Act''),[4] in general, and Section 6(b)(5) of the Act,[5] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, 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)[6] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

In particular, the proposed rule change to change the name Google to Alphabet to reflect the new ownership structure is consistent with the Act because the proposed change is merely updating the current name associated with the stock symbol GOOGL to allow for the continued ability for mini option trading on Google's class A shares. The proposed change will allow for continued benefit to investors by providing them with additional investment alternatives.

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 proposed change does not impose any burden on intra-market competition because it applies to all members and member organizations uniformly. There is no burden on inter-market competition because the Exchange is merely attempting to continue to permit trading of GOOGL as a Mini Options, as is the case today. As a result, there will be no substantive changes to the Exchange's operations or its rules.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule 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 if consistent with the protection of investors and the public interest, provided that the self-regulatory organization has given the Commission written notice of its intent to file 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,[7] the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[8] and Rule 19b–4(f)(6) thereunder.[9]

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.

[3] The Class C Capital Stock (''GOOG'') which is also impacted by the reorganization are not eligible to be listed as Mini Options on the Exchange, only the Class A Common Stock.

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

[6] *Id.*

[7] The Exchange has fulfilled this requirement.

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(6).

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–2015–37 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–2015–37. 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–2015–37 and should be submitted on or before December 30, 2015.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2015–30939 Filed 12–8–15; 8:45 am]

BILLING CODE 8011–01–P

DEPARTMENT OF STATE

[Public Notice: 9373]

In the Matter of the Designation of the Libyan Islamic Fighting Group, Also Known as LIFG, as a Foreign Terrorist Organization Pursuant to Section 219 of the Immigration and Nationality Act, as Amended

Based upon a review of the Administrative Record assembled in this matter, and in consultation with the Attorney General and the Secretary of the Treasury, I conclude that the circumstances that were the basis for the designation of the Libyan Islamic Fighting Group also known as LIFG as foreign terrorist organization have changed in such a manner as to warrant revocation of the designation.

Therefore, I hereby determine that the designation of the Libyan Islamic Fighting Group as a foreign terrorist organization, pursuant to Section 219 of the Immigration and Nationality Act, as amended (8 U.S.C. 1189), shall be revoked.

This determination shall be published in the **Federal Register**.

Dated: November 30, 2015.

John F. Kerry,

Secretary of State.

[FR Doc. 2015–31034 Filed 12–8–15; 8:45 am]

BILLING CODE 4710–AD–P

DEPARTMENT OF STATE

[Public Notice: 9374]

Notice of a Decision To Deny a Presidential Permit to TransCanada Keystone Pipeline LP for the Proposed Keystone XL Pipeline

AGENCY: Department of State.

ACTION: Notice of a Decision To Deny a Presidential Permit to TransCanada Keystone Pipeline LP for the Proposed Keystone XL Pipeline.

SUMMARY: On November 6, 2015, the Department of State announced the Secretary of State's determination under Executive Order 13337 that issuing a Presidential Permit to TransCanada Keystone Pipeline LP (''TransCanada'') for the proposed Keystone XL pipeline's border facilities would not serve the national interest, and denied the Permit application. This decision prohibits TransCanada from constructing, connecting, operating, and maintaining pipeline facilities at the border of the United States and Canada in Phillips County, Montana, for the export of crude oil from Canada to the United States.

FOR FURTHER INFORMATION CONTACT: Office of Policy Analysis and Public Diplomacy, Bureau of Energy Resources, U.S. Department of State (ENR/EGA/PAPD), 2201 C St. NW., Ste. 4422, Washington DC 20520; Tel: 202–647–3423.

SUPPLEMENTARY INFORMATION: Additional information concerning the Keystone XL pipeline Presidential Permit application and documents related to the Department of State's review of the application can be found at *www.keystonepipeline-xl.state.gov.*

Dated: November 27, 2015.

Matthew T. McManus,

Acting Director, Office of Policy Analysis and Public Diplomacy, Bureau of Energy Resources, U.S. Department of State.

[FR Doc. 2015–31038 Filed 12–8–15; 8:45 am]

BILLING CODE 4710–AE–P

DEPARTMENT OF STATE

[Public Notice 9372]

In the Matter of the Designation of the Libyan Islamic Fighting Group, Also Known as LIFG, as a ''Terrorist Organization'' Pursuant to Section 212(a)(3)(B)(vi)(II) of the Immigration and Nationality Act, as Amended

Acting under the authority of Section 212(a)(3)(B)(vi)(II) of the INA, I hereby revoke the designation of the Libyan Islamic Fighting Group also known as LIFG as a ''terrorist organization'' under Section 212(a)(3)(B)(vi)(II) of the INA.

This determination shall be published in the **Federal Register**.

Dated: November 30, 2015.

John F. Kerry,

Secretary of State.

[FR Doc. 2015–31035 Filed 12–8–15; 8:45 am]

BILLING CODE 4710–AD–P

[10] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2015–67]

Petition for Exemption; Summary of Petition Received; Southern AeroMedical Institute

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 December 29, 2015.

ADDRESSES: Send comments identified by docket number FAA–2015–3596 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: Brent Hart (202) 267–4034, 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 December 3, 2015.

James Crotty,

Manager, Aircraft and Airport Division.

Petition for Exemption

Docket No.: FAA–2015–3596.

Petitioner: Southern AeroMedical Institute (SAMI).

Section(s) of 14 CFR Affected: 61.31(g)(2).

Description of Relief Sought: To further enhance and reinforce the training objective as to the dangers of cabin depressurization.

[FR Doc. 2015–31032 Filed 12–8–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

[Summary Notice No. 2015–66]

Petition for Exemption; Summary of Petition Received; Great Lakes Aviation, Ltd

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 December 29, 2015.

ADDRESSES: Send comments identified by docket number FAA–2015–4903 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: Brent Hart (202) 267–4034, 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 December 3, 2015.

James Crotty,

Manager, Aircraft and Airport Division.

Petition for Exemption

Docket No.: FAA–2015–4903.

Petitioner: Great Lakes Aviation, Ltd.

Section(s) of 14 CFR Affected: 110.2.

Description of Relief Sought: This exemption would allow Great Lakes Aviation to operate Beechcraft 1900D aircraft in a 19 seat configuration under a ''Commuter Operation'' definition and apply the provisions of FAR Part 135 Sections 135.245, 135.243(a)(1) and 135.265 while maintaining the provisions of FAR Part 121 for all other requirements.

[FR Doc. 2015–31033 Filed 12–8–15; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[Docket No. MARAD–2015 0121]

Requested Administrative Waiver of the Coastwise Trade Laws: Vessel SAMBA; Invitation for Public Comments

AGENCY: Maritime Administration, Department of Transportation.

ACTION: Notice.

SUMMARY: As authorized by 46 U.S.C. 12121, the Secretary of Transportation, as represented by the Maritime Administration (MARAD), is authorized to grant waivers of the U.S.-build requirement of the coastwise laws under certain circumstances. A request for such a waiver has been received by MARAD. The vessel, and a brief description of the proposed service, is listed below.

DATES: Submit comments on or before January 8, 2016.

ADDRESSES: Comments should refer to docket number MARAD–2015–0121. Written comments may be submitted by hand or by mail to the Docket Clerk, U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590. You may also send comments electronically via the Internet at *http://www.regulations.gov.* All comments will become part of this docket and will be available for inspection and copying at the above address between 10 a.m. and 5 p.m., E.T., Monday through Friday, except federal holidays. An electronic version of this document and all documents entered into this docket is available on the World Wide Web at *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Linda Williams, U.S. Department of Transportation, Maritime Administration, 1200 New Jersey Avenue SE., Room W23–453, Washington, DC 20590. Telephone 202–366–0903, Email *Linda.Williams@dot.gov.*

SUPPLEMENTARY INFORMATION:

As described by the applicant the intended service of the vessel SAMBA is:

INTENDED COMMERCIAL USE OF VESSEL: ''Week long charters teaching navigation, boat handling, boat systems, particularly for future owners of Nordhavn Yachts.''

GEOGRAPHIC REGION: ''Alaska (excluding waters in Southeastern Alaska and waters north of a line between Gore Point to Cape Suckling [including the North Gulf Coast and Prince William Sound]). Operating primarily in Kodiak.''

The complete application is given in DOT docket MARAD–2015–0121 at *http://www.regulations.gov.* Interested parties may comment on the effect this action may have on U.S. vessel builders or businesses in the U.S. that use U.S.-flag vessels. If MARAD determines, in accordance with 46 U.S.C. 12121 and MARAD's regulations at 46 CFR part 388, that the issuance of the waiver will have an unduly adverse effect on a U.S.-vessel builder or a business that uses U.S.-flag vessels in that business, a waiver will not be granted. Comments should refer to the docket number of this notice and the vessel name in order for MARAD to properly consider the comments. Comments should also state the commenter's interest in the waiver application, and address the waiver criteria given in § 388.4 of MARAD's regulations at 46 CFR part 388.

Privacy Act

Anyone is able to search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78).

By Order of the Maritime Administrator.
Dated: December 1, 2015.

T. Mitchell Hudson, Jr.,

Secretary, Maritime Administration.

[FR Doc. 2015–30916 Filed 12–8–15; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[U.S. DOT Docket No. NHTSA–2015–0112]

Reports, Forms, and Record Keeping Requirements; 60 Day Federal Register Notice

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Request for public comment on proposed collection of information.

SUMMARY: Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatements of previously approved collections.

This document describes one collection of information for which NHTSA intends to seek OMB approval.

DATES: Comments must be received on or before January 8, 2016.

ADDRESSES: You may submit comments identified by DOT Docket ID Number NHTSA- 2015–0112 using any of the following methods:

Electronic submissions: Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.

Mail: Docket Management Facility, M–30, U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590.

Hand Delivery: 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 all comments received will be posted without change to *http://www.regulations.gov* including any personal information provided.

FOR FURTHER INFORMATION CONTACT: Mary T. Byrd, Contracting Officer's Representative, Office of Behavioral Safety Research (NTI–132), National Highway Traffic Safety Administration, 1200 New Jersey Avenue SE., W46–466, Washington, DC 20590. Mary T. Byrd's phone number is 202–366–5595 and her email address is *mary.byrd@dot.gov.*

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995, before an agency submits a proposed collection of information to OMB for approval, it must publish a document in the **Federal Register** providing a 60-day comment period and otherwise consult with members of the public and affected agencies concerning each proposed collection of information. The OMB has promulgated regulations describing what must be included in such a document. Under OMB's regulations (at 5 CFR 1320.8(d)), an agency must ask for public comment on the following:

(i) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the

validity of the methodology and assumptions used;

(iii) how to enhance the quality, utility, and clarity of the information to be collected; and

(iv) how to minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

In compliance with these requirements, NHTSA asks public comment on the following proposed collection of information:

Title: Evaluation of Community-Oriented Enforcement Demonstrations.

Type of Request: New information collection requirement.

OMB Clearance Number: None.

Form Number: NHTSA Forms 1321, 1322, 1325.

Requested Expiration Date of Approval: 3 years from date of approval.

Summary of the Collection of Information—The National Highway Traffic Safety Administration (NHTSA) proposes to conduct public awareness surveys to help evaluate two traffic safety demonstration projects: *Building Community Support for (1) Seat Belt Enforcement and (2) Impaired Driving Enforcement.* If clearance is granted, the public awareness surveys would be administered in-person at Department of Motor Vehicles Offices pre-, mid-, and post-program in the two program locations and the two comparison locations. Over the total data collection effort, 9,600 people would be surveyed, 4,800 for each program. Estimated administration length would be approximately 5 minutes for the recruitment questionnaire and 10 minutes for the awareness survey questionnaire. For the recruitment questionnaire, information on licensure status and age would be collected. For the awareness survey questionnaire, information on attitudes, awareness, knowledge, and behavior would be collected.

A Spanish-language translation of the awareness survey questionnaire would be used to minimize language barriers to participation. Additionally, participation in the proposed data collection would be anonymous; the questionnaires would not collect any personal information that would allow anyone to identify respondents. Participant names would not be collected.

Description of the Need for the Information and Proposed Use of the Information—The National Highway Traffic Safety Administration (NHTSA) was established by the Highway Safety Act of 1970 (23 U.S.C. 101) to carry out a Congressional mandate to reduce the mounting number of deaths, injuries, and economic losses resulting from motor vehicle crashes on the Nation's highways. As part of this statutory mandate, NHTSA is authorized to conduct research as a foundation for the development of motor vehicle standards and traffic safety programs.

In 2013, there were 10,076 fatalities in crashes involving a driver with a BAC of .08 or higher, which is 31% of total traffic fatalities in 2013.[1] In the same year, 49% of passenger vehicle occupants killed in crashes were unrestrained.[2] These data point to the continued need for countermeasure development to decrease impaired driving and increase seat belt use. The purpose of the proposed data collection is to evaluate the effectiveness of two programs designed to increase seat belt use and reduce alcohol-impaired and unrestrained crashes, injuries, and fatalities. The programs are designed to accomplish these goals by using increased enforcement activity driven by law enforcement and community partnerships that maximize community support for impaired driving and seat belt enforcement. The proposed data collection would survey licensed drivers eighteen years and older visiting Department of Motor Vehicles Offices residing in the program and comparison locations to find out about public support for enforcement, awareness of enforcement activity, exposure to community partner activities, and self-reported impaired driving and seat belt use. The collected responses would inform how well the program created community support and influenced safe driving behavior. An essential part of the proposed data collection would be to compare pre-, mid-, and post-program measures to determine how the program contributed to changes in participant responses; therefore, multiple measurements would be required.

The findings from this proposed information collection would support NHTSA, the States, localities, and law enforcement agencies by providing evidence as to the effectiveness of the community-oriented enforcement approach under examination. The findings could be used to refocus existing impaired driving and seat belt programs in order to enhance their effect or to guide the development of new programs.

Description of the Likely Respondents (Including Estimated Number, and Proposed Frequency of Response to the Collection of Information)—Under this proposed effort, the potential respondent universe would be licensed drivers eighteen years and older visiting Department of Motor Vehicles Offices residing in the locations where the impaired driving and seat belt programs would be conducted, and in the two selected comparison locations. As of the time of this Notice, the program and comparison locations have not been selected. Over the total data collection effort, a total of 9,600 licensed drivers eighteen years and older would be surveyed, including 4,800 for each program. Based upon precision estimates, the target sample for the awareness survey questionnaire is 4,800, with 2,400 in each location. However, because NHTSA has estimated a 50% response rate based upon previously conducted data collections of a similar nature, NHTSA is estimating that a total of 9,600 potential participants would need to be administered a recruitment questionnaire in order to find 4,800 eligible volunteers to completed the target number of awareness survey questionnaires. NHTSA estimates that each recruitment questionnaire would take 5 minutes and that each awareness survey questionnaire would take an additional 10 minutes to complete.

Throughout the data collection, the privacy of all participants would be protected. Names, addresses, phone numbers, and email addresses would not be collected. The only information that would be collected would be participant zip code and demographic characteristics, such as age, gender, race, and ethnicity. Zip code would need to be collected to match the participant with either the program or comparison location to ensure that the measured change in public awareness could be associated with the program activity. Demographic information would need to be collected to conduct post-stratification weighting of the sample to U.S Census data to reduce sample bias. All collected data would be stored in restricted folders on secure password protected servers that are only accessible to research personnel with needed access to such information. In addition, all data collected from participants would be reported in aggregate, and individual participants

[1] National Center for Statistics and Analysis. (2014, December). *Alcohol-impaired driving: 2013 data.* (Traffic Safety Facts. DOT HS 812 102). Washington, DC: National Highway Traffic Safety Administration. Retrieved from *http://www-nrd.nhtsa.dot.gov/Pubs/812102.pdf.*

[2] National Center for Statistics and Analysis. (2015, May). *Occupant protection: 2013 data.* (Traffic Safety Facts. DOT HS 812 153). Washington, DC: National Highway Traffic Safety Administration. Retrieved from *http://www-nrd.nhtsa.dot.gov/Pubs/812153.pdf.*

would not be independently reported on in any reports resulting from this project.

Estimate of the Total Annual Reporting and Record Keeping Burden Resulting from the Collection of Information—NHTSA estimates that the total time for each respondent to participate in the data collection effort would either be 5 minutes or 15 minutes depending on eligibility and desire to participate. NHTSA estimates a 50% response rate, in which case 9,600 potential participants would to be administered the recruitment questionnaire in order to find 4,800 eligible volunteers to complete the awareness survey questionnaire. The total burden for the participants that would only complete the recruitment questionnaire would be 400 hours (*i.e.,* 5 minutes × 4,800). The total burden for the participants that would complete the recruitment questionnaire and the awareness survey questionnaire would be 1,200 hours (*i.e.,* 15 minutes × 4,800). The total burden for all participants would be 1,600 hours (*i.e.,* 400 + 1,200). Because participants would be sampled from Department of Motor Vehicles Offices while they are waiting for service, participation would not include any participant reporting cost, record keeping cost, or record keeping burden.

Comments are invited on the following:

(i) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(ii) the accuracy of the agency's estimate of the burden of the proposed information collection;

(iii) ways to enhance the quality, utility, and clarity of the information to be collected; and

(iv) ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

Authority: 44 U.S.C. Section 3506(c)(2)(A).

Issued on: December 4, 2015.

Jeff Michael,

Associate Administrator, Research and Program Development.

[FR Doc. 2015–30995 Filed 12–8–15; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Petition for Exemption From the Federal Motor Vehicle Theft Prevention Standard; Jaguar Land Rover North America LLC

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Grant of petition for exemption.

SUMMARY: This document grants in full the Jaguar Land Rover North America LLC's, (Jaguar Land Rover) petition for an exemption of the Jaguar XE vehicle line in accordance with 49 CFR part 543, *Exemption from Vehicle Theft Prevention Standard.* This petition is granted because the agency has determined that the antitheft device to be placed on the line as standard equipment is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of 49 CFR part 541, *Federal Motor Vehicle Theft Prevention Standard* (Theft Prevention Standard).

DATES: The exemption granted by this notice is effective beginning with the 2017 model year (MY).

FOR FURTHER INFORMATION CONTACT: Ms. Carlita Ballard, Office of International Policy, Fuel Economy and Consumer Programs, NHTSA, W43–439, 1200 New Jersey Avenue SE., Washington, DC 20590. Ms. Ballard's phone number is (202) 366–5222. Her fax number is (202) 493–2990.

SUPPLEMENTARY INFORMATION: In a petition dated October 9, 2015, Jaguar Land Rover requested an exemption from the parts-marking requirements of the Theft Prevention Standard for the Jaguar XE vehicle line beginning with MY 2017. The petition requested an exemption from parts-marking pursuant to 49 CFR part 543, *Exemption from Vehicle Theft Prevention Standard,* based on the installation of an antitheft device as standard equipment for the entire vehicle line.

Under 49 CFR part 543.5(a), a manufacturer may petition NHTSA to grant an exemption for one vehicle line per model year. In its petition, Jaguar Land Rover provided a detailed description and diagram of the identity, design, and location of the components of the antitheft device for the Jaguar XE vehicle line. Jaguar Land Rover stated that the MY 2017 Jaguar XE vehicle line will be equipped with a passive, transponder based, electronic engine immobilizer antitheft device as standard equipment. Key components of its antitheft device will include a power train control module (PCM), instrument cluster, body control module (BCM), remote frequency receiver (RFR), remote frequency actuator (RFA), immobilizer antenna unit (IAU), Smart Key, and door control units (DCU). Jaguar Land Rover stated that its antitheft device will also be installed with an audible and visual perimeter alarm system as standard equipment. If unauthorized entry is attempted by opening the vehicle's hood, trunk or doors, the alarm will sound and the vehicle's exterior lights will flash. Jaguar Land Rover also stated that the perimeter alarm system can be armed either with the Smart Key or programmed to be passively armed.

Jaguar Land Rover's submission is considered a complete petition as required by 49 CFR 543.7, in that it meets the general requirements contained in § 543.5 and the specific content requirements of § 543.6.

The immobilizer device is automatically activated when the Smart Key is removed from the vehicle. Deactivation occurs once the driver approaches the vehicle by pulling on the driver's door handle or using the Smart Key unlock button to unlock the doors. Jaguar Land Rover stated that the Smart Key is programmed and synchronized to the vehicle through the means of a unique identification key code and a randomly generated secret code that is unique to each vehicle.

In addressing the specific content requirements of § 543.6, Jaguar Land Rover provided information on the reliability and durability of its proposed device. To ensure reliability and durability of the device, Jaguar Land Rover conducted tests based on its own specified standards. Jaguar Land Rover provided a detailed list of the tests conducted (*i.e.,* temperature and humidity cycling, high and low temperature cycling, mechanical shock, random vibration, thermal stress/shock tests, material resistance tests, dry heat, dust and fluid ingress tests). Jaguar Land Rover stated that it believes that its device is reliable and durable because it has complied with specified requirements for each test. Jaguar Land Rover stated that reliability and durability of its device is further supported by equipping its vehicles with a key recognition sequence that has over a billion code combinations with encrypted data that are secure against duplication. Jaguar Land Rover stated that the coded data transfer between the modules that will be installed on its XE vehicles use a unique, secure identifier, a random number and a secure public algorithm. Jaguar Land Rover further

stated that since the Jaguar XE vehicle line will utilize a push button vehicle ignition, it does not have a conventional mechanical key barrel which would allow for forcible bypass of the key-locking system.

Jaguar Land Rover stated that there will be three methods of system operation for its XE vehicle line. Specifically, operation of the engine is accomplished when either the Smart Key is automatically detected by the vehicle, the vehicle is unlocked using the Smart Key unlock button or by using the emergency key blade. Jaguar Land Rover stated that automatic detection of the Smart key method occurs when authentication of the correct Smart Key via a low frequency to remote frequency challenge response sequence occurs after the driver/operator approaches the vehicle, pulls the driver's door handle, and unlocks the doors. When the driver presses the ignition start button, a search begins to find and authenticate the Smart Key within the vehicle interior. Jaguar Land Rover stated that if this is successful, the information is passed through a coded data transfer to the BCM via the RFA. Then, the BCM will pass the valid key status to the instrument cluster, send the ''key valid'' message to the PCM, initiate a coded data transfer and authorize the engine to start. Method two of unlocking the vehicle with the Smart Key unlock button occurs when the driver approaches the vehicle; presses the Smart Key unlock button and unlocks the doors. Jaguar Land Rover stated that once the driver presses the ignition start button, the operation process is the same as method one. Jaguar Land Rover stated that if the Smart Key has a discharged or damaged battery, the driver/operator can use method three of removing an emergency key blade from the Smart Key to unlock the doors. After using this method, once the driver presses the ignition start button, a search begins to find and authenticate the Smart Key within the vehicle interior. If this is unsuccessful, the Smart Key needs to be docked under the foot well lamp on the driver's side knee bolster. Once the Smart Key is placed in the correct position and the ignition start button is pressed again, the BCM and Smart Key enter a coded data exchange via the immobilizer antenna unit. The BCM passes the valid key status to the instrument cluster, via a code data transfer, and then the BCM sends the ''key valid'' message to the PCM initiating a coded data transfer. If successful, the engine will start the vehicle.

Jaguar Land Rover stated that the Jaguar XE is a new vehicle line and therefore theft rate data is not available. Jaguar Land Rover further stated that its immobilizer antitheft device is substantially similar to the antitheft device installed on the Jaguar XF-Type, Land Rover Discovery Sport, Jaguar F-Type, Jaguar XJ, and the Land Rover Range Rover Evoque vehicle lines which have all been granted parts-marking exemptions by the agency. Jaguar Land Rover stated that based on MY 2012 theft information published by NHTSA, the Jaguar Land Rover vehicles equipped with immobilizers had a combined theft rate of 0.81 per thousand vehicles, which is below NHTSA's overall theft rate of 1.13 thefts per thousand vehicles. Using an average of 3 MYs data (2011–2013), NHTSA's theft rates for the Jaguar XF-Type, Jaguar XJ and the Land Rover Range Rover Evoque are 0.7237, 1.1466 and 0.4495 respectfully. Theft data for the Jaguar F-Type and the Land Rover Discovery Sport is not available. Jaguar Land Rover believes these low theft rates demonstrate the effectiveness of the immobilizer device. Additionally, Jaguar Land Rover notes a Highway Loss Data Institute news release (July 19, 2000) showing approximately a 50% reduction in theft for vehicles installed with an immobilizer device. The agency agrees that the device is substantially similar to devices installed on other vehicle lines for which the agency has already granted exemptions

Based on the supporting evidence submitted by Jaguar Land Rover on its device, the agency believes that the antitheft device for the Jaguar XE vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard (49 CFR 541). The agency concludes that the device will provide the five types of performance listed in § 543.6(a)(3): Promoting activation; attract attention to the efforts of an unauthorized person to enter or move a vehicle by means other than a key; preventing defeat or circumvention of the device by unauthorized persons; preventing operation of the vehicle by unauthorized entrants; and ensuring the reliability and durability of the device.

Pursuant to 49 U.S.C. 33106 and 49 CFR 543.7 (b), the agency grants a petition for exemption from the parts-marking requirements of Part 541 either in whole or in part, if it determines that, based upon substantial evidence, the standard equipment antitheft device is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of Part 541. The agency finds that Jaguar Land Rover has provided adequate reasons for its belief that the antitheft device for the Jaguar XE vehicle line is likely to be as effective in reducing and deterring motor vehicle theft as compliance with the parts-marking requirements of the Theft Prevention Standard (49 CFR part 541). This conclusion is based on the information Jaguar Land Rover provided about its device.

For the foregoing reasons, the agency hereby grants in full Jaguar Land Rover's petition for exemption for the Jaguar XE vehicle line from the parts-marking requirements of 49 CFR part 541. The agency notes that 49 CFR part 541, Appendix A–1, identifies those lines that are exempted from the Theft Prevention Standard for a given model year. 49 CFR part 543.7(f) contains publication requirements incident to the disposition of all Part 543 petitions. Advanced listing, including the release of future product nameplates, the beginning model year for which the petition is granted and a general description of the antitheft device is necessary in order to notify law enforcement agencies of new vehicle lines exempted from the parts-marking requirements of the Theft Prevention Standard. If Jaguar Land Rover decides not to use the exemption for this line, it must formally notify the agency. If such a decision is made, the line must be fully marked according to the requirements under 49 CFR parts 541.5 and 541.6 (marking of major component parts and replacement parts).

NHTSA notes that if Jaguar Land Rover wishes in the future to modify the device on which this exemption is based, the company may have to submit a petition to modify the exemption. Part 543.7(d) states that a Part 543 exemption applies only to vehicles that belong to a line exempted under this part and equipped with the antitheft device on which the line's exemption is based. Further, Part 543.9(c)(2) provides for the submission of petitions ''to modify an exemption to permit the use of an antitheft device similar to but differing from the one specified in that exemption.''

The agency wishes to minimize the administrative burden that Part 543.9(c)(2) could place on exempted vehicle manufacturers and itself. The agency did not intend in drafting Part 543 to require the submission of a modification petition for every change to the components or design of an antitheft device. The significance of many such changes could be *de minimis.* Therefore, NHTSA suggests that if the manufacturer contemplates making any changes, the effects of which might be characterized as *de*

minimis, it should consult the agency before preparing and submitting a petition to modify.

Issued in Washington, DC under authority delegated in 49 CFR 1.95.

Raymond R. Posten,

Associate Administrator for Rulemaking.

[FR Doc. 2015–30930 Filed 12–8–15; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[Docket No. AB 331 (Sub-No. 2X)]

The Bi-State Development Agency of the Missouri–Illinois Metropolitan District—Abandonment Exemption—in the City of St. Louis, MO

The Bi-State Development Agency of the Missouri–Illinois Metropolitan District (Metro) has filed a verified notice of exemption under 49 CFR part 1152 subpart F–*Exempt Abandonments* to abandon 1.43 miles of rail line extending from milepost 1.8 to milepost 3.23 within the City of St. Louis, Missouri (the Line). The Line traverses United States Postal Service Zip Codes 63110 and 63108.

Metro has certified that: (1) No local traffic has moved over the Line for at least two years; (2) no overhead traffic has moved over the Line for at least two years, and if there were any overhead traffic, it could be rerouted over other lines; (3) no formal complaint filed by a user of rail service on the Line (or by a state or local government entity acting on behalf of such user) regarding cessation of service over the line either is pending with the Surface Transportation Board (Board) or with any U.S. District Court, or has been decided in favor of complainant within the two-year period; and (4) the requirements at 49 CFR 1105.7(c) (environmental report), 49 CFR 1105.11 (transmittal letter), 49 CFR 1105.12 (newspaper publication), and 49 CFR 1152.50(d)(1) (notice to governmental agencies) have been met.

As a condition to this exemption, any employee adversely affected by the abandonment shall be protected under *Oregon Short Line Railroad—Abandonment Portion Goshen Branch Between Firth & Ammon, in Bingham & Bonneville Counties, Idaho,* 360 I.C.C. 91 (1979). To address whether this condition adequately protects affected employees, a petition for partial revocation under 49 U.S.C. 10502(d) must be filed.

Provided no formal expression of intent to file an offer of financial assistance (OFA) has been received, this exemption will be effective on January 8, 2016, unless stayed pending reconsideration. Petitions to stay that do not involve environmental issues,[1] formal expressions of intent to file an OFA under 49 CFR 1152.27(c)(2),[2] and interim trail use/rail banking requests under 49 CFR 1152.29 must be filed by December 21, 2015. Petitions to reopen or requests for public use conditions under 49 CFR 1152.28 must be filed by December 29, 2015, with the Surface Transportation Board, 395 E Street SW., Washington, DC 20423–0001.

A copy of any petition filed with the Board should be sent to Metro's representative: James C. Hetlage, Lashly & Baer, P.C., 714 Locust Street, St. Louis, MO 63101.

If the verified notice contains false or misleading information, the exemption is void ab initio.

Metro has filed a combined environmental and historic report that addresses the effects, if any, of the abandonment on the environment and historic resources. OEA will issue an environmental assessment (EA) by December 14, 2015. Interested persons may obtain a copy of the EA by writing to OEA (Room 1100, Surface Transportation Board, Washington, DC 20423–0001) or by calling OEA at (202) 245–0305. Assistance for the hearing impaired is available through the Federal Information Relay Service at (800) 877–8339. Comments on environmental and historic preservation matters must be filed within 15 days after the EA becomes available to the public.

Environmental, historic preservation, public use, or trail use/rail banking conditions will be imposed, where appropriate, in a subsequent decision.

Pursuant to the provisions of 49 CFR 1152.29(e)(2), Metro shall file a notice of consummation with the Board to signify that it has exercised the authority granted and fully abandoned the line. If consummation has not been effected by Metro's filing of a notice of consummation by December 9, 2016, and there are no legal or regulatory barriers to consummation, the authority to abandon will automatically expire.

[1] The Board will grant a stay if an informed decision on environmental issues (whether raised by a party or by the Board's Office of Environmental Analysis (OEA) in its independent investigation) cannot be made before the exemption's effective date. *See Exemption of Out-of-Serv. Rail Lines,* 5 I.C.C. 2d 377 (1989). Any request for a stay should be filed as soon as possible so that the Board may take appropriate action before the exemption's effective date.

[2] Each OFA must be accompanied by the filing fee, which is currently set at $1,600. *See* 49 CFR 1002.2(f)(25).

Board decisions and notices are available on our Web site at ''*WWW.STB.DOT.GOV.*''

Decided: December 4, 2015.

By the Board, Rachel D. Campbell, Director, Office of Proceedings.

Brendetta S. Jones,

Clearance Clerk.

[FR Doc. 2015–31006 Filed 12–8–15; 8:45 am]

BILLING CODE 4915–01–P

DEPARTMENT OF TRANSPORTATION

[Docket Number: RITA–2008–0002]

Office of the Assistant Secretary for Research and Technology (OST–R); Agency Information Collection Activity; Notice of Renewal To Continue To Collect Information: Confidential Close Call Reporting for a Transit System

AGENCY: Bureau of Transportation Statistics (BTS), Office of the Assistant Secretary for Research Technology (OST–R), U.S. Department of Transportation.

ACTION: Notice and request for comments.

SUMMARY: In accordance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, this notice announces the intention of the BTS to request the Office of Management and Budget (OMB) to approve the continuation of the following information collection: Confidential Close Call Reporting for a Transit System. This data collection effort supports a multi-year program focused on improving transit safety by collecting and analyzing data and information on close calls and other unsafe occurrences in the Washington Metropolitan Area Transit Authority (WMATA) system. The program is co-sponsored by WMATA's Office of the Deputy General Manager Operations (DGMO) and the President/Business Agent of the Amalgamated Transit Union (ATU) Local 689. It is designed to identify safety issues and propose preventative safety actions based on voluntary reports of close calls submitted confidentially to the Bureau of Transportation Statistics (BTS), U.S. Department of Transportation. This information collection is necessary to aid WMATA/ATU in systematically collecting and analyzing data to identify root causes of potentially unsafe events.

DATES: Comments must be received by January 8, 2016.

ADDRESSES: *BTS seeks public* comments on its proposed continuation of information collection. Comments

should address whether the information will have practical utility; the accuracy of the estimated burden hours of the proposed information collection; ways to enhance the quality, utility and clarity of the information to be collected; and ways to minimize the burden of the collection of information on respondents, including the use of automated collection techniques or other forms of information technology. Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 17th Street NW., Washington, DC 20503, Attention: BTS Desk Officer.

FOR FURTHER INFORMATION CONTACT: Demetra V. Collia, Bureau of Transportation Statistics, Office of the Assistant Secretary for Research and Technology (OST–R), U.S. Department of Transportation, Office of Statistical and Economic Analysis (OSEA), RTS–31, E36–302, 1200 New Jersey Avenue SE., Washington, DC 20590–0001; Phone No. (202) 366–1610; Fax No. (202) 366–3383; email: *demetra.collia@dot.gov.* Office hours are from 8:30 a.m. to 5 p.m., EST, Monday through Friday, except Federal holidays.

Data Confidentiality Provisions: The confidentiality of Close Calls data is protected under the BTS confidentiality statute (49 U.S.C. 111(k)) and the Confidential Information Protection and Statistical Efficiency Act (CIPSEA) of 2002 (Pub. L. 107–347, Title V). In accordance with these confidentiality statutes, only statistical and non-identifying data will be made publicly available through reports. Further, BTS will not release to FRA or any other public or private entity any information that might reveal the identity of individuals or organizations mentioned in close call reports.

SUPPLEMENTARY INFORMATION:

I. The Data Collection

The Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35; as amended) and 5 CFR part 1320 require each Federal agency to obtain OMB approval to continue an information collection activity. BTS is seeking OMB approval for the following BTS information collection activity:

Title: Confidential Close Call Reporting for a Transit System.

OMB Control Number: 2139– 0010.

Type of Review: Approval to continue to collect data.

Respondents: WMATA Employees.

Number of Respondents: 100 (per annum).

Estimated Time per Response: 60 minutes.

Frequency: Intermittent for approximately five (5) years. (Reports are submitted when there is a qualifying event, *i.e.* a close call occurs within WMATAs Transit System.

Total Annual Burden: 100 hours.

Please note that the 60 day notice was incorrectly posted as a Notice of Request for approval to Collect New Information: Confidential Close Call Reporting for Transit System. Also, the Confidential Close Call Program has been renamed the Close Call Data Program (CCDP). Confidential Close Call Reporting and CCDP are one in the same in all other aspects identical.

II. Public Participation and Request for Public Comments

On September 1, 2015, BTS published a notice (80 FR 52846) encouraging interested parties to submit comments to docket number RITA–2008–0002 and allowing for a 60-day comment period. The comment period closed on November 2, 2015. To view comments, go to *http://www.regulations.gov* and insert the docket number, ''RITA–2008–0002'' in the ''Search'' box and click ''Search.'' Next, click ''Open Docket Folder'' button and choose document listed to review. If you do not have access to the Internet, you may view the docket 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. Monday through Friday, except Federal holidays.

Privacy Act

All comments the BTS received were posted without change to *http://www.regulations.gov.* Anyone may search the electronic form of all comments received into any of our dockets by the name of the individual submitting the comment (or of the person signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on January 17, 2008 (73 FR 3316), or you may visit *http://edocket.access.gpo.gov/2008/pdf/E8-785.pdf.*

III. Discussion of Public Comments and BTS Responses

BTS announced on September 1, 2015, in a **Federal Register** Notice (80 FR 52846), its intention to request that OMB approve the following continuation of information collection: Confidential Close Call Reporting for a Transit System. BTS received no comments during the 60-day public comment period.

Issued on: December 2, 2015.

Patricia Hu,

Director, Bureau of Transportation Statistics, Office of the Assistant Secretary for Research and Technology.

[FR Doc. 2015–30996 Filed 12–8–15; 8:45 am]

BILLING CODE 4910–HY–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Notice 2000–28

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Notice 2000–28, Coal Exports.

DATES: Written comments should be received on or before February 8, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Christie Preston, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the regulations should be directed to LaNita Van Dyke at Internal Revenue Service, Room 6517, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet at *Lanita.VanDyke@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Coal Exports.

Notice Number: 1545–1690.

Abstract: Notice 2000–28 provides guidance relating to the coal excise tax imposed by section 4121 of the Internal Revenue Code. The notice provides rules under the Code for making a nontaxable sale of coal for export or for obtaining a credit or refund when tax has been paid with respect to a nontaxable sale of coal for export.

Current Actions: There are no changes being made to the notice at this time.

Type of Review: Extension of currently approved collection.

Affected Public: Business or other-for-profit organizations.

Estimated Number of Respondents: 400.

Estimated Time per Respondent: 1 hour.

Estimated Total Annual Burden Hours: 400.

The following paragraph applies to all of the collections of information covered by this notice:

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 OMB control number. 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 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: December 1, 2015.

Michael Joplin,

Supervisory Tax Analyst.

[FR Doc. 2015–30923 Filed 12–8–15; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 4972

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 4972, Tax on Lump-Sum Distributions (From Qualified Plans of Participants Born Before January 2, 1936).

DATES: Written comments should be received on or before February 8, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Christie Preston, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to LaNita Van Dyke, at Internal Revenue Service, Room 6517, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet at *Lanita.VanDyke@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Tax on Lump-Sum Distributions (From Qualified Plans of Participants Born Before January 2, 1936).

OMB Number: 1545–0193.

Form Number: Form 4972.

Abstract: Internal Revenue Code section 402(e) and regulation section 402(e) and regulations section 1.402(e) allow recipients of lump-sum distributions from a qualified retirement plan to figure the tax separately on the distributions. The tax can be computed on the 10 year averaging method and/or by a special capital gain method. Form 4972 is used to compute the separate tax and to make a special 20 percent capital gain election on lump-sum distributions attributable to pre-1974 participation.

Current Actions: There are no changes being made to the form at this time.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals or households.

Estimated Number of Responses: 21,709.

Estimated Time per Respondent: 4 hrs. 24 min.

Estimated Total Annual Burden Hours: 95,520.

The following paragraph applies to all of the collections of information covered by this notice:

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 OMB control number. 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 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: December 1, 2015.

Michael Joplin,

IRS Reports Clearance Officer.

[FR Doc. 2015–30927 Filed 12–8–15; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Notice 2006–40

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Notice 2006–40, Credit for Production From Advanced Nuclear Facilities.

DATES: Written comments should be received on or before February 8, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Christie Preston, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to LaNita Van Dyke,

at Internal Revenue Service, Room 6517, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet at *Lanita.VanDyke@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: Credit for Production From Advanced Nuclear Facilities.

OMB Number: 1545–2000.

Form Number: Notice 2006–40.

Abstract: This notice provides the time and manner for a taxpayer to apply for an allocation of the national megawatt capacity limitation under § 45J of the Internal Revenue Code. This information will be used to determine the portion of the national megawatt capacity limitation to which a taxpayer is entitled. The likely respondents are corporations and partnerships.

Current Actions: There is no change in the paperwork burden previously approved by OMB. However, the Title and Notice number has changed from originally approved by OMB. This form is being submitted for renewal purposes only.

Type of Review: Extension of a currently approved collection.

Affected Public: Businesses and other for-profit organizations.

Estimated Number of Respondents: 15.

Estimated Time per Respondent: 40 hours.

Estimated Total Annual Burden Hours: 600.

The following paragraph applies to all of the collections of information covered by this notice:

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 OMB control number. 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 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: December 1, 2015.

Michael Joplin,

IRS Reports Clearance Officer.

[FR Doc. 2015–30925 Filed 12–8–15; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

Proposed Collection; Comment Request for Form 14145

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). Currently, the IRS is soliciting comments concerning Form 14145, IRS Applicant Contact Card.

DATES: Written comments should be received on or before February 8, 2016 to be assured of consideration.

ADDRESSES: Direct all written comments to Christie Preston, Internal Revenue Service, Room 6129, 1111 Constitution Avenue NW., Washington, DC 20224.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form and instructions should be directed to LaNita Van Dyke, at Internal Revenue Service, Room 6517, 1111 Constitution Avenue NW., Washington, DC 20224, or through the internet at *Lanita.VanDyke@irs.gov.*

SUPPLEMENTARY INFORMATION:

Title: IRS Applicant Contact Information.

OMB Number: 1545–2240.

Form Number: Form 14145.

Abstract: The Internal Revenue Service contact card is used to collect contact information from individuals who may be interested in working for the IRS now, or at any time in the future (potential applicants) Form 14145 requests information to enter into a database to allow the IRS to send information about jobs to potential applicants. Cards are then destroyed after input into the database. The potential applicant is only contacted about jobs which correspond to the job categories selected by the IRS Recruiter on Form 14145.

Current Actions: There is no change in the paperwork burden previously approved by OMB.

Type of Review: Extension of a currently approved collection.

Affected Public: Individuals and households.

Estimated Number of Respondents: 16,045.

Estimated Time per Respondent: 4 hours 6 minutes.

Estimated Total Annual Burden Hours: 66,085.

The following paragraph applies to all of the collections of information covered by this notice:

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 OMB control number. 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 26 U.S.C. 6103.

Request for Comments: Comments submitted in response to this notice will be summarized and/or included in the request for OMB approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

Approved: December 1, 2015.

Michael Joplin,

Supervisory Tax Analyst.

[FR Doc. 2015–30926 Filed 12–8–15; 8:45 am]

BILLING CODE 4830–01–P

DEPARTMENT OF THE TREASURY

Proposed Information Collection; Comment Request; Treasury Financial Empowerment Innovation Fund Research on Thrive 'n' Shine Financial Capability Curriculum and Application (App)

AGENCY: Departmental Offices, Department of the Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Department of the Treasury, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on proposed and/or continuing information collections, as required by the Paperwork Reduction Act of 1995, Public Law 104–13 (44 U.S.C. 3506(c)(2)(A)). The Department of the Treasury is soliciting comments concerning a proposed information collection under a Treasury Financial Empowerment Innovation Fund project to assess the effectiveness of classroom-based financial capability curriculum and technology application (app) to enhance financial decision-making skills of high school students.

DATES: Written comments must be submitted on or before February 8, 2016 to be assure of consideration.

ADDRESSES: Comments regarding this information collection should be addressed to the Treasury Office of Consumer Policy contact listed below. All responses to this notice will be included in the request for OMB's approval. All comments will also become a matter of public record.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the information collection instrument and instructions should be directed to James Gatz, Senior Policy Analyst, Office of Consumer Policy, Room 1426, Department of the Treasury, 1500 Pennsylvania Avenue NW., Washington, DC 20220, by telephone on 202–622–3946, or by email at *James.Gatz@Treasury.gov.*

SUPPLEMENTARY INFORMATION:

OMB Number: 1505–NEW.

Title: Information Collections for Research to Evaluate the Effectiveness of the Thrive 'n' Shine Financial Capability Curriculum and Application (App).

Abstract: The Department of the Treasury, Office of Consumer Policy, will use a combination of in-person interviews and web-based products to survey high school students and classroom teachers from approximately six to eight high schools to participate in the evaluation of the Thrive 'n' Shine Financial Capability curriculum and technology application (app). The information collections are planned to be implemented in the classroom setting in spring 2016. The data collected will be used to evaluate the effectiveness of the new financial capability curriculum and app.

Type of Review: New information collection.

Affected Public: Individuals and households.

Obligation to Respond: Voluntary.

Estimated Number of Respondents: Approximately 700 Students and 10 Instructors.

Estimated Average Time per Respondents: Students: 45–60 minutes; Instructors: 60 minutes.

Estimated Total Annual Burden Hours: Approximately 750.

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 Office of Consumer Policy, including whether the information shall have practical utility; (b) the accuracy of the above estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology, and (e) estimates of capital or start-up costs and costs of operation, maintenance, and purchase of service to provide information.

Dated: December 3, 2015.

Dawn D. Wolfgang,

Treasury PRA Clearance Officer.

[FR Doc. 2015–30957 Filed 12–8–15; 8:45 am]

BILLING CODE 4810–25–P

FEDERAL REGISTER

Vol. 80 Wednesday,
No. 236 December 9, 2015

Part II

The President

Federal Register
Vol. 80, No. 236
Wednesday, December 9, 2015

Presidential Documents

Title 3—

The President

Proclamation 9378 of December 4, 2015

150th Anniversary of the 13th Amendment

By the President of the United States of America

A Proclamation

On December 6, 1865, a coalition comprising three-quarters of our Nation's States ratified the 13th Amendment to our Constitution, abolishing slavery in the United States and affirming the truth that no union founded on the principles of liberty and equality could survive half-slave and half-free. Bringing to a close one of the most painful chapters in our country's history, the Amendment ushered in a new birth of freedom. Today, we celebrate it for the protections it restored and the lives it liberated, and in honor of the millions of slaves who endured brutal violence and daily indignities, we rededicate ourselves to the proposition manifested in its ratification.

This Amendment to the Constitution came not only at the culmination of years of Civil War, but also as a result of courageous individuals advocating and agitating for an America in which slavery was no longer an institution of society. President Lincoln gave his last full measure of devotion to the cause he would not live to see codified. He knew the basic rights he sought for slaves could only be secured by a whole and unified Government, and he pursued reconciliation while remaining fierce in his conviction. Volunteers along the Underground Railroad aided slaves seeking freedom, providing safety and comfort in the midst of deep anguish. And soldiers who fought, sometimes against their own sisters and brothers, did so for both the preservation of our Union and liberty itself. The 13th Amendment was the product of generations of men and women who, through centuries of bloodshed and systemic oppression, stayed true to their belief in what America could be and kept marching toward justice.

The courage to change that sustained the abolitionist movement carried forth in a long line of heroes who followed—individuals who loved our country profoundly and answered the patriotic call to push it to expand the boundaries of freedom. From ordinary women stepping into an extraordinary role, bravely fighting for their right to participate in our democracy, to a coalition of conscience that marched on our Nation's Capital and protested for equality, the last century and a half has been defined by those who stood resolute in keeping lit the flame that burned in the hearts of all those determined to secure what they knew to be their God-given rights.

Today, we continue the long journey toward an America and a world where liberty and equality are not reserved for some, but extended to all. Across the globe, including right here at home, millions of men, women, and children are victims of human trafficking and modern-day slavery. We remain committed to abolishing slavery in all its forms and draw strength from the courage and resolve of generations past.

One hundred and fifty years after the 13th Amendment's ratification, the United States endures, and though the scourge of slavery is a stain on our history, we remain a people not trapped by the mistakes of our past, but one that can look at our imperfections with humility and decide it is within our power to remake our Nation to more closely align with our highest ideals. On this historic occasion, let us pay tribute to those who suffered for too long and to those who risked everything to make this

country better. With unyielding determination to stand on their shoulders and reach for an even freer and more equal tomorrow, we can honor them with the recognition and respect worthy of their extraordinary contributions to our country.

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 December 6, 2015, as the 150th Anniversary of the 13th Amendment. I call upon the people of the United States to observe this day with appropriate programs, ceremonies, and activities that celebrate the 13th Amendment.

IN WITNESS WHEREOF, I have hereunto set my hand this fourth day of December, in the year of our Lord two thousand fifteen, and of the Independence of the United States of America the two hundred and fortieth.

[FR Doc. 2015–31221
Filed 12–8–15; 11:15 am]
Billing code 3295–F6–P

Presidential Documents

Proclamation 9379 of December 4, 2015

National Pearl Harbor Remembrance Day, 2015

By the President of the United States of America

A Proclamation

Nearly seven and a half decades ago, as dawn broke over the island of Oahu, bombs broke through the sky as Japanese forces launched an unprovoked attack on our Nation—absorbing America into a conflict that would change the course of human dignity and freedom. More than 2,400 precious lives and much of our Pacific Fleet were lost, yet the ensuing unification of our people proved mightier than the attack that aimed to weaken us. On National Pearl Harbor Remembrance Day, we pay tribute to the men, women, and children—military and civilian—who lost their lives on December 7, 1941, honor all who served in the wake of that infamous day, and recognize the sacrifices today's service members make to carry forward the inextinguishable torch of liberty for generations to come.

Reacting to the surprise attack, patriots from every corner of our country answered the call to serve and banded together in common cause. Sixteen million Americans left behind everything they knew and everyone they loved to fight for freedom far from home and liberate a continent from the grip of tyranny. Courageous individuals from all walks of life crossed oceans and stormed beaches, uplifting a generation and paving the way for our fiercest adversaries to become some of our closest allies. In the example of those who came forth in the months and years following the attack on Pearl Harbor, we see an enduring truth: that no challenge is too great when we stand as one people committed to the ideals which the stars and stripes symbolize.

Seventy-four years after the attack on Pearl Harbor, we endure as a Nation dedicated to affirming the inherent dignity of every person—even in the face of unspeakable violence. As President Franklin D. Roosevelt said the day after the attack, ''the American people in their righteous might will win through to absolute victory.'' On this day, let us honor the memory of all who gave their lives so that President Roosevelt's words could be realized, and let us resolve to uphold the legacy of our country, for which generations of brave men and women have fought and sacrificed.

The Congress, by Public Law 103–308, as amended, has designated December 7 of each year as ''National Pearl Harbor Remembrance Day.''

NOW, THEREFORE, I, BARACK OBAMA, President of the United States of America, do hereby proclaim December 7, 2015, as National Pearl Harbor Remembrance Day. I encourage all Americans to observe this solemn day of remembrance and to honor our military, past and present, with appropriate ceremonies and activities. I urge all Federal agencies and interested organizations, groups, and individuals to fly the flag of the United States at half-staff this December 7 in honor of those American patriots who died as a result of their service at Pearl Harbor.

IN WITNESS WHEREOF, I have hereunto set my hand this fourth day of December, in the year of our Lord two thousand fifteen, and of the Independence of the United States of America the two hundred and fortieth.

[FR Doc. 2015–31222
Filed 12–8–15; 11:15 am]
Billing code 3295–F6–P

Reader Aids

Federal Register

Vol. 80, No. 236

Wednesday, December 9, 2015

CUSTOMER SERVICE AND INFORMATION

Federal Register/Code of Federal Regulations	
General Information, indexes and other finding aids	**202–741–6000**
Laws	**741–6000**
Presidential Documents	
Executive orders and proclamations	**741–6000**
The United States Government Manual	**741–6000**
Other Services	
Electronic and on-line services (voice)	**741–6020**
Privacy Act Compilation	**741–6064**
Public Laws Update Service (numbers, dates, etc.)	**741–6043**

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FEDERAL REGISTER PAGES AND DATE, DECEMBER

74965–75418	1
75419–75630	2
75631–75784	3
75785–75920	4
75921–76200	7
76201–76354	8
76355–76628	9

CFR PARTS AFFECTED DURING DECEMBER

At the end of each month the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

2 CFR

802 74965
5900 76355

3 CFR

Proclamations:
9373 75781
9374 75783
9375 76197
9376 76199
9377 76353
9378 76625
9379 76627

Administrative Orders:
Presidential Determinations:
No. 2016-03 of November 18, 2015 75921
Memorandums:
Memorandum of December 2, 2015 76195

5 CFR

337 75785
576 75785
792 75785
831 75785
842 75785

7 CFR

504 74966
761 74966
769 74966
958 75787

8 CFR

100 75631

9 CFR

300 75590
441 75590
530 75590
531 75590
532 75590
533 75590
534 75590
537 75590
539 75590
540 75590
541 75590
544 75590
548 75590
550 75590
552 75590
555 75590
557 75590
559 75590
560 75590
561 75590

10 CFR

1 74974
2 74974
4 74974
7 74974
9 74974
11 74974
15 74974
19 74974
20 74974
21 74974
25 74974
26 74974
30 74974
32 74974
37 74974
40 74974
50 74974
51 74974
52 74974
55 74974
60 74974
61 74974
62 74974
63 74974
70 74974
71 74974
72 74974
73 74974
74 74974
76 74974
81 74974
95 74974
100 74974
110 74974
140 74974
150 74974
170 74974
171 74974
431 76355

Proposed Rules:
26 76394
50 75009

12 CFR

217 76374
225 75419
252 75419

Proposed Rules:
249 75010

14 CFR

23 76379
39 ..... 74982, 75788, 76201, 76381
97 ..... 75923, 75924, 75926, 75928

Proposed Rules:
39 ..... 75952, 76398, 76400, 76402
382 75953

15 CFR

730 76383
734 76383

736.....76383
738.....75633
740.....75633
742.....76383
743.....75633
744.....76383
745.....76383
772.....75633
774.....75633
922.....74985

Proposed Rules:

701.....75438

16 CFR

Proposed Rules:

Ch. II.....76955
433.....75018
1028.....75020
1408.....75639

21 CFR

510.....76384
520.....76384, 76387
522.....76384
524.....76384
558.....76384, 76387

24 CFR

4.....75931
5.....75931
91.....75791
92.....75931
115.....75931
125.....75931
135.....75931
200.....75931
202.....75931
214.....75931
236.....75931
242.....75931
248.....75931
266.....75931
401.....75931
570.....75931
573.....75931
574.....75931
576.....75931
578.....75791,75931
582.....75931
583.....75931
700.....75931
761.....75931
880.....75931
881.....75931
882.....75931
883.....75931
884.....75931
886.....75931
891.....75931
902.....75931
905.....75931
943.....75931
963.....75931
964.....75931
965.....75931
970.....75931
982.....75931
990.....75931
1000.....75931
1003.....75931
1006.....75931

26 CFR

1.....75946, 76205

Proposed Rules:

1.....75956

29 CFR

4044.....74986

Proposed Rules:

1635.....75956

30 CFR

250.....75806

31 CFR

Proposed Rules:

538.....75957
560.....75957

32 CFR

88.....76206
505.....74987

33 CFR

100.....76206
117.....75636, 75811
165.....76206, 76209
334.....75947

Proposed Rules:

110.....75020

36 CFR

7.....74988

Proposed Rules:

7.....75022
230.....76251

38 CFR

17.....74991
41.....74965
43.....74965

40 CFR

9.....75812
52 .....75636, 76211, 76219, 76222, 76225, 76230, 76232
60.....75178
63 .....75178, 75817, 76152
81.....76232
180 .....75426 75430, 76388
721.....75812

Proposed Rules:

52 .....75024, 75442, 75444, 75706, 75845, 76257, 76258, 76403
63.....75025
78.....75024, 75706
97.....75024, 75706
180.....75442, 75449

42 CFR

433.....75817

44 CFR

64.....76391

45 CFR

95.....75817

Proposed Rules:

144.....75488
146.....75488
147.....75488
153.....75488
154.....75488
155.....75488
156.....75488
158.....75488
1604.....75847
1609.....75847
1611.....75847
1614.....75847
1626.....75847
1635.....75847

47 CFR

1.....75431
73.....75431

Proposed Rules:

20.....75042

48 CFR

Ch. I.....75902, 75918
1 .....75903, 75907, 75908, 75915, 75918
3.....75911
4.....75903, 75913
9.....75903
12.....75903
22 .....75907, 75908, 75915
52 .....75903, 75907, 75908, 75911, 75915
1501.....75948
1502.....75948
1852.....75843

49 CFR

238.....76118

Proposed Rules:

672.....75639

50 CFR

17.....76235
622.....75432
635 .....74997, 74999, 75436
648.....75008
665.....75437
679 .....75843, 76249, 76250

Proposed Rules:

223.....76068
224.....76068
679.....76405, 76425

LIST OF PUBLIC LAWS

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws**.

Last List December 8, 2015

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